Long-term results of bilateral mandibular distraction osteogenesis using an intraoral tooth-borne device in adult Class II patients

T. H. El-Bialy, Y. Razdolsky, N. D. Kravitz, S. Dessner, R. F. Elgazzar

Abstract. The aim of this prospective clinical study was to evaluate the short-term and long-term skeletal and dental changes after mandibular osteodistraction with tooth-borne appliances in adult orthodontic patients. The sample consisted of 10 non-growing Caucasian patients with a Class II skeletal relationship due to mandibular deficiency, together with Class II dental malocclusion. All patients underwent mandibular distraction osteogenesis (MDO) using the ROD1 tooth-borne device. Lateral cephalograms were evaluated at four time intervals: pretreatment (T1), after mandibular distraction (T2), after orthodontic fixed appliance therapy (T3), and at long-term observation 8-year post-distraction (T4). Statistical analyses compared the skeletal and dental changes in intervals T1–T2, T2–T3, T3–T4, T1–T4, and T2–T4. MDO with the ROD1 tooth-borne device produced significant long-term (T1–T4) increases in the SNB angle (2.3°), total mandibular length (5.9 mm), and corpus length (4.5 mm). Potential adverse sequelae included significant increases in mandibular plane angle (4.3°), lower anterior dental height (2.8 mm), and lower posterior dental height (2.5 mm). Significant increases in lower incisor proclination occurred during distraction (7.5°). Distraction osteogenesis with tooth-borne appliances offers a minimally invasive surgical method with stable results for correcting mandibular deficiency in non-growing patients.

Key words: tooth-borne distractor; mandibular retrognathia; distraction osteogenesis; long term.

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Introduction
The orthodontic treatment of adult Class II patients with mandibular retrognathia often entails dental camouflage or mandibular advancement surgery, including bilateral sagittal split or vertical ramus osteotomies. Distraction osteogenesis (DO), the biological process of new bone formation by gradually stretching the healing callus that joins surgically divided bone segments, has become an important alternative surgical technique for the craniofacial region. Mandibular DO (MDO) is frequently performed in young children with congenital
craniofacial skeletal deformities including severe micrognathia, as well as children and adults with ankylosis of the temporomandibular joint (TMJ) to elongate the mandible, improve function, and enhance the soft tissue profile. However, MDO is performed less often in adult Class II patients for skeletal correction of mandibular retrognathia.

The advantages of MDO compared to the conventional orthognathic surgery include: enables extensive bone lengthening, eliminates the need for bone grafting and inter-maxillary fixation; the incremental skeletal movements allow for accommodation of the soft tissues; reduces surgical stress; and reduces the incidence of inferior alveolar nerve dysesthesia. The primary disadvantages of MDO include: the total length of treatment, which may take up to 3-4 months to ensure adequate stabilization of the regenerate, and the potential for bite opening.

The appliances used for MDO can be categorized with regard to whether they are internal or external, the direction of distraction, and the site of application. External devices are inserted through the skin to the mandible. These devices are capable of extensive distraction and multidimensional control; however they are conspicuous and bulky, and more likely to cause traction scarring on the face. Internal or intraoral devices are attached either to bone or less commonly to teeth adjacent to the osteotomy site. Some devices are attached to teeth and bone (known as hybrid devices), thereby providing both direct and indirect skeletal fixation. Most internal distractors are capable of unidirectional distraction only. Internal devices are less visible than external devices and will not cause scarring, though they are often limited to the extent and direction of distraction and the distraction rod may create excessive pressure on the lower lip.

In regards to intraoral devices, toothborne distraction offers numerous advantages in comparison to bone-borne distraction, including: eliminates the need for a second surgery to remove the distraction device; the distraction screws are removable which maximizes the surgical access; and interdental distraction osteotomies and seating of the device are performed in an outpatient setting, which minimizes operation time, surgical morbidity, and hospital expenses. Despite these advantages, the literature regarding bilateral intraoral MDO is limited to cases of intrabony defects in adult patients who have been treated for orthognathic procedures.

