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Abstract: Purpose: To evaluate the efficacy and stability of anterior maxillary distraction in the management of cleft maxillary hypoplasia and to demonstrate the complications associated with the procedure in a large series of patients with a long term follow-up of upto 4 years.
Materials and methods: A total of 164 patients 10 years and older with cleft maxillary hypoplasia were included in the study irrespective of gender, type of cleft lip and palate and amount of advancement needed. Anterior maxillary distraction using a tooth borne distractor appliance was carried out in all patients following which all patients were followed up upto 4 years (range 1-4 years) to evaluate the stability of the procedure and to document any relapse using digitalised lateral cephalograms and Orthopantamograms taken at 3 intervals viz pre-distraction, immediately following distraction and at the last follow up visit (range 1-4 years). The development of complications either intra-operatively or post-operatively was also noted. The data was tabulated and analysed.
Results: 17 patients were lost to follow-up. A significant amount of advancement ranging from 4.0 mm to 13.1 mm (mean 9.42 mm) was noted in all patients. Among the remaining 147 patients, 140 (95.23%) patients showed stable results on both lateral cephalograms and orthopantomograms. A relapse rate of 4.76%(n=7) was noted. A overall complication rate of 35.37% (n=52) was noted with bleeding and appliance dislodgement been the most common intra-operative and post-operative complications respectively noted in 10 patients each (10.2%).
Conclusion: Anterior maxillary distraction has definitely carved its niche in the management of mild to moderate cleft maxillary hypoplasia and should be instituted as a first line treatment in such cases.Stable long term results with no skeletal relapse are possible with this technique with an added advantage of unhampered or even improved velopharyngeal function.

Cover Letter

17 Feb. 16

To,

Dr James R. Hupp

Editor in Chief

Journal of Oral and Maxillofacial Surgery

Subject: Submission of manuscript titled '**Tooth Borne Anterior Maxillary Distraction for Cleft Maxillary Hypoplasia: Our Experience with 147 Patients'**

Respected Sir,

We intend to publish our manuscript titled '**Tooth Borne Anterior Maxillary Distraction for Cleft Maxillary Hypoplasia: Our Experience with 147 Patients'** in your prestigious and renowned Journal of Oral and Maxillofacial Surgery.

On behalf of all the contributors, I will act and guarantor and will respond with the journal from this point onward.

Prior publication: Nil

Support: Nil

Conflicts of interest: Nil

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The undersigned author understands that if the manuscript is accepted, the Editors reserve the right to determine whether it will be published in the print edition or solely in the Internet edition of the Journal. Articles accepted for publication are subject to editorial revision.

Yours sincerely

Dr Sunil Richardson

***Title Page**

Title of the Manuscript:

Tooth Borne Anterior Maxillary Distraction for Cleft Maxillary Hypoplasia: Our Experience with 147 Patients.

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Abstract

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Materials and methods: A total of 164 patients 10 years and older with cleft maxillary hypoplasia were included in the study irrespective of gender, type of cleft lip and palate and amount of advancement needed. Anterior maxillary distraction using a tooth borne distractor appliance was carried out in all patients following which all patients were followed up upto 4 years (range 1-4 years) to evaluate the stability of the procedure and to document any relapse using digitalised lateral cephalograms and Orthopantamograms taken at 3 intervals viz pre-distraction, immediately following distraction and at the last follow up visit (range 1-4 years). The development of complications either intra-operatively or post-operatively was also noted. The data was tabulated and analysed.

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Conclusion: Anterior maxillary distraction has definitely carved its niche in the management of mild to moderate cleft maxillary hypoplasia and should be instituted as a first line treatment in such cases. Stable long term results with no skeletal relapse are possible with this technique with an added advantage of unhampered or even improved velopharyngeal function.

Keywords: Anterior maxillary distraction, cleft maxillary hypoplasia, distraction osteogenesis, speech, tooth borne device.

Introduction

Maxillary hypoplasia is a frequently observed problem in individuals born with cleft lip and palate (CLP). The impairment of the maxillary growth coupled with extensive post-operative scarring as a result of multiple

surgeries brings about maxillary deficiency in all the three planes viz vertical, horizontal and transverse planes. It has been clearly documented in the literature that in about 25% of the CLP patients, orthodontics alone may not be able to address the issue of maxillary hypoplasia and that these patients necessarily require surgical intervention to achieve desirable aesthetic and functional results.[1-3] This can be accomplished with the help of orthognathic surgery or distraction osteogenesis or a combination of these.

Distraction of the anterior maxillary segment using a tooth borne distractor device is a novel surgical technique that brings about improvement in facial balance and aesthetics and provides stable occlusion and without any detrimental effect on speech and velopharyngeal function which is commonly observed with the advancement of the entire maxilla by either the conventional orthognathic surgery or distraction osteogenesis.[4,5] Although most studies utilising this technique for management of cleft maxillary hypoplasia have demonstrated encouraging results, the sample size and the follow up period in all these studies was found to be inadequate to truly understand the ultimate outcome of the technique in terms of overall stability and relapse.[4-10] Furthermore, no previous study has provided an in-depth view about the complications that could be associated with the procedure.

This study was therefore intended to evaluate the efficacy and stability of anterior maxillary distraction (AMD) in the management of cleft maxillary hypoplasia and to demonstrate the complications associated with the procedure in a large series of 147 patients with a long term follow-up of upto 4 years.

Materials and Methods

A total of 164 patients, aged atleast 10 years and above, reporting to our unit from January 2009 to October 2014 with cleft maxillary hypoplasia were included in the study irrespective of gender, type of cleft lip and palate and amount of advancement needed. All patients had undergone bone grafting of the cleft alveolus atleast 3 months before the surgery. Only those patients presenting with persistent anterior palatal fistulas were excluded from the study. An informed written consent was sought from all the participants of the study. The study was ethically approved by the institutional ethical committee.

Preoperatively, all patients underwent routine haematological and digitalised radiographic investigations (orthopantomogram (OPG) and lateral cephalograms), photographic documentation (frontal, profile and intra-oral views) in addition to fabrication of upper and lower dental casts. The anteroposterior maxillary deficiency was analysed clinically and radiographically using the lateral cephalograms.

The cleft team consisted of the operating cleft surgeon, the orthodontist, the speech pathologist, the dental surgeon and the dental technician. The appliance was designed by the orthodontist in discussion with the cleft surgeon and then fabricated in the laboratory by the dental technician (Figure 1 A-B). Initially, the first and second premolars and first and second molars on either side were banded. In cases where the premolars were missing or placed palatally, the canine was used for the purpose of banding. The arms of the hyrax screw (Forestadent Co., Pforzheim, Germany) were then soldered onto the bands making certain that the orientation of the screw was 90 degrees to the transverse plane and parallel to the sagittal plane such that its activation would result in an antero-posterior movement rather than a transverse movement. Posteriorly, acrylic bite blocks were fabricated on the molars to open the bite and to avoid any interference during distraction. The fabricated appliance was then tried in the patient's mouth and any minor corrections if required were performed, following which the appliance was cemented onto the selected teeth with the acrylic blocks been cemented separately using GC II cement (GC Corporation, Tokyo, Japan) a day prior to surgery (Figure 1 C). In addition, acrylic coverage of the anterior teeth including the premolars was carried out in all patients for firm anchorage of the anterior fragment and to distribute the forces of distraction evenly

All patients were operated by a single cleft surgeon. Under general anesthesia with oral intubation, a horizontal incision was planned in the maxillary vestibule from one first molar to another and a full thickness mucoperiosteal flap was reflected upto the infraorbital foramen and piriform aperture (Figure 2 A). A horizontal osteotomy cut was made on either side from the piriform rim to the predetermined distraction site between the second premolar and first molar and parallel to the occlusal plane making certain that the cut was above the maxillary teeth (Figure 2B). With the nasal mucosa adequately protected, the lateral nasal osteotomy was carried out from the piriform rim at the same horizontal level. The septum was then osteotomised at its base using a guarded septal osteotome. The vertical interdental osteotomies were made on either side consistently through the buccal cortex between the second premolar and first molar and then deepened using a spatula osteotome (Figure 2 B). The extension of the osteotomies medial to the palatal bone from the buccal alveolus was then established. The cementation of the tooth borne appliance onto the selected teeth a day before surgery made the use of tactile sensation when making the palatal cut difficult. Therefore, to avoid damage to the palatal mucosa, the palatal bone was not cut directly. Keeping the palatal pedicle intact, the anterior maxilla was fractured using luxation on either side. The completion of the osteotomy cut by activation of the distractor screw intraoperatively and symmetrical movement on both sides was again confirmed. Closure of the vestibular incision was then performed using 3-0 vicryl sutures.

