

Complex Orthodontic Treatment Using a New Protocol for the Invisalign Appliance

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The Invisalign* system was introduced at an orthodontic meeting in 1999¹ and first described in a peer-reviewed publication in 2000.² Controversy remains over whether the system is appropriate for moderate-to-difficult cases.³⁻¹⁹

Early longitudinal clinical trials demonstrated successful use of Invisalign for tipping movements, incisor rotations, and closure of naturally occurring spaces.¹⁷⁻¹⁹ The system was less effective in more difficult procedures such as extraction space closure. These trials were conducted during the first four years of appliance development, however, when significant problems existed with bodily movement, root torquing, extrusion, and premolar and canine rotation. One of the studies tested soft and hard aligner materials that were never used commercially^{17,18} (Invisalign appliances are now manufactured using a material of intermediate stiffness). It also evaluated whether a one- or two-week interval between aligners was more effective (for the past eight years, the standard protocol has been two weeks of wear for each aligner). Another study

showed predictable intrusion using clear aligners.¹⁹ Both of the longitudinal trials found a statistically significant reduction of plaque and gingivitis during treatment. Numerous other studies have shown that orthodontic treatment using fixed appliances often increases plaque and gingivitis, even when a highly structured preventive program is followed to minimize the effects on periodontal tissues and enamel.^{20,21}

An early cross-sectional study compared the first 50 consecutive clear aligner cases treated by the senior author to 50 matched cases treated with fixed appliances.¹² Fixed appliances generally yielded better results than the clear aligners, but the author had more than 25 years of experience with fixed appliances, and the aligner patients were treated between 1999 and 2002.

More recently, successful outcomes have been reported from Invisalign treatment of patients with more complex malocclusions.^{11,13-15} This article reports on four patients of various ages with moderate-to-severe malocclusions who were successfully treated using preliminary versions of a new Invisalign protocol.

Case Selection

Many patients who request Invisalign treatment have previously undergone orthodontic treatment with fixed appliances and do not want to repeat the experience.¹¹ Esthetic concerns are often a significant factor for adult patients, many of whom are unwilling to wear braces, but teenagers also request Invisalign nowadays because they do not want the look of fixed appliances.¹¹ In addition, Spear reported that patients who require minor restorative dentistry or bleaching tend to

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prefer the combination of orthodontic treatment with less invasive restorative dentistry to extensive full coronal restorations and no orthodontic treatment.²²

Patients with short dental roots may be better candidates for clear aligners than for fixed appliances. A recent longitudinal study of 100 consecutive Invisalign patients showed no measurable root resorption.²³ In contrast, an average 10% of patients treated with fixed appliances have clinically significant root resorption of at least 3mm.^{24,25}

Clear aligners may also be a good choice for patients with mild anterior open bite.¹¹ The double thickness of the clear plastic appliances on the occlusal surfaces, in combination with the patient's own force of mastication, exerts an intrusive force on the posterior teeth, slightly closing the bite.^{26,27} Treatment with fixed appliances may also extrude the teeth, further opening the bite, especially when interarch elastics are used on the anterior teeth.^{28,29}

Clear aligners may be more effective than fixed appliances in correcting deep overbite because of their more predictable intrusion mechanics; in addition, the disclusion of the teeth avoids the occlusal interferences of fixed appliances.^{3,9,11} Anterior and posterior dental crossbites are also effectively treated with clear aligners, probably because of their disclusion effect.¹¹ Skeletal crossbite, on the other hand, should be treated with orthopedic or surgical methods. It has recently been shown that presurgical treatment involving clear aligners in combination with fixed appliances can be effective in patients requiring complex orthognathic surgery with corrections in all three planes of space.¹³

Patients with bruxism may also be good candidates for treatment with aligners, which prevent occlusal wear. After treatment, clear retainers are generally worn at night indefinitely, extending their protective benefits. Studies by Nedwed and Miethke³⁰ and Miller and colleagues³¹ have shown that clear aligner treatment reduces myofascial discomfort from clenching and grinding, presumably because of the disarticulation of the teeth by the appliances. In general, clear aligner treatment has been found to

cause much less patient discomfort than treatment with fixed appliances, which are often associated with mucosal irritation, tooth soreness, and other problems.³¹

Clear aligner treatment is especially appropriate for patients with extensive porcelain or metal restorations. These artificial surfaces do not allow as secure a bond with a fixed appliance as a natural tooth surface does, and the restorations may also be damaged in debonding.