Hamada et al. presented a case report of bilateral MDO using a bone-borne appliance for the treatment of obstructive sleep apnea syndrome (OSAS) in a 31-year-old male with severe retrognathia (SNB = 67.4°). At the end of distraction, the cephalometric analyses revealed a 2.8° decrease in ANB, a 3.0° increase in mandibular plane angle (MPA), a 7.6° increase in lower incisor angulation, and a 3.5 mm increase in LL to E-line. After 3 years and 1 month of post-distraction orthodontic treatment, followed by 9 months in retention, ANB relapsed slightly (0.9°) and the mandibular incisors further proclined (1.2°), while the MPA remained constant.

Karacay et al. presented a case report of MDO using the MD-DOS bone-borne appliance in a 20-year-old female with a hyperplastic maxilla (SNA = 86°, ANB = 6°) and excessive overjet (16 mm). At the end of consolidation (10 weeks after distraction at the time of device removal), the cephalometric analyses revealed a 4° decrease in ANB, an 11 mm increase in total effective mandibular length, a 6 mm increase in corpus length, a 7° increase in y-axis, a 15° increase in lower incisor angulation, and a 4 mm increase in LL to E-line. At the 1-year follow-up appointment (17 months after removal of the distraction device), ANB relapsed 2°, total mandibular length relapsed 4 mm, corpus length relapsed 2 mm, y-axis returned to the original pretreatment value, lower incisors maintained their proclination, and the lower lip maintained protrusion relative to the E-plane.

Muttick et al. presented three case reports of bilateral mandibular advancement by MDO using the intraoral bone-borne device in Class II adult patients (mean age 22 years). At the end of fixed orthodontic treatment (4-7 months post-distraction), cephalometric analyses revealed a mean 4.7° decrease in ANB, a mean 11.1 mm increase in total effective mandibular length, and a 1.8° decrease in lower incisor angulation.

Sadakah et al. performed bilateral MDO using a bone-borne appliance in two adult Class II patients (mean age 29 years) with TMJ ankylosis and retrognathia (mean SNB = 63°). At a mean 15 months post-distraction, the authors reported a mean 13° increase in SNB from the pretreatment value, despite a mean 4.5 mm of relapse in mandibular length.

In 1997, Razdolsky introduced the ROD1 (Oral Osteodistraction, LP, Buffalo Grove, IL, USA), a tooth-borne distraction device for multiplanar interdental distraction. The main indications for using ROD1 are in cases with skeletal Class II due to mandibular deficiency, especially when accompanied by lower incisor crowding and/or flaring in horizontal growth pattern. Currently, no prospective clinical study has evaluated the long-term effects of bilateral antero-posterior MDO using a tooth-borne appliance in non-growing patients. The purpose of this study was to evaluate the long-term skeletal and dental changes after antero-posterior mandibular distraction using the tooth-borne ROD1 distraction device in Class II adult orthodontic patients.

Materials and methods

The sample for this study consisted of 10 consecutively treated adult patients (seven males, three females) from a private orthodontic practice, who underwent mandibular advancement distraction osteogenesis using the ROD1 tooth-borne device. All patients presented with a Class II skeletal relationship (mean ANB = 6.6°) due to mandibular retrognathia (mean SNB = 73.2°), Class II dental malocclusion (mean molar relationship = 1.4 mm, overjet = 8.0 mm, lower crowding of 5.1 ± 1 mm, lower incisor inclination relative to mandibular plane of 94.6 ± 7°), and average curve of Spee. All patients had mesocephalic facial types and normal forward and backward growth of the mandible. Sample demographics included Caucasian patients from either first- or second-generation Eastern-European descent.

The inclusion criteria for patient selection included: (1) Class II skeletal
relationship due to mandibular retrognathia, (2) Class II dental malocclusion, (3) non-growing adult patient, with (4) healthy periodontium. Prior to enrollment, all patients were presented three treatment options: (1) non-surgical dental camouflage with or without upper premolar extraction, (2) mandibular advancement via bilateral sagittal split osteotomy, or (3) mandibular interdental distraction using the ROD1 tooth-borne distraction device. All patients chose the third option, i.e., mandibular interdental distraction using the ROD1 tooth-borne distraction device.