Following a latency period of 5 days, distraction was performed at the rate of 3 turns twice a day. The pitch of the screw was 0.18 mm. Hence the daily movement was approximately 1.08 mm. The distraction was continued until positive inter-incisor relationship was achieved, following which the appliance was left in situ for a consolidation period of 8-10 weeks. Following the removal of the distractor, an acrylic plate was inserted for the occlusion to settle as well as for healing of the gingival tissues to occur that appeared to be inflamed from the placement of the appliance assembly. This was subsequently followed by tooth replacement using a fixed crown and bridge prosthesis in the gap created between the distracted segments in most cases. In such cases, the acrylic plate was retained for a period of only 2 weeks. In other cases presenting with crowding in the anterior teeth and requiring correction and subsequent alignment of teeth orthodontically, the acrylic plate was retained for a period of 8-10 weeks. Check radiographs (OPG and lateral cephalograms) were taken during the active distraction period, immediately following distraction and after the consolidation period before the appliance removal to confirm adequate bone formation. The radiographs were then repeated regularly upto the last follow-up visit ranging from atleast1 year to upto 4 years. Our hospital's protocol for AMD is depicted in Table 1.

Post-operatively, all patients were regularly followed up for upto 4 years (range 1-4 years) and were assessed using profile photographs as well as radiographically. All radiographs were performed using the Orthophos XG Machine (Sirona Dental Company, Germany) with similar exposure parameters used for all the patients thereby eliminating bias. Using the OPG and lateral cephalograms, angular as well as linear measurements were recorded at three different intervals i.e. pre-distraction (T1), immediately following distraction before removal of the distractor appliance (T2) and at the last follow up visit extending from atleast 1 year to upto 4 years (T3) to check for stability of the procedure as well as to document any relapse if present. The angular as well as linear measurements were traced using the Sidexis 4 software (Sirona Dental Company, Germany).

On the lateral cephalograms, angular measurements recorded included Sella-Nasion-Point A (SNA) and Point A-Nasion-Point B (ANB) whereas linear measurement recorded included distance between anterior nasal spine (ANS) to posterior nasal spine (PNS) (Figure 3). On the OPG, since the osteotomy cuts were consistently made between the second premolar and first molar in all patients, a point was marked on either tooth (mesial root surface of first molar and distal root surface of second premolar), 5 mm from the root apices of these teeth. The linear measurement between these two points on either side was then measured.

The development of complications either intra-operatively or post-operatively was also noted. The data obtained was tabulated and analysed.

Results

A total of 17 patients were lost to follow up and therefore we are presenting our results in the remaining 147 patients. The study population included 96 females and 51 males with the age ranging from 10 to 52 years (mean 17.52 years). 78 patients had unilateral complete cleft lip/palate with cleft alveolus, 37 patients had bilateral cleft lip/palate with cleft alveolus, 18 patients had incomplete cleft of the soft and hard palate extending upto the incisive foramen whereas 14 patients had cleft of the soft palate only The follow up of the patients ranged from atleast 1year to upto 4 years. Among these, 21 patients were followed up for 1 year, 26 for 2 years, 48 for 3 years and 52 for 4 years.

Using the lateral cephalograms, the angular and linear measurements were studied. The SNA angle was seen to increase from 4.3^0 to 14.1^0 (mean 8.23^0) when the immediate post distraction values (T2) were compared with the pre-distraction values (T1). When the T2 values were compared with the last follow up visit ranging from atleast 1 year to upto 4 years (T3), only 7 patients (4.76%) showed a slight decrease in the SNA angle ranging from 0.8^0 to 2.8^0 (Table 2). The remaining 140 patients (95.23%) demonstrated stable results with no change in the angular measurement. The increase in the ANB angle was in the range of 2.1^0 to 8.3^0 (mean 4.52^0) when T2 values were compared with T1. When T2 values were compared with T3, a decrease in the ANB angle ranging from 1.0^0 to 2.1^0 was seen in 18 patients (12.04%) (Table 2). The remaining 129 patients (87.96%) demonstrated stable values. Among the 18 patients who demonstrated a decrease in the ANB angle, 7 patients showed posterior movement of the point A while in the remaining 11 patients, the mandible continued to grow as evidenced by forward movement of the point B. The point A was stable in all these 11 patients when T2 values were compared with T3. With regard to ANS-PNS linear distance, a significant amount of advancement ranging from 4.0 mm to 13.1 mm was observed (range 9.42 mm) when T2 values were compared with T1. The advancement obtained was seen to be maintained in 140 patients (95.23%) when T2 values were compared with T3 (Table 3). The remaining 7 patients demonstrated a relapse of 0.7 mm to 2.7 mm (mean 2.3 mm) (Figure 4 A-C, Figure 5 A-C).

On the OPG, the linear measurement on either side in the distraction gap was recorded. There was an increase of 5.4 to 11.9 mm (mean 8.58 mm) on the right side and an increase of 5.1 to 12.8 mm (mean 8.98 mm) on the left side when the T2 values were compared with T1. The values were found to be stable in 140 patients (95.23%) when T2 values were compared with T3. A relapse of 1.2 to 3.1 mm and 0.9-2.6 mm was seen in the remaining 7 patients on the right side and left side respectively (Figure 6 A-C) (Table 3).

Therefore from linear and angular measurements, it was seen that only 7 patients (4.76%) demonstrated relapse, the remaining 140 patients (95.23%) showed stable results. Out of these 7 patients, 4 patients had an advancement of more than 12 mm and the remaining 3 patients had failed to undergo tooth replacement at the distraction site. Among the 140 patients without relapse, 124 had undergone tooth replacement in the form of fixed prosthesis at the distraction site and the remaining 16 patients had undergone orthodontic treatment to correct the crowding in the anterior region and realign the teeth into the created space.

The soft tissue profile was studied using profile photographs of the patient that were taken pre-operatively, immediately following distraction and at regular visits till the last follow up (ranging from atleast 1 to upto 4 years). A reasonably straight to convex profile from the pre-existing concave profile was achieved in all the patients. The facial balance was restored and the previously retruded lips were seen to attain normal protrusion. Furthermore, an increased tip support to the nose was achieved (Figure 7 A-B, Figure 8 A-B, Figure 9 A-B and Figure 10 A-B).

With regard to complications, 22 patients demonstrated complications intra-operatively whereas 30 patients showed post-operative complications for an overall complication rate of 35.37% (n=52). Bleeding was the most common intra-operative complication observed in 10 patients followed by appliance dislodgement (n=5), tear of the palatal mucosa (n=4), transection of the root tips of canine (n=2) and wrong fracture of the anterior segment (n=1) (Table 4). Appliance dislodgement was the most common post-operative complication seen in 10 patients followed by non-vital second premolars (n=6), anterior open bite (n=5), delayed bleeding (n=5), extrusion of teeth during distractor removal (n=3) and palatal fistula (n=1) (Table 5).

On a subset of 50 patients, the perceptual speech assessment was carried out using Perkins et al[11] scoring system (2005) that allowed for assessment of 5 parameters viz velopharyngeal insufficiency, resonance, nasal air emission, articulation and intelligibility. We observed an improvement in all the speech parameters in nearly 62% of the study population with no worsening noted in the remaining patients.

