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7 **Interim use of Hyrax Screw Assembly for Single-Step Closure of Small**
8 **Alveolar Cleft Prior to Anterior Maxillary Distraction Osteogenesis**

9 *A technical note*

10 **Sonal Mishra,¹ *Harpreet Singh,² Dhirendra Srivastava,¹ Poonam Sharma²**

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12 *Departments of ¹Oral & Maxillofacial Surgery and ²Orthodontics & Dentofacial*
13 *Orthopedics, ESIC Dental College and Hospital, New Delhi, India*

14 **Corresponding Author's e-mail: drhpreet_mamc04@yahoo.co.in*
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16

16 **Abstract**

17 Anterior maxillary distraction osteogenesis (AMDO) is often used for correction of maxillary
18 retrognathia in select cleft lip and palate cases. Restoration of alveolar arch continuity is
19 desirable prior to initiation of AMDO in these cleft maxillary deformities. However, AMDO
20 is technically difficult in a patient with coexisting alveolar cleft where there is a discontinuity
21 of the defect that presents a challenge in terms of adequate vector control of movement of
22 anterior segment and potential risk of tipping of teeth which already have compromised
23 anchorage/bone support on the cleft side. Treatment process becomes further challenging
24 when ongoing management is compounded by failed previous alveolar cleft grafting
25 procedures along with the patient's reluctance to undergo further grafting of alveolar clefts.
26 Herein, we report a technical note demonstrating a novel application of the modification of
27 the hyrax screw wherein an initially fully opened Hyrax screw was utilized as an interim
28 assembly for accomplishing single-step closure of small alveolar cleft prior to
29 commencement of anterior maxillary distraction osteogenesis. This technique may prove to
30 be feasible for patients presenting with alveolar cleft defects of smaller widths of up to 5 mm
31 and relatively well-aligned upper arches.

32 **Keywords:** Alveolar Cleft; AMDO; Hyrax Screw; Single-Step Closure.
33

34 **Introduction**

35 Maxillary hypoplasia and retrusion represent a significant component of Class III deformity
36 in most patients with cleft lip and palate. In spite of being widely adopted technique for one-
37 stage correction of maxillary retrusion in cleft patients,¹ Le Fort I osteotomy technique is
38 associated with higher relapse rates and may lead to emergence of velopharyngeal
39 insufficiency and hypernasality of voice, especially with advancements greater than 10
40 mm.^{2,3} On the other hand, by virtue of offering sufficient time for overcoming the tension on
41 the palatal scar and for regeneration of the membranous bone along with coverage of
42 adequate soft tissue, distraction osteogenesis (DO) results in better skeletal stability when
43 compared to conventional Le Fort I orthognathic surgery.^{4,5} However, when extraoral or
44 intraoral distraction is performed at a Le Fort I level, the risk of velopharyngeal insufficiency
45 and speech impairment has been shown to be similar to the risk observed in conventional Le
46 Fort I advancement surgery.⁶

47

48 To overcome this potential disadvantage, tooth borne distraction of the anterior maxilla using
49 anterior maxillary distraction osteogenesis (AMDO) has proven to be a feasible and stable
50 modality,⁶ while also offering alveolar bone space for correction of tooth malalignment and
51 without hampering speech.¹ Rao Janardhan et al⁷ reported successful utilization of tooth-
52 borne distraction device for advancement of the anterior maxilla with no worsening of
53 speech. Promising results with the use of hyrax distractor (for anteroposterior maxillary
54 advancement) in terms of its efficacy, patient's satisfaction, and stability have also been
55 demonstrated in literature.⁸ However, AMDO is difficult in a patient with alveolar cleft
56 where there is a discontinuity of the defect that presents difficulty in terms of vector control
57 of movement of anterior segment and the probable risk of tipping of teeth which already have
58 compromised anchorage/bone support on the cleft side. The present manuscript describes the
59 novel application of the modification of the hyrax screw wherein a conventional Hyrax screw
60 after being fully opened was utilized as an interim assembly for accomplishing single-step
61 closure of small alveolar cleft of up to 5 mm prior to commencement of anterior maxillary
62 distraction osteogenesis.