Prior to fabrication of the tooth-borne distraction appliance, presurgical orthodontic tooth alignment was performed with 0.018 slot prescription twin brackets and first molar bands. The purpose of the presurgical orthodontics was to provide the surgeon with enough interdental space to perform the surgical cuts without risking trauma to the neighbouring teeth. After building to 0.016 x 0.022 stainless steel wires, the maxillary and mandibular arches were coordinated. The lower first premolars and second molars were fitted with preformed stainless steel crowns (3 M Unitek, Monrovia, CA, USA), and alginate impressions were taken to transfer the bands to a heat-resistant stone model for laboratory processing. Patients were prepared before surgery by the orthodontist who cemented the male component of the ROD1 appliance on the teeth adjacent to the distraction site using glass ionomer cement (Fujif Ortho LC, GC America, Inc., Alsip, IL, USA).

All patients were treated surgically by the same oral maxillofacial surgeon. Each surgery was performed in an outpatient setting under local anaesthesia and intravenous sedation. Bilateral mandibular corticotomies were performed between the mandibular second premolar and the first molar or the first and second molar using a reciprocating saw. Lateral corticotomies extended vertically from the inferior border to a point just inferior to the alveolar crest, and transversely through the corpus without perforating the lingual cortical plate to prevent damage to the lingual nerves and vessels. A parallel lingual corticotomy was made extending from the mylohyoid ridge convexity to a point just short of the lingual alveolar crest. The lingual cortex was separated with an osteotome to perform a complete ostectomy before placing the female component of the distractor.

The distraction protocol was as follows: (1) 5 and 7 days postsurgery latency period (5 days for younger patients and 7 days for older patients); (2) distraction rate of 1.0 mm/day; (3) distraction rhythm of three turns per day (0.33 mm/180° turn) until proper length was attained; (4) moulding of the regenerate with an elastic chin-up appliance, worn a minimum of 14 h per day, to counteract downward pull of the suprahyoid muscles on the anterior segment; (5) consolidation for 6 weeks after the last day of distraction; (6) removal of the ROD1 appliance after radiographic evidence of bone formation or calcification of the callus (confirmed by panoramic radiographs); (7) delay of 2–3 additional months for bone remodelling along with continued wear of the elastic chin-up before initiating orthodontic tooth movement through the new regenerate. Arch coordination was performed during the postsurgical orthodontics. The retention protocol involved upper fixed 2–2, lower fixed 3–3, Upper Essex retainer and fixed retainers in the distraction areas. Inferior alveolar nerve sensation was assessed using a two-point contact test on the lower lip before and at 3–6 months after distraction.26

Lateral cephalometric radiographs were collected at four time intervals: T1, pretreatment; T2, end of distraction; T3, end of fixed appliances; and T4, 8 years after finishing orthodontic treatment. Lateral cephalometric superimpositions were performed for each patient using Dolphin Imaging 10.0 (Dolphin Imaging Solutions, Chatsworth, CA, USA) by an independent orthodontist. Superimposition was performed on the outlines of the anterior cranial base and registered on the centre of the sella. Statistical analyses using paired t-tests compared the skeletal and dental changes between intervals T1 and T2, T2 and T3, T3 and T4, T1 and T4, and T2 and T4. Subsets of five radiographs were digitized by the same investigator over a period of 2 weeks and comparison of the two measurements was performed by paired t-test. There was no significant difference at the P = 0.05 level of significance, revealing the measurements to be reliable.

Results

The mean pretreatment sample age was 24.7 years (males 25.4, females 23.9) with an age range of 16–34 years. Inferior alveolar nerve sensory tests revealed that there was no difference between the before and after distraction values for all the patients, indicating that the inferior alveolar nerve was not affected by the procedure.