Discussion

Cleft maxillary hypoplasia especially in the anteroposterior direction with a relative class III malocclusion is probably the most challenging problem to deal with from an aesthetic and functional point of view.[12-13] Traditionally, the management has focussed on sagittal advancement of the entire maxilla at the Lefort I level by orthognathic surgery to correct the anteroposterior relationship. But, studies have shown this procedure to be

highly unstable especially when the maxillary advancement exceeds 6 mm due to soft tissue tension exerted by scar contracture from multiple surgical interventions thereby contributing to higher relapse rates in cleft cases as compared to non-cleft cases.[14, 15]

The limitations observed with conventional orthognathic surgery were effectively dealt with by applying the principles of distraction osteogenesis (DO) in the management of cleft maxillary hypoplasia. DO allows for slow regeneration of bone accompanied by expansion of the surrounding soft tissue envelope which has shown to provide better long term stability, lessening the risk of relapse.[1] Literature has documented evidence that the horizontal relapse following distraction ranges between 1.8% to 31%.[1] Although the success of this treatment is well documented and larger movements are possible with minimal relapse rates, many studies have shown worsening of the velopharyngeal function and hampering of speech.[16,17]

Block and Brister first reported on the clinical application of AMD using an intra-oral tooth borne distractor on dogs in 1994 followed by Dolanmaz D on humans in 2003.[18] In contrast to conventional orthognathic surgery and DO of the entire maxilla, only the anterior maxillary segment is advanced by distraction keeping the posterior aspect of the maxillary segment in contact with the posterior pharyngeal wall. Therefore the procedure has been shown to have no effect on the velopharyngeal sphincter and no adverse bearing on the patient's speech.[19]

In the present study, we utilised a tooth borne palatal distractor similar to the one proposed by Gunaseelan R et al[7] but modified his existing technique by cementing the distractor appliance a day before surgery under adequate visualisation. This was done to provide better control over the vector of movement and to minimise the risk of cement failure from either contamination or inability to achieve adequate isolation. Also, the intraoperative time decreased considerably. However, due to pre-operative cementation of the distractor device, the use of tactile sensation while making the palatal cut was lost and this serves as a disadvantage of the procedure.

Although a number of published studies have demonstrated the efficacy of AMD in managing cleft maxillary hypoplasia, all these studies have lacked a large study sample and a long term follow-up to draw meaningful conclusions about the stability and the amount of relapse that actually happens with this technique.[4-10] Furthermore, no previous study has discussed the complications associated with the technique in detail.

In the present study, a total of 147 patients with cleft maxillary hypoplasia were treated by AMD and followed for upto 4 years (range 1-4 years). The stability and the presence of any relapse were assessed by studying a set of angular and linear measurements on the OPG and lateral cephalograms. The SNA angle was found to be stable in 140 patients when the T2 values were compared with T3. A relapse of 1.2 to 3.1 mm (mean 2.1 mm) was seen in the remaining 7 patients.

Among the 147 patients, a decrease in the ANB angle was seen in 18 patients (12.04%) when T2 values were compared with T3. The remaining 129 patients (87.96%) demonstrated stable values. Among the 18 patients who demonstrated a decrease in the ANB angle, 7 patients showed posterior movement of the point A. In the remaining 11 patients, the mandible continued to grow leading to a relative class III malocclusion. All these patients were young in the age group of 11-15 years. The authors are of the view that there is pre-programmed less growth in the maxilla as a result of multiple reasons including scarring from previous surgical interventions and therefore the maxillary growth fails to keep pace with the mandibular growth thereby contributing to relapse observed in the ANB angle in these patients, although in true sense it cannot be considered as relapse as the point A was found to be stable in all the patients.

With regard to linear measurements, ANS-PNS distance was measured and 140 patients demonstrated stable values when T2 values were compared with T3. A mean advancement of 9.42 mm was achieved in all patients irrespective of the type of cleft. Similarly, linear measurements using OPG showed stable results in 140 patients.

Overall, relapse was observed in only 7 patients (4.76%) in the entire series. 4 of these patients had advancements in excess of 12 mm and in the remaining 3 patients, the tooth replacement in the form of fixed prosthesis was delayed. The authors believe that the use of acrylic plate during the consolidation period, immediate tooth replacement in the distraction gap following consolidation and a positive overbite are possible reasons of minimal relapse that was seen in the present study. The authors are of the view that AMD using a tooth borne distractor is a stable procedure for mild to moderate cleft maxillary hypoplasia. For severe cases requiring advancement more than 12 mm, consideration should be given for distraction of the entire maxilla. In such patients, the risk of worsening of the velopharyngeal function and speech must be explained prior to the patient.

Based on the photographic documentation, the soft tissue profile of the patient was studied. A significant improvement in the facial balance with increased nasal tip support and normal protrusion of previously retruded lips was seen. The pre-operative concave profile changed to a straight or convex profile. The results were in

accordance to the study conducted by Rao S et al which also demonstrated similar results in their study population with cleft maxillary hypoplasia following AMD.[5]

The technique of AMD is not without any complications. Bleeding and appliance dislodgement, either intraoperatively or post-operatively were the most common complications observed in the present study in 15 patients each (10.20%). Tear of the palatal mucosa (n=4), transection of the root tips of canine (n=2) and wrong fracture of the anterior segment (n=1) were also observed intra-operatively, whereas non-vital second premolars (n=6), anterior open bite (n=5), extrusion of teeth during distractor removal (n=3) and palatal fistula (n=1) were the other complications observed post-operatively. It is noteworthy that most of the complications in the present study were observed during the first year of commencement of this technique at our unit indicating that a learning curve is present before the technique can be mastered. Nevertheless, complications can still occur.

Bleeding both intraoperatively (n=10) and post-operatively (n=5) is a cumbersome complication and can pose a significantly arduous task in management as no downfracture is affected in this technique. In the authors view, the ragged edges of palatal bone that might have resulted as a result of performing the palatal cut blindly abrade the vessels and palatal periosteal tissue leading to this complication. We resorted to simple manoeuvres like pressure packing between the distractor and the palate at the greater palatine foramen and nasal packing to arrest bleeding. In two instances of intra-operative bleeding, these manoeuvres proved ineffective and therefore cauterization of the greater palatine pedicle on the side of the bleeding was carried out successfully using a bipolar cautery. In both cases, no further complication as a consequence of this manoeuvre was noted.

Dislodgement of the appliance was observed both intra-operatively (n=5) as well as post-operatively (n=10) during the period of active distraction. Intra-operative dislodgement of the appliance occurs while trying to complete the osteotomy cuts with osteotome. As the appliance is seated pre-operatively, the tactile sensation is lost when performing the palatal cut. Therefore, the palatal cut is not completed with burs or saws; instead a handled osteotome is used to bring about luxation of the fragment for fracture. While doing so, the appliance gets dislodged. Dislodgement of the appliance during the period of active distraction could be because the vibrations of using the handled osteotome to bring about luxation and fracture of the fragment might have weakened the cement-tooth interface that gives away during the period of active distraction. Cement contamination as a result of poor isolation or inadequate cementation could also be other possible reasons. In an event of such a complication both intra-operatively and post-operatively, the role of the orthodontist aided by a general dentist and a dental technician is instrumental in management. It is prudent that immediately following

re-cementation of the appliance, the screw must be activated and checked to appreciate movement of the anterior segment.

Tear of the palatal mucosa intra-operatively can also occur and was observed in 4 patients in the present study. The use of the handled osteotome to complete the palatal cut was seen to accidentally slip during luxation of the palatal bone and tear through the palatal mucosa. In these patients, the latency period was extended by another 6 days to allow time for healing to occur. Healing without any consequences was seen in 3 of these patients. The remaining one patient developed a palatal fistula during active distraction that was managed successfully after consolidation period using Von Langenbeck's technique of palatoplasty.

Transection of root tips of canine can also occur and was seen in 2 patients. Root canal treatment of the affected teeth was performed in both the patients. A single case of wrong fracture of the anterior segment was also observed intra-operatively. The cleft segment in this case was very small and weak that might have resulted in such a split. It was managed by intra-operative 2 hole plate fixation of the segment followed by normal protocol of distraction (Figure 11 A-C). The plate was removed 6 months after delivering the FPD.

With regard to post-operative complications, vitality of the second premolars was found to be lost in 6 patients. As the buccal osteotomy is consistently placed between the second premolars and first molars in all cases, damage to the apical portion of the second premolars may offer the most logical explanation. Root canal treatment of the offended teeth before delivery of FPD was performed in all patients. Pre-surgical orthodontics to bring about divergence of roots at the osteotomy site can be performed to avoid this complication. A wrong vector of distractor can give rise to anterior open bite that was observed in 5 of our patients (Figure 12 A-B). In all these cases, following removal of the appliance, brackets were placed on the upper and lower teeth and callous molding was carried out to close the open bite. In some cases, some amount of coronoplasty was also performed.