63

64 **Methods**

65 *Case Description*

66 An 18-year-old female patient with an operated left cleft lip and palate presented seeking
67 treatment for correction of mid face retrusion. Case history was indicative of two previous

68 alveolar cleft grafting surgeries at ages of 11 years and 15 years, respectively, at another
69 institution. The cleft was present between maxillary right central incisor (11) and left canine
70 (23) and was 5 mm wide at the level of the cemento-enamel junction/ cervical margin of the
71 adjoining teeth. Reverse overjet of 11 mm was noticed (Fig. 1a, b, c & d). The upper
72 dentition was relatively well-aligned. There was scarring at the sites of surgery in the palate,
73 alveolus and lip.

74
75 The patient as well as her parents declined for any further grafting of the alveolar cleft. In
76 order to correct the alveolar discontinuity prior to maxillary advancement, closure of this
77 small alveolar cleft as well as osteotomy cuts for AMDO were planned in a single step. The
78 treatment protocol was approved by the Institutional Ethical Committee and patient gave
79 informed consent and acceptance about the treatment protocol.

81 ***Description of technique***

82 Following preparation of the models in die-stone, proposed vertical osteotomy cuts were
83 made on both sides between the premolar and molar on the cast. A 9 mm Hyrax expansion
84 screw (Leonne, Italy) (pitch = 1 mm) was fully opened, and its arms were adapted at the
85 labial aspect of the anterior teeth with its body positioned between 11 and 23. The appliance
86 was acrylicized in self-cure polymerizing resin at the labial, occlusal, and lingual aspects, and
87 subsequently finished, polished and tried-in for passive fit (Fig 2a, b).

88
89 Intraoperatively, the osteotomy was performed as follows: Under general anesthesia with oral
90 endotracheal intubation, a maxillary vestibular incision was made from first molar to first
91 molar. A mucoperiosteal flap was reflected to expose the maxilla. A horizontal osteotomy cut
92 parallel to the occlusal plane was made on both sides 5mm above the level of the root apices
93 from the lateral nasal rim to the distraction site between the premolars and molars. Lateral
94 nasal osteotomies were performed whilst protecting the nasal mucosa. The nasal septum was
95 detached by using a guarded septal osteotome. Vertical osteotomy/interdental cuts were made
96 in the buccal cortex between the second premolar and first molar (Fig. 3a). The palatal
97 osteotomy was executed gently under tactile guidance with curved osteotome while taking
98 care not to damage the palatal mucoperiosteum.

99
100 After confirming the completion of osteotomy, the acrylicized Hyrax assembly was seated
101 passively over the segment anterior to the osteotomy cuts, and the screw was closed with the

102 key till approximation was achieved by mesial movement and docking of two bony segments
103 towards the cleft between teeth 11 and 23 (Fig.3b). As the bony segments from both sides
104 closely approximated towards each other in an evenly controlled vector (without over-riding
105 of segments), the closure of the cleft was visualized. Bone chips produced during osteotomy
106 were placed in the region of the residual cleft site. A 1.5 mm titanium straight plate was
107 adapted on both bony segments across the cleft and fixed with monocortical screws ensuring
108 that the anterior maxilla remained as one single unit (Fig. 3c), in preparation for facilitating
109 AMDO for correction of cleft maxillary retrognathia. The interim Hyrax assembly was
110 removed following closure using a 3-0 Vicryl suture. Thereafter, a three-part tooth-borne
111 bonded Hyrax distractor assembly (with 90° orientation for anteroposterior movement)
112 oriented parallel to mid palatine plane was cemented. Gap created at the area of the two
113 vertical osteotomies was utilized for anterior maxillary distraction at a rate of 1 mm per day
114 as follows (Fig. 3d): After a latency period of 5 days, AMDO was initiated by turning the
115 screw of the distractor assembly by half a turn (0.5 mm) every 12 hours, resulting to a total of
116 one full turn every day i.e. 1mm/day. The screw was activated for 13 days, thereby
117 amounting to a total correction of 13 mm. After completion of distraction, the central portion
118 of the distractor assembly was sealed with composite resin and retained through a
119 consolidation period of 4 months to allow for the mineralization and corticalization of the
120 newly formed bone tissue prior to removal of distractor assembly. Postoperatively, the
121 recovery period was uneventful with no detection of any relapse and complications.