Figures 2–4 show clinical records of one of the patients at different treatment times. Figure 5 shows cephalometric superimposition of the average values of the 10 patients at different treatment times. Descriptive statistics and statistical comparisons for cephalometric skeletal and dental changes at the four treatment intervals are presented in Tables 1 and 2. At the end of distraction (T1–T2), significant increases occurred in the SNB angle (1.9°), total mandibular length (5.0 mm), corpus length (4.6 mm), MPA (5.3°), lower incisor inclination (7.9°), lower anterior dental height (1.3 mm), lower posterior dental height (2.7 mm), and lower lip protrusion (1.4 mm).

By the debonding appointment (T2–T3), significant decreases had occurred in lower incisor angulation (–14.7°) and lower lip protrusion (–3.6 mm); however, lower anterior dental height continued to increase significantly. No significant changes occurred in the antero-posterior position of the mandible, MPA, corpus length, total mandibular length, or lower posterior dental height. At the 8-year postdistraction follow up (T3–T4), no significant changes had occurred from the debonding appointment. Comparison of T2–T4 revealed statistical differences only between T2 and T4 in the lower incisor angulation and in the lower lip protrusion, consistent with T2–T3.

When comparing the long-term changes from the presenting pretreatment cephalometric analyses (T1–T4), significant increases had occurred in the SNB angle (2.3°), total mandibular length (5.9 mm), corpus length (4.5 mm), MPA (4.3°), as well as lower anterior and posterior dental heights (2.8 mm and 2.5 mm, respectively). The lower incisors were proclined (7.5°) during distraction; however they were uprighted by the end of the active orthodontic treatment. There were no noted changes in the gingival architectures or gingival recession at the end of treatment or at T4.

The degree of association between variable changes during treatment was evaluated (Table 3). There was a strong correlation between total anterior facial height (TAFH) changes and the changes in mandibular corpus length (Go–Gn), mandibular total length (Cd–Gn), and mandibular plane inclination to Frankfurt horizontal plane (MPA). Also, there was a strong association between the changes in y-axis and lower anterior facial height (LAFH) that confirmed the increased facial height. Further, there was a strong association between the changes in lower incisor inclination to MPA and lower lip position relative to the E-plane.
Fig. 2. Clinical extraoral photographs for one of the patients: preoperative (A), immediately after finishing distraction (B), after finishing orthodontic treatment (C), and 8 years in retention (D).

Discussion

The purpose of this preliminary prospective clinical study was to evaluate the short-term and long-term effects of bilateral tooth-borne osteodistraction for Class II correction in adult patients. The final data collection was performed in December 2006. The mean length of active distraction was 15 ± 5 days. The average period of orthodontic treatment post-distraction was 14.6 ± 9 months.

The total mandibular length and corpus length increased 5.0 mm and 4.6 mm, respectively, during osteodistraction and remained stable throughout long-term retention. The amount of distraction was slightly less than previously reported in bone-borne studies. However, less skeletal relapse occurred in comparison to previous bone-borne studies with shorter post-distraction recalls.

Furthermore, skeletal relationships in all patients in our study were corrected during distraction and maintained Class I canine during the 8-year follow-up.

Despite the increase in mandible length, the SNB angle only increased 1.9° during distraction, which is less than previous reports using bone-borne appliances. The modest increase in antero-posterior position of the mandible during the distraction phase was likely influenced by the opening rotation of the mandible. Karacay et al. reported a mean 6° increase in SNB despite a 7° increase in the y-axis. van Strijen et al. reported that the antero-posterior position of B-point was likely to relapse in high-angle patients. In our study, the SNB angle did not decrease after distraction; however, greater antero-posterior position of the mandible would have likely been achieved with better vertical control.

The MPA increased 5.3° during distraction and remained relatively constant during the 8-year follow-up period. These results are consistent with similar previous bone-borne studies. For example, Hamada et al. reported a 3° increase in the MPA during distraction, which remained almost constant after distraction. However, Gonzalez et al. reported a 4.1° increase in MPA during distraction and 2.7° of further opening rotation during the consolidation period, which was likely a result of muscular pull on the developing callus. In this study, the opening rotation that occurred during distraction was likely a combination of significant posterior dental extrusion and poor compliance with the elastic chin-cup in a few patients. It could also be argued that the consolidation period is the main reason for the increase in

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MPA secondary to removing the appliance before complete mineralization occurred, and the created interdental space was closed by reciprocal forces while the suprhyoid muscles exerted important relapse pressure allowing clockwise mandibular rotation. This also could contribute to the relapse in the inferior border and the increased incisor mandibular plane angle (IMPA).