The removal of the distractor following the consolidation period is a laborious task. Unnecessary pulling to remove the distractor appliance can lead to extrusion of teeth as seen in 3 of our earlier cases. The second premolar was extruded in two instances probably because of decrease bone support on one side as a result of the osteotomy cut. The arms soldered to the teeth and the acrylic bunks need to be cut first with a bur taking great care not to damage the underlying mucosa or teeth. Only then, can the appliance be easily removed.

From our experience we can say that the technique has some definite indications. It is best suited for patients with mild to moderate cleft maxillary hypoplasia having negative or zero overjet or malaligned or crowded anterior teeth. An anterior cross bite and a concave profile can also be addressed by this technique.

The timing and the rate of distraction are important parameters for new bone formation in DO. The rate should be neither too fast nor too slow to prevent either non-union or premature fusion respectively. In our study, the distraction was commenced following 5 days of latency period. As the pitch of the screw was 0.18 mm, the maxilla was distracted at the rate of 1.08 mm per day in a rhythm of three turns twice daily. Such rhythm was found to be convenient to manipulate and tolerable to the patient. The distraction rate of around 1 mm per day is the most common protocol in distraction of the maxilla.[15,20] A consolidation period of 8-10 weeks was fixed and is usually required.[20] New bone formation was confirmed on OPG.

Although, both external and internal distractors like dynaform system, modified hyrax appliance and hybrid distractors have been described in relation to AMD[9,10,21], we resorted to a custom made distractor prefabricated on the dental cast that afforded the best fit for the patient with good patient tolerance other than been cost effective and time saving.

Any technique has its inherent advantages and disadvantages. The advantages of our technique are:

1. Addresses the problem of cleft maxillary hypoplasia at mixed dentition age (following the eruption of second premolars that corresponds roughly to 10 years of age), earlier than other technique of DO.

2. Patients schooling, work and social life is not affected due to the intra-oral nature of the distractor

3. The velopharyngeal function improves or remains unhampered.

4. Stable procedure with negligible relapse (4.76%).

5. Corrects mild to moderate cleft maxillary hypoplasia (advancement upto 12 mm is possible without relapse).

6. Cost effective in low resource setting as the distractor is custom made.

7. Allows for global improvement in the facial aesthetics.

The disadvantages of the procedure include:

1. Cannot be used for severe cases of cleft maxillary hypoplasia necessitating advancements beyond 12 mm.

2. As the tactile sensation is lost due to preoperative fixation of the distractor appliance, it is technically difficult to perform the palatal cut. But after the learning curve, this problem can be easily managed.

3. A team approach constituting of a cleft surgeon, an orthodontist, a speech pathologist, a dental surgeon and a dental technician is a must for overall results.

4. The deficiency in the malar region is not addressed.

Conclusion

We believe that AMD using a tooth borne device should be the primary line of treatment for management of mild to moderate cleft maxillary hypoplasia. Stable long term results with no skeletal relapse are possible with this technique with an added advantage of unhampered or even improved velopharyngeal function. Furthermore, AMD enables the surgeons to address the problem of cleft maxillary hypoplasia at a younger age immediately following the eruption of second premolar.

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Figure Legends:

Figure 1 A-C: Photographs of distractor appliance

A: Planning of the vector on the dental cast.

B: Pre-fabrication of the appliance on the dental cast.

C: Distractor appliance luted onto the selected teeth prior to surgery.

Figure 2 A-B: Exposure and design of the osteotomy

A: Exposure of the site.

B: Osteotomy design for anterior maxillary distraction.

Figure 3: Cephalometric landmarks studied on the lateral cephalograms

N: Nasion, S: Sella, ANS: Anterior nasal spine, PNS: Posterior nasal spine, A: Point A, B: Point B

Figure 4: Assessment of angular and linear measurements on the lateral cephalograms in one patient.

A: Pre-distraction view: SNA: 68^0, ANB: -4.2^0, ANS-PNS: 52.52 mm

B: Immediate post-distraction view: SNA: 75.1^0, ANB: 2.9^0, ANS-PNS: 61.36 mm. Amount of advancement achieved is 8.84 mm.

C: Post-distraction view at 4 years showing stable results. SNA: 75.1^0, ANB: 2.9^0, ANS-PNS: 61.36 mm.

Figure 5 A-C: Assessment of angular and linear measurements on the lateral cephalograms in one patient.

A: Pre-distraction view: SNA: 81.8^0, ANB: -0.2^0, ANS-PNS: 65.24 mm

B: Immediate post-distraction view: SNA: 88.5^0, ANB: 6.5^0, ANS-PNS: 69.68 mm. Amount of advancement achieved is 4.44 mm.

C: Post-distraction view at 2 years showing relapse due to failure to undergo fixed prosthesis in the distraction gap. SNA: 87.1^0, ANB: 5.4^0, ANS-PNS: 68.42 mm. Decrease in SNA angle by 1.4^0, ANB by 1.1^0 and ANS-PNS by 1.26 mm.

Figure 6 A-C: Assessment of linear measurements on the orthopantomograms in one patient.

A: Pre-distraction view

B: Immediate post-distraction view

C: Post-distraction view at 1 year showing stable results.

Figure 7 A-B: Assessment of soft tissue profile in a 10 year old patient.

A: Pre-distraction view.

B: Post-distraction view

Figure 8 A-B: Assessment of soft tissue profile in a 23 year old patient.

A: Pre-distraction view.

B: Post-distraction view

Figure 9 A-B: Assessment of soft tissue profile in a 16 year old patient.

A: Pre-distraction view.

B: Post-distraction view

Figure 10 A-B: Assessment of soft tissue profile in a 42 year old patient.

A: Pre-distraction view.

B: Post-distraction view

Figure 11 A-C: An instance of wrong fracture of the anterior segment.

A: Orthopantamogram showing stabilisation of the segment using 2 plate fixation

B: Achievement of satisfactory distraction despite the fracture

C: Orthopantamogram showing application of fixed prosthesis following adequate consolidation period.

Figure 12 A-B: An instance of anterior open bite.

A: Development of anterior open bite due to wrong vector of distraction.

B: Closure of open bite following callous molding.

Table 1. AMD protocol

TIME PERIOD	TASK PERFORMED	ROLE OF CLEFT TEAM
Day 1	Photographic documentation, radiographs (OPG and Lateral cephalograms), haematological investigations, upper and lower impressions and fabrication of dental casts and pre-operative speech assessment and recording.	Meeting of cleft team comprising of the cleft surgeon, the orthodontist, the speech pathologist, the general dentist and dental technician. Impression and dental casts fabricated by dental surgeon
Day 2	Fabrication of the distractor appliance on the maxillary dental cast	Under the supervision and guidance of the orthodontist, the dental technician fabricates the distractor.
Day 3	Seating of the appliance in the mouth	The orthodontist checks the fit of the appliance followed by cementation on the selected teeth by the dental surgeon.
Day 4	Surgery	Performed by the operating cleft surgeon.
Day 5-9	Latency period. Patient stays in the hospital.	
Day 10 to end of distraction	Active distraction at the rate of 1.08 mm per day Check OPG every 5 days to assess symmetric movement. OPG, lateral cephalograms at the end of active distraction.	Activation done by surgeon, orthodontist or the dental surgeon. 3 turns twice daily to achieve 1.08 mm distraction per day (Pitch of the screw is 0.18 mm)
8-10 Weeks post-distraction	Consolidation period Check OPG and Lateral Cephalograms to assess bone formation.	
At the end of 10 weeks of consolidation	Distractor appliance removal Oral prophylaxis Upper impression and dental cast fabrication for making an acrylic plate	Requires cutting of the acrylic bunks and the soldered arms with a bur before attempting removal. Performed by the dental surgeon.
2-10 weeks after consolidation	Use of acrylic plate Check radiographs every month to check for any relapse In patients planned for FPD, the acrylic plate removed after 2 weeks and FPD delivered. In patients having crowding in the anterior teeth needing teeth alignment orthodontically, the acrylic plate is retained for 8-10 weeks	
At 6 months from surgery	Post-operative speech assessment	Performed by speech pathologist
Review	Review every 6 months for the first year. Thereafter, yearly review. Lateral cephalograms and OPG taken at every review	Reviewed by the entire Cleft team.