122

123 Favourable results of the technique showing postoperative approximation of the bone in the
124 cleft site and satisfactory improvement in esthetics along with good bone regeneration at the
125 area of distraction are demonstrated through Figure 4a-4c. Alveolar space with good,
126 regenerated bone quality and implants placed bilaterally in the distracted bone are evident by
127 IOPA radiographs (Fig. 4d).

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129 Ethical approval to report this case was obtained from the Institutional Research Ethics
130 Committee. Written informed consent was obtained from the patient for her information and
131 images to be published in this article.

132

133 **Discussion**

134 Premaxillary/ anterior maxillary and alveolar distraction osteogenesis (DO) have been widely
135 used for management of severe midfacial retrusion including anterior crossbite in cleft lip and
136 palate patients.⁹⁻¹¹

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138 Restoration of alveolar arch continuity is desirable prior to initiation of AMDO in cleft
139 maxillary deformities. Restoration of large alveolar cleft defects by alveolar distraction
140 osteogenesis utilizing intraoral tooth-borne distractor has been successfully reported in
141 literature.^{1,9} The tooth-borne trifocal distraction appliance involving the use of two Hyrax-
142 screws has also been described for the controlled closure of a large alveolar cleft.¹² In cases
143 of small alveolar clefts with enhanced chances of graft survival, bone grafting is an ideal
144 option for the closure of cleft defects in order to achieve arch continuity, stabilise the
145 maxillary segments, eliminate oronasal fistulae, optimise nasal morphology through nasal
146 alar cartilage support, and finalize implant placement.¹³ However, before commencement of
147 AMDO, waiting time of at least 3-6 months is recommended for stabilization of graft.
148 Challenge is usually encountered when some patients with history of previously failed
149 alveolar bone grafting surgeries refuse to undergo another grafting procedure.

150

151 The conventional application of the Hyrax screw for closure of large alveolar clefts
152 (activation of the appliance by opening the screw) has been widely documented in
153 literature.^{9,12} The majority of these applications involving Hyrax screw and fan-shaped screw
154 entail opening of the screws to facilitate approximation of the alveolar segments towards each
155 other.^{8,12,14} On the other hand, the current technical note describes the novel application of the
156 modification of the hyrax screw wherein a conventional Hyrax screw after being fully opened
157 was utilized as an interim assembly for accomplishing single-step closure of small alveolar
158 cleft of up to 5 mm prior to commencement of anterior maxillary distraction osteogenesis.
159 The present interim tooth-borne Hyrax screw assembly facilitated controlled mobilization,
160 docking and evenly close approximation of the bony segments (without over-riding of
161 segments) towards the defect. This assembly enabled more precise bony movements while
162 simultaneously maintaining bone to bone contact and stabilization of the osseous segments in
163 the intended position during fixation, thereby aiding in accomplishing the anatomic objective
164 in a single step.

165

166 Thus, based on the principle of patient-centred outcome and in accordance with patient's
167 wishes, this technique involving the use of interim tooth-borne Hyrax screw assembly is
168 suitable for clinical application in patients who are potential candidates for AMDO and also
169 presenting with small alveolar interdental clefts (of up to 5 mm) that persist even after
170 previous alveolar bone grafting surgeries. The advantages of this technique are the possibility
171 of achieving arch continuity in the same operation by evenly controlled mesial movements of
172 the bony segments towards each other, thus obviating the need for additional alveolar bone
173 grafting surgery and preventing creation of any extraoral wound, making such therapy
174 feasible especially for patients with small alveolar cleft defects of up to 5 mm. Simplicity of
175 the design, ease of fabrication and exclusive tooth-borne usage minimizes the invasiveness of
176 the procedure.

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178 *Limitations in generalizing the innovation:* This technique cannot not be employed in large
179 alveolar cleft defects wherein significant bone segment movements may be associated with
180 significant relapse. Compromised periodontal support and advanced interdental bone loss are
181 contraindications to the use of this approach.