The elastic chin-cup functions to reduce the MPA and control bite opening in two ways: the vertical compression minimizes pull from the suprhyoid muscles and moulds the immature regenerate, both of which help guide the distracted segment back into proper occlusal position. The efficacy of regenerate moulding is well documented; however, there exists some debate regarding the proper timing, duration, and method of callus manipulation. Wei et al. advocated moulding the regenerate during the consolidation phase, whereas McCarthy et al. and Peltomaki...
advocated manipulation during the activation phase. Regenerate moulding is typically achieved by attaching intermaxillary elastics or orthodontic springs to maxillary archwire; however, this method can result in significant incisor extrusion. In our study, the regenerate was moulded with an elastic chin-cup during active distraction and throughout the 6-week consolidation period. Significant increases in bite opening and dental extrusion occurred during the distraction phase, and only slight closure of the MPA was observed after removal of the distraction device.

There was noticeable extrusion of the anterior and posterior dental height during the distraction period, which was expected with the use of a tooth-borne appliance. The posterior dental extrusion opened the bite, weakened the antero-posterior position of B-point, and impeded the improvement of the Class II facial profile. The amount of extrusion for the lower first molar was more than twice that of the lower incisor. Posterior dental extrusion was likely a result of the proximity of the

![Diagram](image)

Fig. 5. Mean cephalometric changes: superimposition at different treatment times.

**Table 1.** Descriptive statistics for the cephalometric analyses at the four time (T) intervals (N = 10).

<table>
<thead>
<tr>
<th>Cephalometric variables</th>
<th>T1</th>
<th>T2</th>
<th>T3</th>
<th>T4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>SNA (°)</td>
<td>79.9</td>
<td>3.6</td>
<td>79.8</td>
<td>3.6</td>
</tr>
<tr>
<td>SNB (°)</td>
<td>73.2</td>
<td>3.7</td>
<td>75.1</td>
<td>3.8</td>
</tr>
<tr>
<td>ANB (°)</td>
<td>6.6</td>
<td>3.7</td>
<td>4.7</td>
<td>3.1</td>
</tr>
<tr>
<td>LAFH (%)</td>
<td>23.9</td>
<td>6.8</td>
<td>29.2</td>
<td>6.7</td>
</tr>
<tr>
<td>IMPA (%)</td>
<td>60.9</td>
<td>4.9</td>
<td>61.8</td>
<td>4.3</td>
</tr>
<tr>
<td>Go–Gn (mm)</td>
<td>63.6</td>
<td>7.9</td>
<td>68.2</td>
<td>5.2</td>
</tr>
<tr>
<td>Cd–Gn (mm)</td>
<td>95.7</td>
<td>6.1</td>
<td>100.7</td>
<td>5.5</td>
</tr>
<tr>
<td>TAFH (NaMe) (mm)</td>
<td>105.5</td>
<td>3.6</td>
<td>110.5</td>
<td>4.1</td>
</tr>
<tr>
<td>LAFH (%)</td>
<td>53.5</td>
<td>3.0</td>
<td>55.5</td>
<td>2.7</td>
</tr>
<tr>
<td>LAFH (ANS–Me) (mm)</td>
<td>58.8</td>
<td>3.8</td>
<td>63.5</td>
<td>3.4</td>
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<tr>
<td>IMPA (%)</td>
<td>94.6</td>
<td>7.9</td>
<td>102.5</td>
<td>8.5</td>
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<td>LADH (mm)</td>
<td>36.4</td>
<td>1.7</td>
<td>37.7</td>
<td>2.4</td>
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<tr>
<td>LPDH (mm)</td>
<td>27.7</td>
<td>1.6</td>
<td>30.4</td>
<td>1.9</td>
</tr>
<tr>
<td>LL–E line (mm)</td>
<td>–1.0</td>
<td>1.9</td>
<td>0.4</td>
<td>2.4</td>
</tr>
</tbody>
</table>