Table 2. Angular measurements studied on the lateral cephalogram

	Increase (expressed as range)	Mean	Decrease (expressed as range)
SNA	$4.3\text{-}14.1^0$ (147 patients)	8.23^0	$0.8\text{-}2.8^0$ (7 patients)
ANB	$2.1\text{-}8.3^0$ (147 patients)	4.52^0	$1.0\text{-}2.1^0$ (18 patients)

Table 3. Linear measurements studied on the lateral cephalograms and OPG.

	Increase (expressed as range)		Mean		Decrease (expressed as range)	
ANS-PNS	4.0-13.1 mm (147 patients)		9.42 mm		0.7-2.7 mm (7 patients)	
OPG	Right	Left	Right	Left	Right	Left
	5.4-11.9 mm (147 patients)	5.1-12.8 mm (147 patients)	8.58 mm	8.98 mm	1.2-3.1 mm (7 patients)	0.9-2.6 mm (7 patients)

Table 4. Intra-operative complications

Sr. No	Type of complication	No of patients (n)
1	Bleeding	10
2	Appliance dislodgement	5
3	Tear of the palatal mucosa	4
4	Transection of root tips of canine	2
5	Wrong fracture of the anterior segment	1
TOTAL		**22**

Table 5. Post-operative complications

Sr. No	Type of complication	No of patients (n)
1	Appliance dislodgement	10
2	Non-vital second premolars	6
3	Delayed bleeding	5
4	Anterior Open bite	5
5	Extrusion of teeth during distractor removal	3
6	Palatal fistula	1
TOTAL		**30**

Figure 1A

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Figure 1B

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Figure 1C

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Figure 2A

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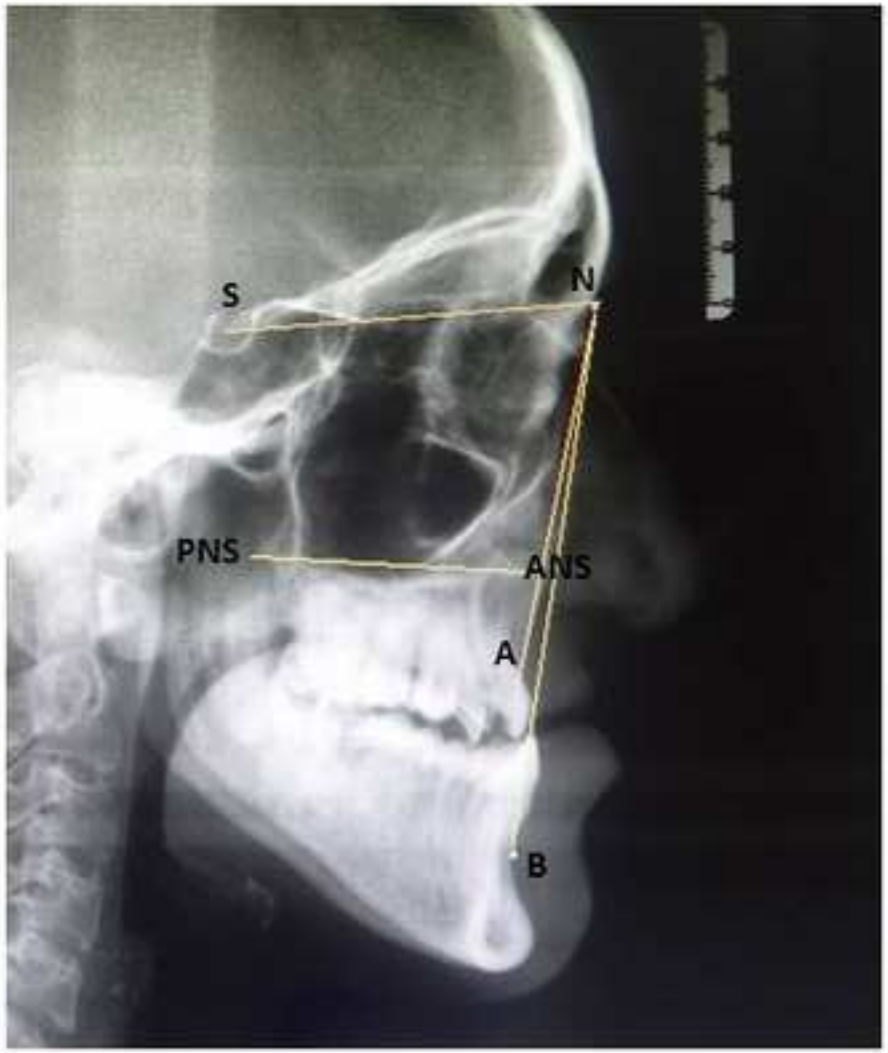

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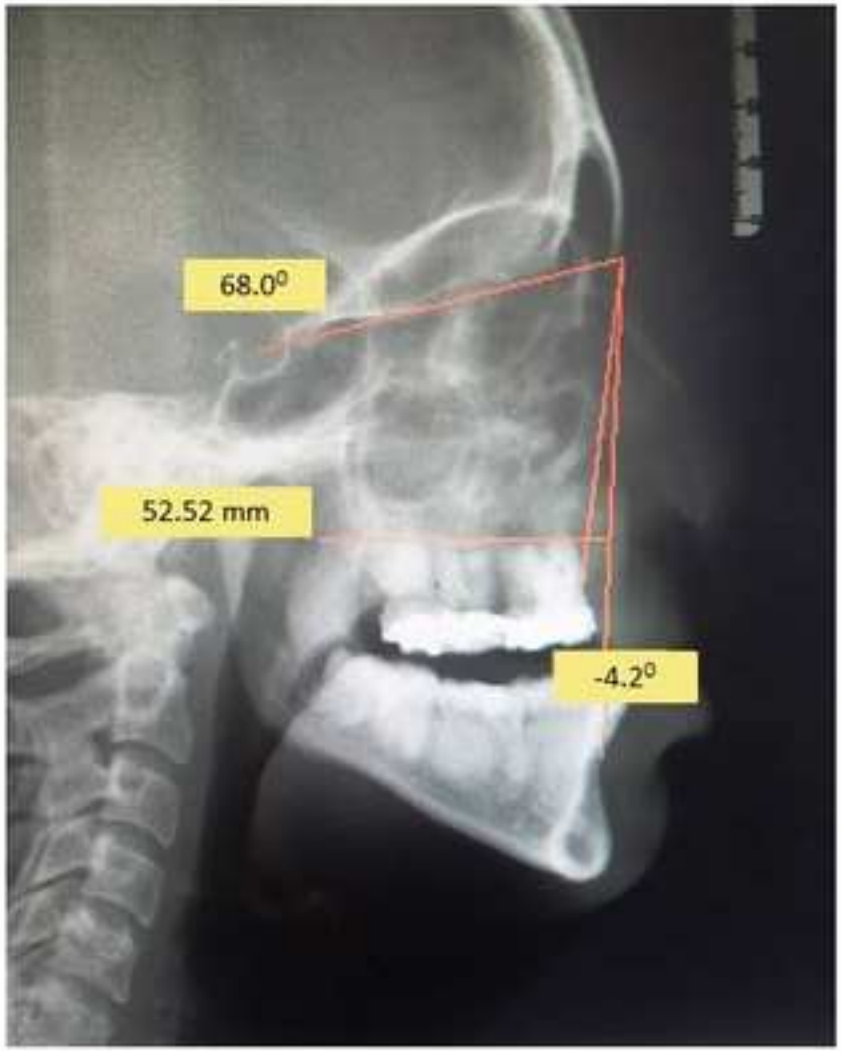