The Invisalign ClinCheck* computer plan can be used as a virtual diagnostic setup, allowing decisions to be made on appropriate treatment strategies such as extractions, molar distalization, interarch elastics, interproximal reduction, or expansion.³²⁻³⁵ Anchorage can be evaluated with the superimposition tool or surgical (interarch movement) simulation tool. The software can be used to demonstrate the limits of treatment to the patient, to create an abbreviated version of the virtual treatment plan that can be e-mailed to patients and referring doctors, and to verify proper tracking of the aligners. The program can also help the orthodontist determine the biomechanical and biological feasibility of a particular treatment plan and analyze the pathways of tooth movement.¹¹

New Treatment Protocol

In 2003, Align Technology formed a Clinical Advisory Board (CAB) consisting of 13 orthodontists who had used Invisalign treatment extensively in their practices. This group decided to adopt a new protocol already being used by several of its members. The success experienced by the CAB members with this protocol prompted Align Technology to adopt most of its elements in a "Best Practices Protocol", which would be recommended for all treatment performed after Jan. 1, 2007.³⁶ The principles of this new protocol are as follows:

1. Simultaneous movement of all involved teeth.

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Similar to the use of light archwires and low-friction brackets for leveling and alignment, this creates the space needed for tooth movement and slows down the movement of all teeth except the one requiring the greatest number of stages to be corrected at a given velocity (the “determining tooth”).

2. Use of beveled 1mm (buccolingual dimension) horizontal rectangular premolar attachments for retention of aligners during intrusive movements such as leveling the lower curve of Spee in cases of deep overbite, for extrusion, and for control of a tooth’s long axis during torquing movements.

3. Use of 1mm vertical rectangular attachments for rotation of round teeth or canines, as well as translation of teeth adjacent to an extraction site.

4. Slowing down certain types of tooth movement, including rotation, extrusion, torquing, and bodily movement, below the previous standard velocity of .25mm per stage.

5. Maintaining visible space (approximately .1mm) between teeth during movement of one tooth past another.

6. Using expansion instead of interproximal reduction as a primary method of increasing the space available for correction of crowding.

7. Delaying any interproximal reduction that may be needed to correct Bolton discrepancies and other tooth-size issues until the teeth are aligned, to avoid removing enamel at an angle.

The following four cases demonstrate successful use of the new Invisalign protocol. All four patients had non-contributory medical histories, no symptoms of TMJ dysfunction, and a strong desire to avoid fixed appliances. All were told that fixed appliances might be necessary to complete treatment. Although no fixed appliances were required, auxiliary devices such as interarch elastics were used in Cases 3 and 4. All patients were offered home bleaching using their clear aligners, primarily during the first month of wear, with 30-minute applications of a 30% carbamide peroxide gel if no dentinal sensitivity was noted, or one-hour applications of a 15% gel if sensitivity was present. All patients wore clear retainers full-time for four to six months after treatment, and then indefinitely at night.

Case 1

A 13-year-old male presented with a Class II, division 1 malocclusion characterized by severe maxillary dentoalveolar prognathism, mild mandibular retrognathia, a 13mm overjet, and a 7mm overbite (Fig. 1). The initial panoramic radiograph showed normal root structure, unerupted third molars, and excellent bone support.