SNA, sella–nasion–A point; SNB, sella–nasion–B point; ANB, A-point–nasion–B point; MPA, mandibular plane angle; SGn, sella–gnathion; FH, Frankfurt horizontal; Go, gonion; Gn, gnathion; Go–Gn, mandibular corpus length; Cd, condyle; Cd–Gn, mandibular total length; TAFH, total anterior facial height; NaMe, nasion to menton; LAFH, lower anterior facial height; IMPA, incisor mandibular plane angle; LADH, lower anterior dental height; LPDH, lower posterior dental height; LL–E line, lower lip protrusion–aesthetic line.

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distraction device, whereas the anterior dental extrusion may have occurred as a sequela of bite opening. The slight relapse in posterior dental height, which occurred by the end of fixed appliances, corresponded with the slight closure in MPA.

The lower incisors were proclined 7.9° during the distraction and were uprighted by the completion of the fixed appliances. The significant advancement and proclination of the lower incisors was consistent with previous bone-borne studies. The uprighting of the lower incisors was greater than described in previous reports, and was likely a result of protracting the lower second molar into the distraction space.

The strong association between the increased y-axis and lower as well as total anterior facial heights confirms the slight increase in the vertical dimension after distraction. This could be due to the increased lower anterior and posterior dental heights after distraction, as evidenced by the strong association between TAFH changes and lower anterior dental height (LADH) as well as with lower posterior dental height (LPDH) changes. The strong association between the changes in the lower incisor inclination to MPA and lower lip position relative to the E-plane indicates that lower incisor position is important for facial aesthetics.

There were several significant limitations to this study. (1) Most significantly, the treatment results were not compared to a control group. Future studies are needed to make comparative evaluations between the long-term effects of bilateral tooth-borne MDO to dental camouflage or conventional mandibular advancement surgery with more complex mandibular movements than 10 mm, which is expected to be associated with counterclockwise mandibular movements. (2) Patient compliance with the elastic chin-cup was not recorded with a daily log. The increase in MPA and dental extrusion indicate that actual compliance may have been less than reported by the patients. Future studies are needed to determine the proper timing and appropriate force for regenerative molding. In addition, the incorporation of temporary anchorage devices with inter-arch elastics or orthodontic springs may eliminate the social burden of wearing an extraoral appliance, control the force level, and eliminate the need for patient compliance. (3) Over the length of the study, two different radiography machines were used, one film and the other digital; this may have resulted in tracing and superimposition errors. (4) Cone-beam computed tomography scans may have provided better insight into the periodontal health of the lower incisors during distraction. It is probable that the significant incisor proclination that occurred during distraction may have influenced the periodontium since we did not witness any gingival recession even after T4.

Based on this study, we can conclude that tooth-borne MDO could be used as an alternative to orthognathic surgery for routine Class II relationship correction and may also be useful in various orthodontic patients. However, the DO technique is not meant to replace the current well-established orthognathic techniques, rather it may be considered as a useful reliable technique in selected candidates. Another recommendation to improve the patient’s profile with compromised aesthetics when noticed with most of the DO techniques used for the treatment of Class II patients, is that advancement genioplasty can easily be done separately if it is indicated.

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It can be suggested within the limitations of the current study that intraoral distraction using tooth-borne distraction devices appears to be predictable and stable. No complications were seen in the treated samples compared to published complications with other bone-borne distraction devices.

The results of this study may help clinicians to select the correct surgical intervention and proper appliance according to the planned treatment, in terms of amount of movement, age of the patient, occlusal plane, and preserving the inferior alveolar nerve (movements over 20% of the mandibular body length should be done anterior to the nerve, or sagittal split distraction).

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**Competing interests**

None.

**Ethical approval**

Institutional Review Board of the University of Illinois at Chicago.

**References**


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