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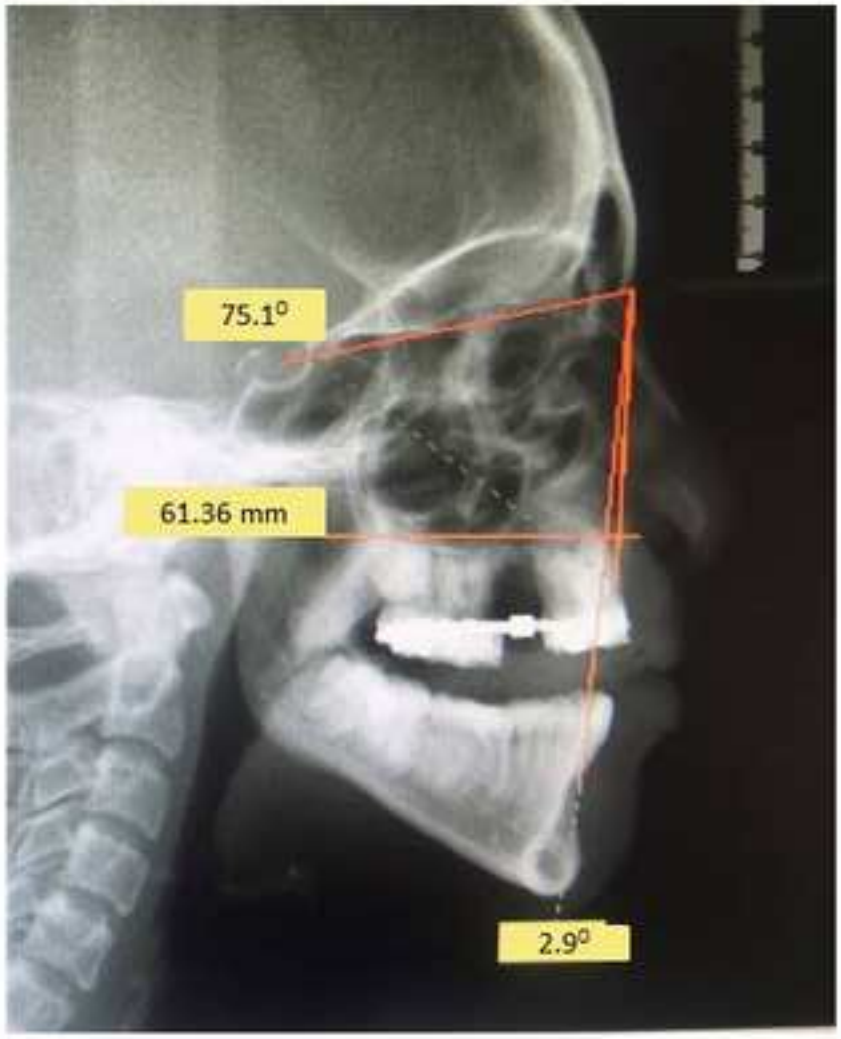

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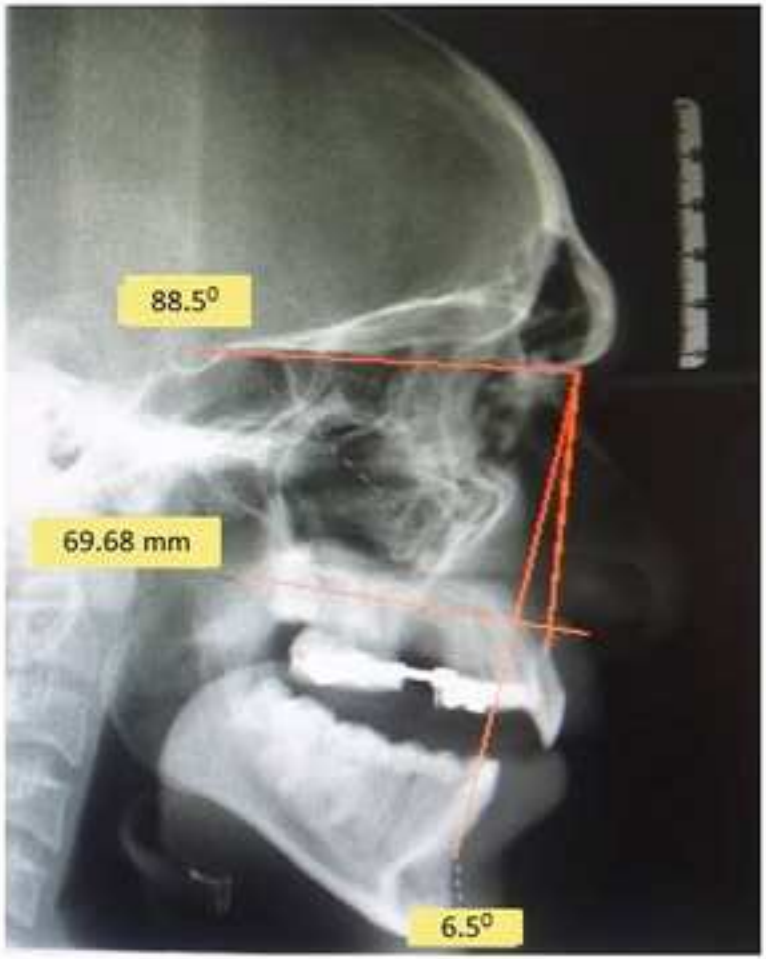

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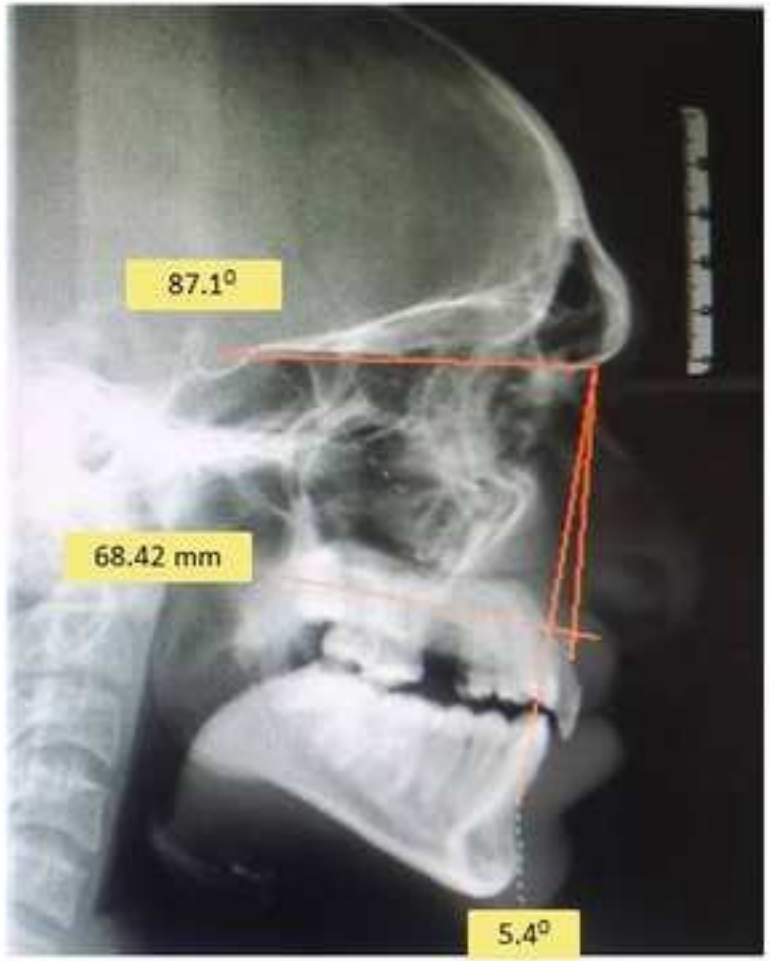