182

183 **Conclusion**

184 In view of the promising results of this approach, this procedure may prove to be feasible for
185 patients presenting with alveolar cleft defects of smaller widths and relatively well-aligned
186 upper arches. Large sample size studies involving different populations with long-term
187 follow-up are necessary to validate the current approach for routine use.

188

189 **Conflict of Interest**

190 The authors declare no conflicts of interest.

191

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194

195 **Authors' Contribution**

196 SM, HS and DS were responsible for the study conception and design and treatment of the
197 patient. HS and SM contributed to the literature search and drafting the article. SM, HS, DS
198 and PS contributed to the final editing and critical revision of the article. All authors have

199 made substantive contribution to this manuscript, and all have reviewed the final paper prior
200 to its submission.

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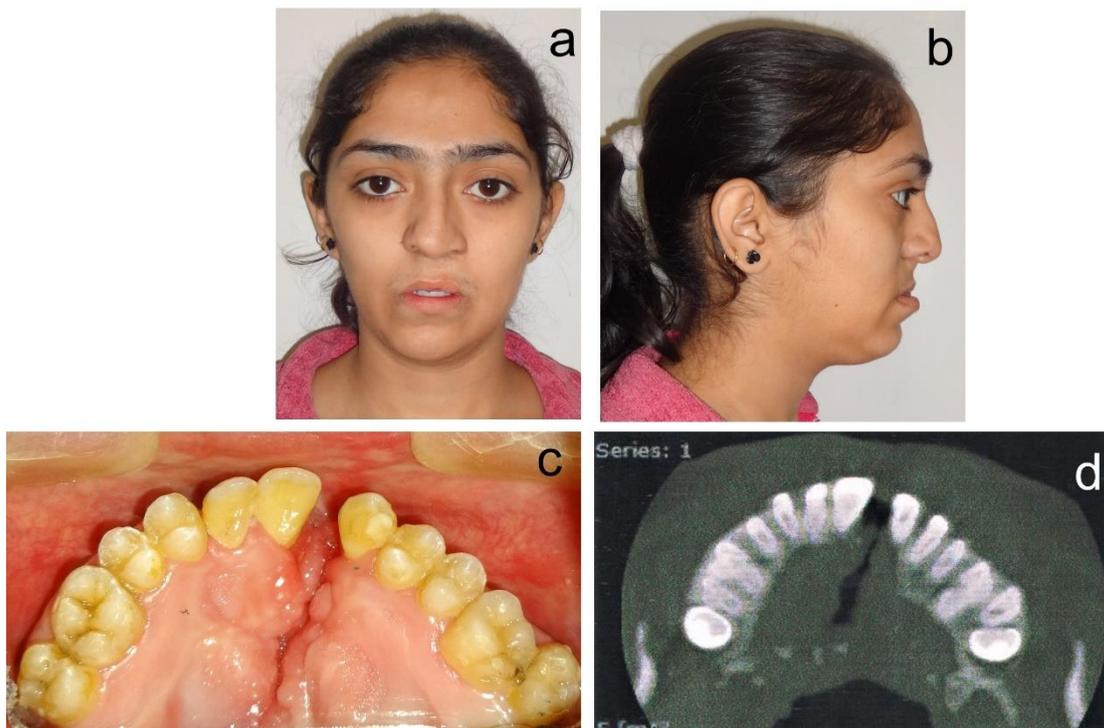
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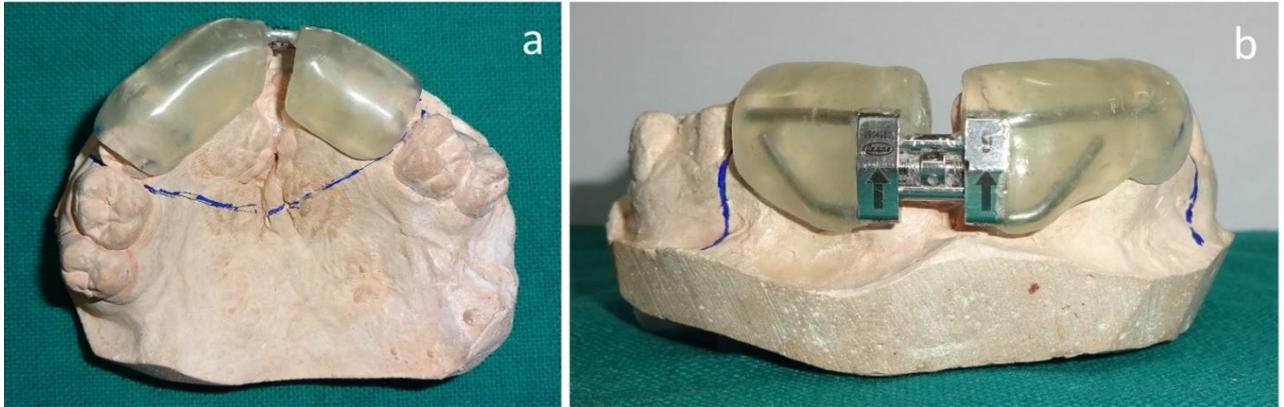
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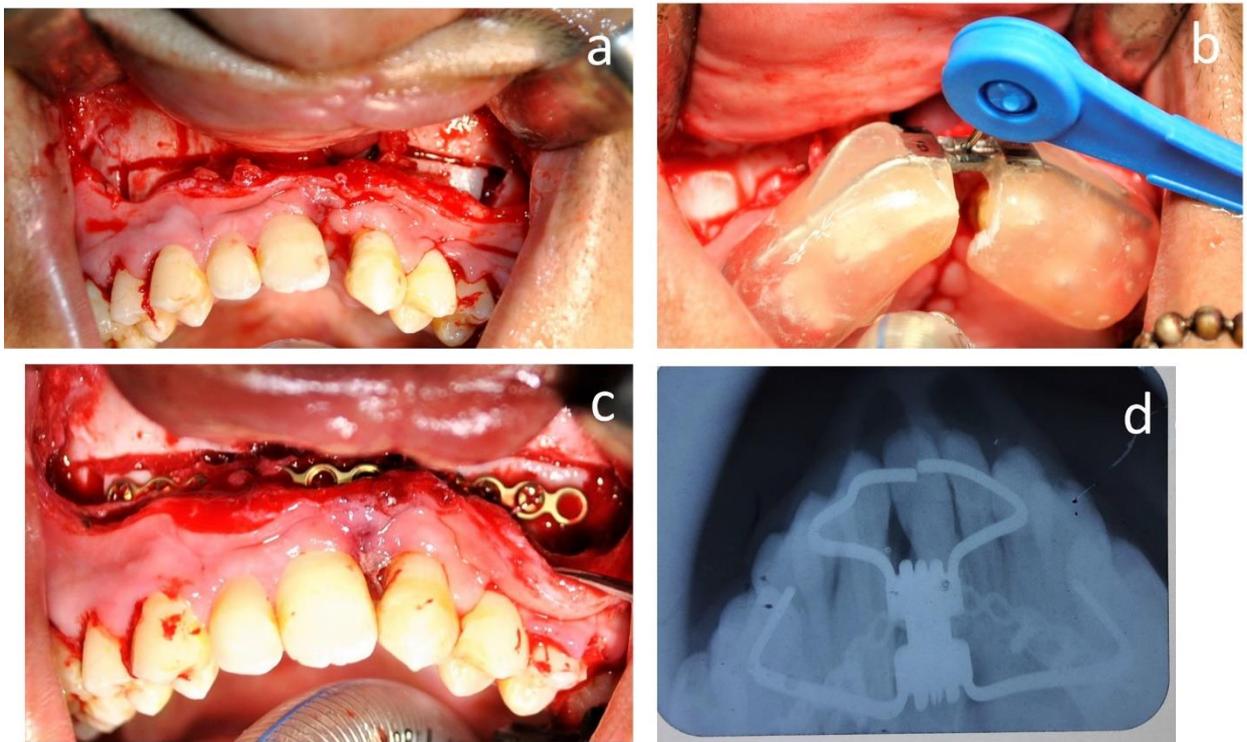
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247 **Figure 1:** Pretreatment extraoral and intraoral photographs showing a cleft palate on the left
248 side and alveolar cleft between 11 and 23: (a) Frontal photograph (b) Profile photograph (c)
249 Intraoral occlusal view (d) Axial view.