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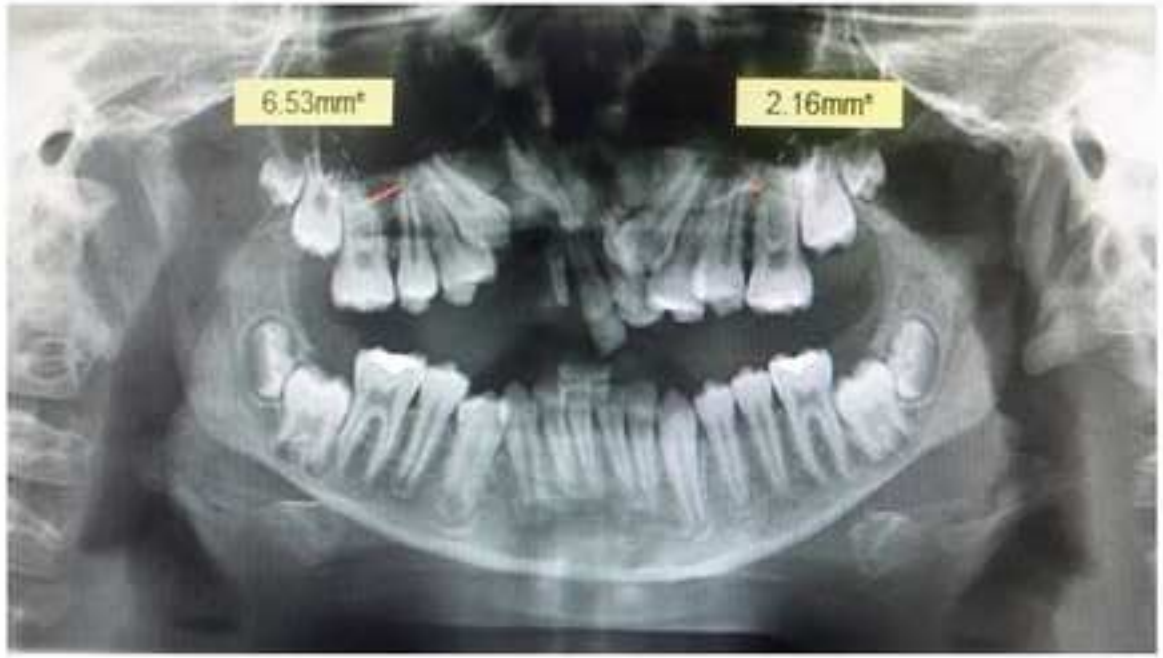

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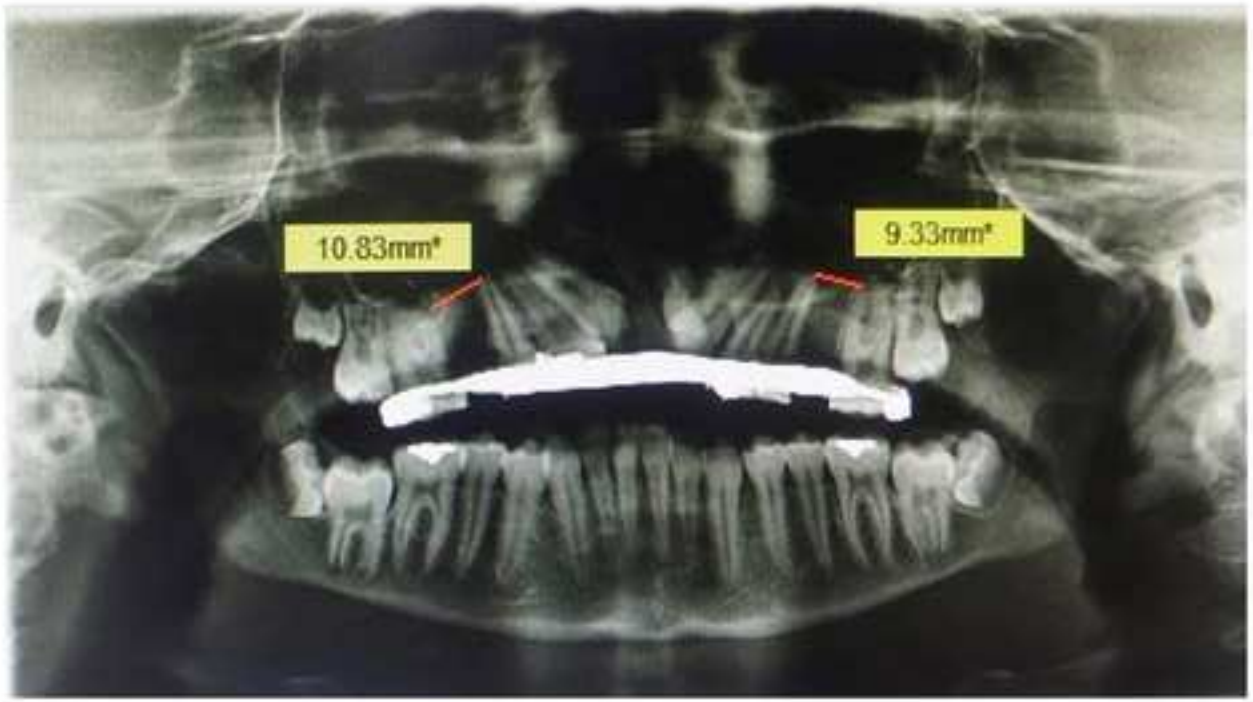

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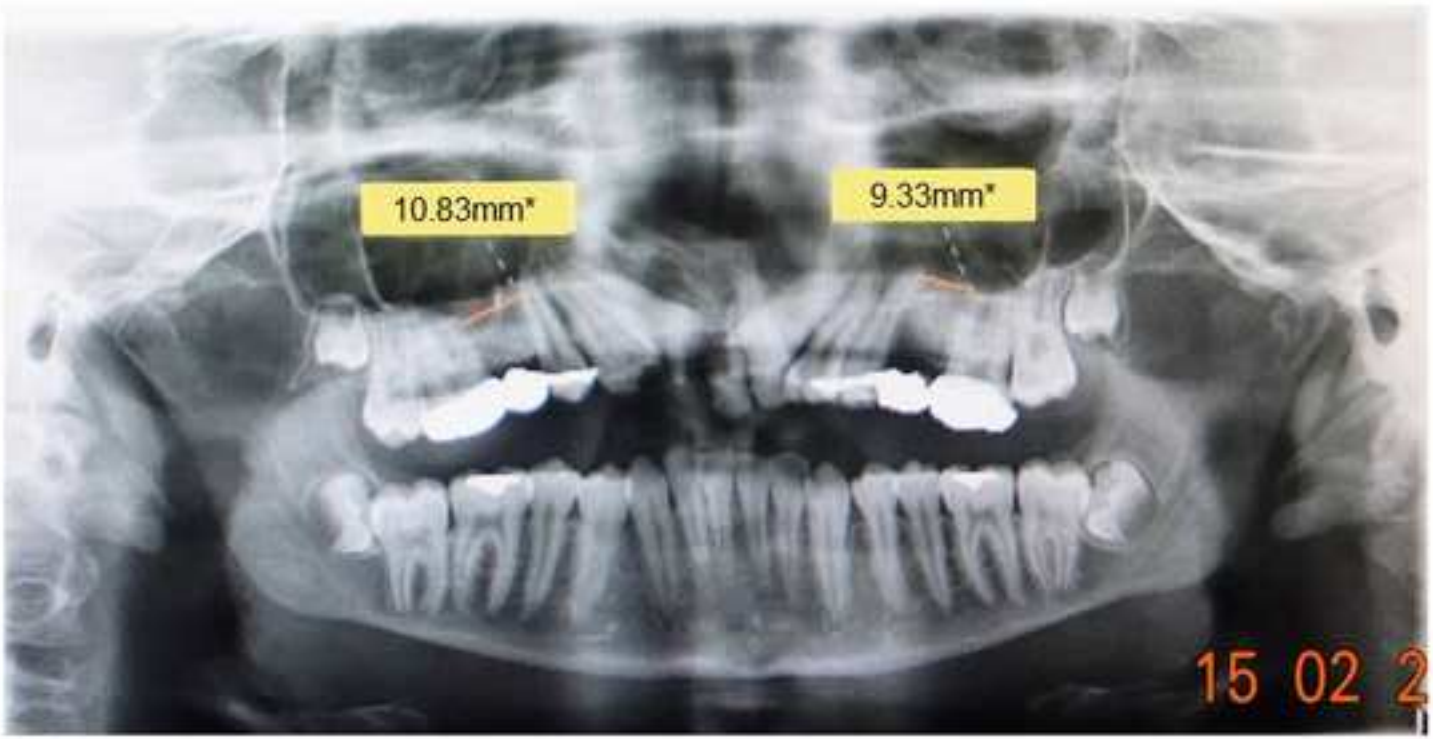

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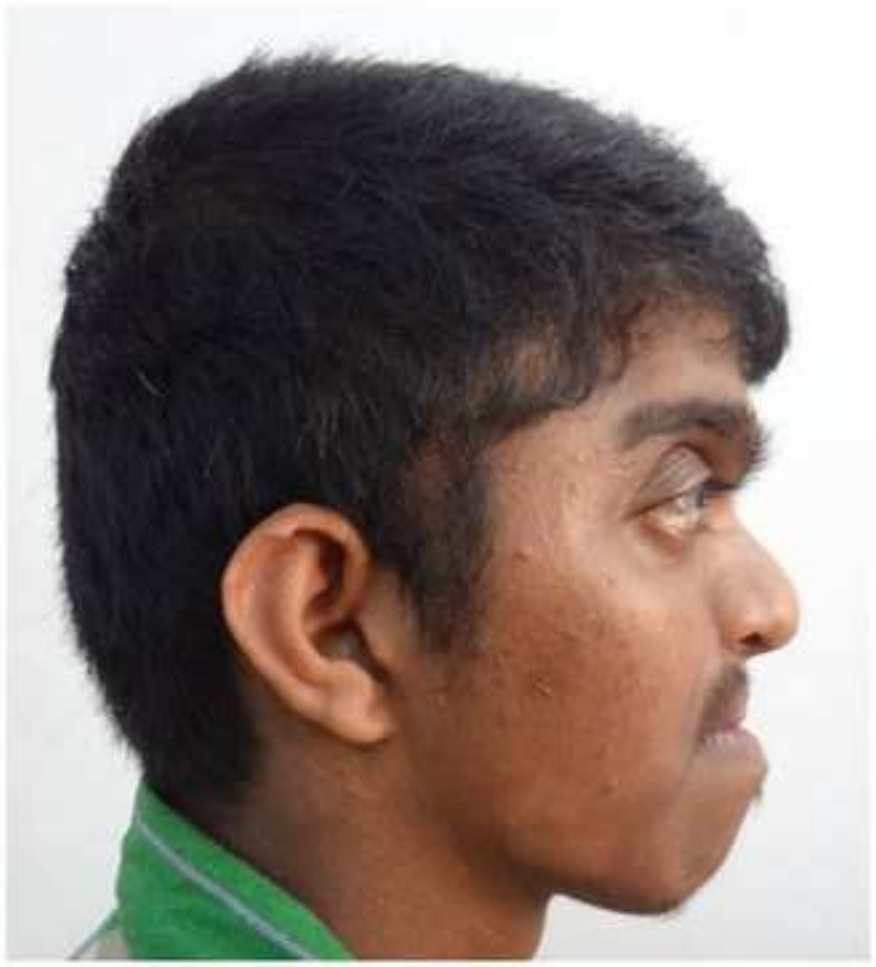

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Figure 11 A

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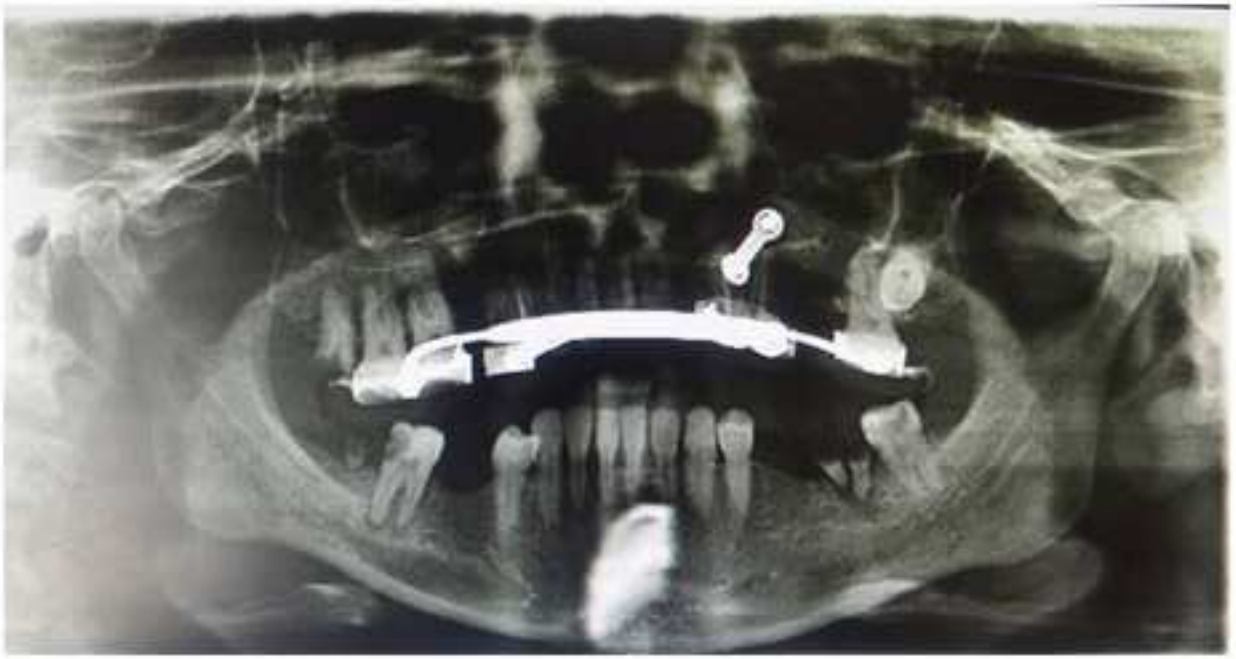

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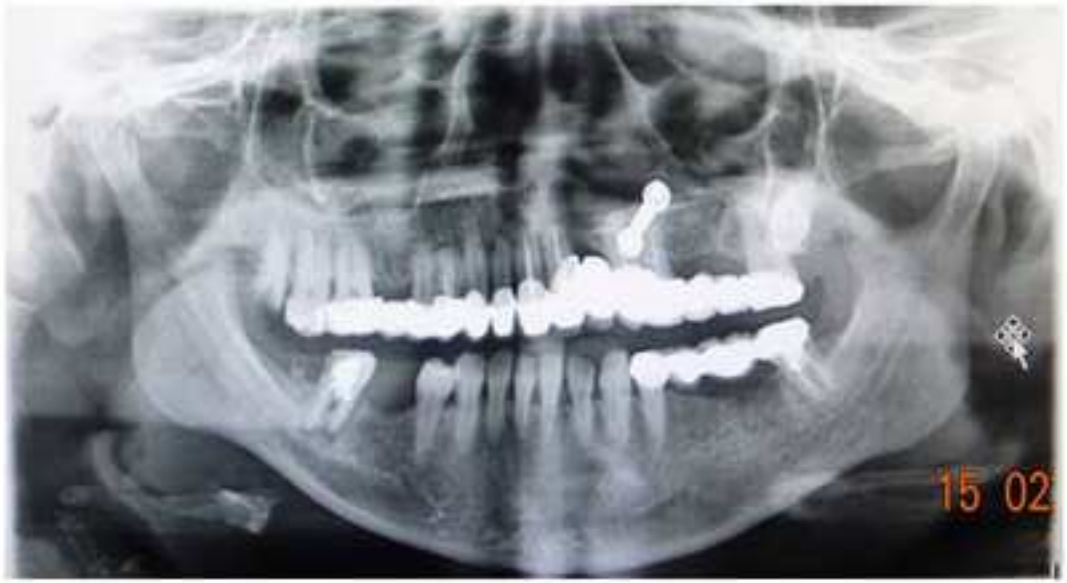

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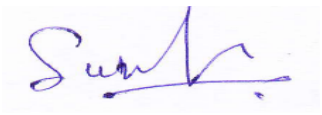
Guardian Signature  Date 13/02/16

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	RELEVANT FINANCIAL RELATIONSHIP(S) RELATED TO YOUR CONTENT (CHECK ALL THAT APPLY)				
Commercial Interest(s) (any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.)	**Research Grant (including funding to an institution for contracted research)**	**Speakers' Bureau**	**Stock/Bonds (excluding Mutual Funds)**	**Consultant**	**Other (Identify)**
☐	☐	☐	☐	☐	☐

☐	☐	☐	☐	☐	☐

✓ 4th Co-Author (if applicable)

Name: Shweta Richardson

DISCLOSURE OF FINANCIAL RELATIONSHIPS WITHIN 12 MONTHS OF DATE OF THIS FORM

➡ **NO**—Neither I, nor any member of my immediate family, has a financial relationship or interest (currently or within the past 12 months) with any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

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☐	☐	☐	☐	☐	☐

___ 5th Co-Author (if applicable)

Name: _____ _____

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☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐

___ 6th Co-Author (if applicable)

Name: _____ _____

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☐	☐	☐	☐	☐	☐

☐	☐	☐	☐	☐	☐