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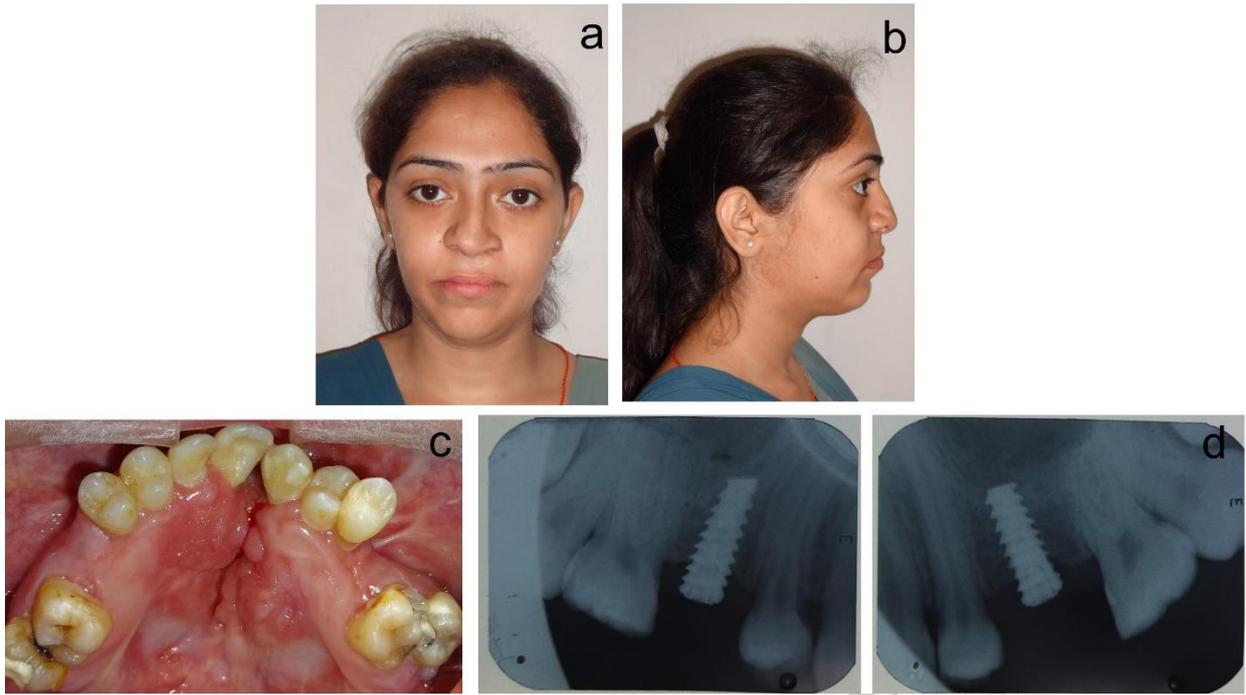
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Figure 2: Marking of osteotomy cuts site and acrylized appliance with Hyrax screw in fully opened position: (a) Palatal view of the appliance (b) Front view of the appliance



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Figure 3: (a) Intraoperative photograph showing placement of osteotomy cuts, (b) Intraoperative photograph showing appliance in seated position and closure of screw assembly with key, (c) Approximation accomplished by mesial movement and docking of bony segments towards the interdental alveolar cleft between teeth 11 and 23, (d) Occlusal radiograph taken intraoperatively before commencement of AMDO



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Figure 4: Treatment results: (a) favourable frontal esthetics after completion of AMDO, (b) improved profile esthetics after completion of AMDO, (c) Immediate post-distraction occlusal view after removal of distractor appliance, (d) IOPA x-rays showing good bone regeneration and implants placed bilaterally in the distracted bone between second premolar and first molar

Accepted Article