After extraction of both maxillary first premolars to gain space for retraction of the maxillary incisors (Fig. 2), 16 lower aligners and 29 upper aligners were used for a total of 14½ months. Compliance was good, with no need for Case Refinement or midcourse correction with additional aligners. Inter- and intra-arch mechanics were also unnecessary.

Vertical rectangular attachments were placed on the teeth adjacent to the extraction sites and on the maxillary molars to keep them upright during extraction space closure. After 12 upper and lower stages of Invisalign treatment, the attachment on the

TABLE 1
CASE 1 CEPHALOMETRIC DATA

	Pre-treatment	Post-Treatment
SNA	86.3°	84.4°
SNB	79.9°	79.2°
ANB	6.4°	5.2°
Wits appraisal	3.8mm	2.1mm
FMIA	55.2°	59.5°
FMA	20.3°	20.7°
IMPA	104.5°	99.8°
SN-GoGn	27.8°	29.6°
U1-SN	106.9°	101.2°
U1-NA	20.5°	16.8°
U1-NA	5.1mm	1.2mm
L1-NB	32.2°	28.6°
L1-NB	6.9mm	5.4mm
Interincisal angle	120.8°	129.4°
Po-NB	0.6°	-0.3°

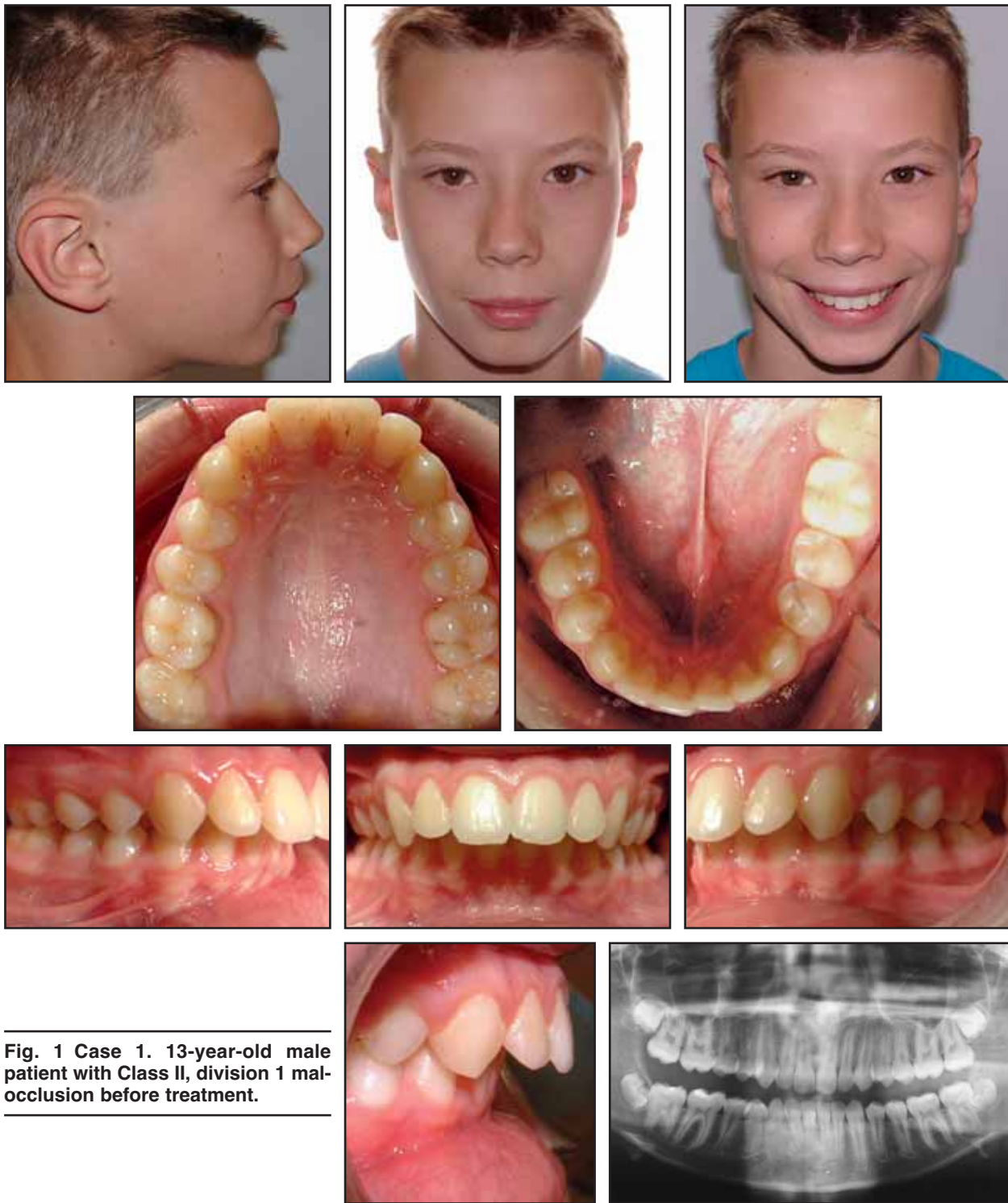


Fig. 1 Case 1. 13-year-old male patient with Class II, division 1 malocclusion before treatment.

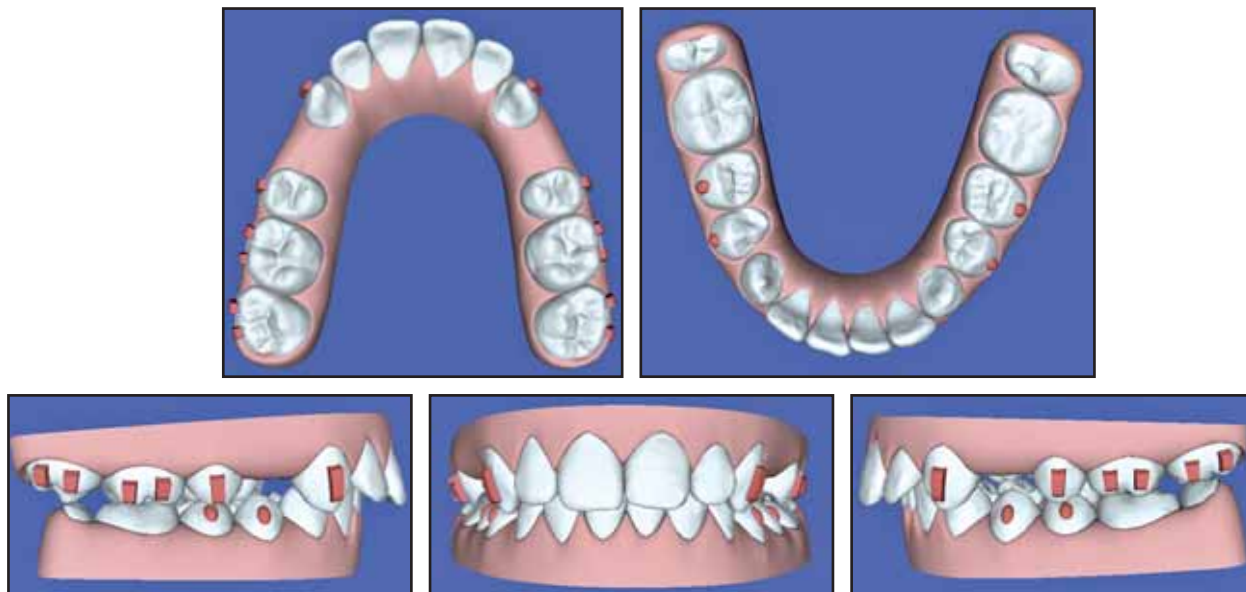


Fig. 2 Case 1. Initial ClinCheck images after extraction of upper first premolars.



Fig. 3 Case 1. Patient after 12 of 29 upper and 12 of 16 lower stages of treatment, showing vertical attachments on aligners.

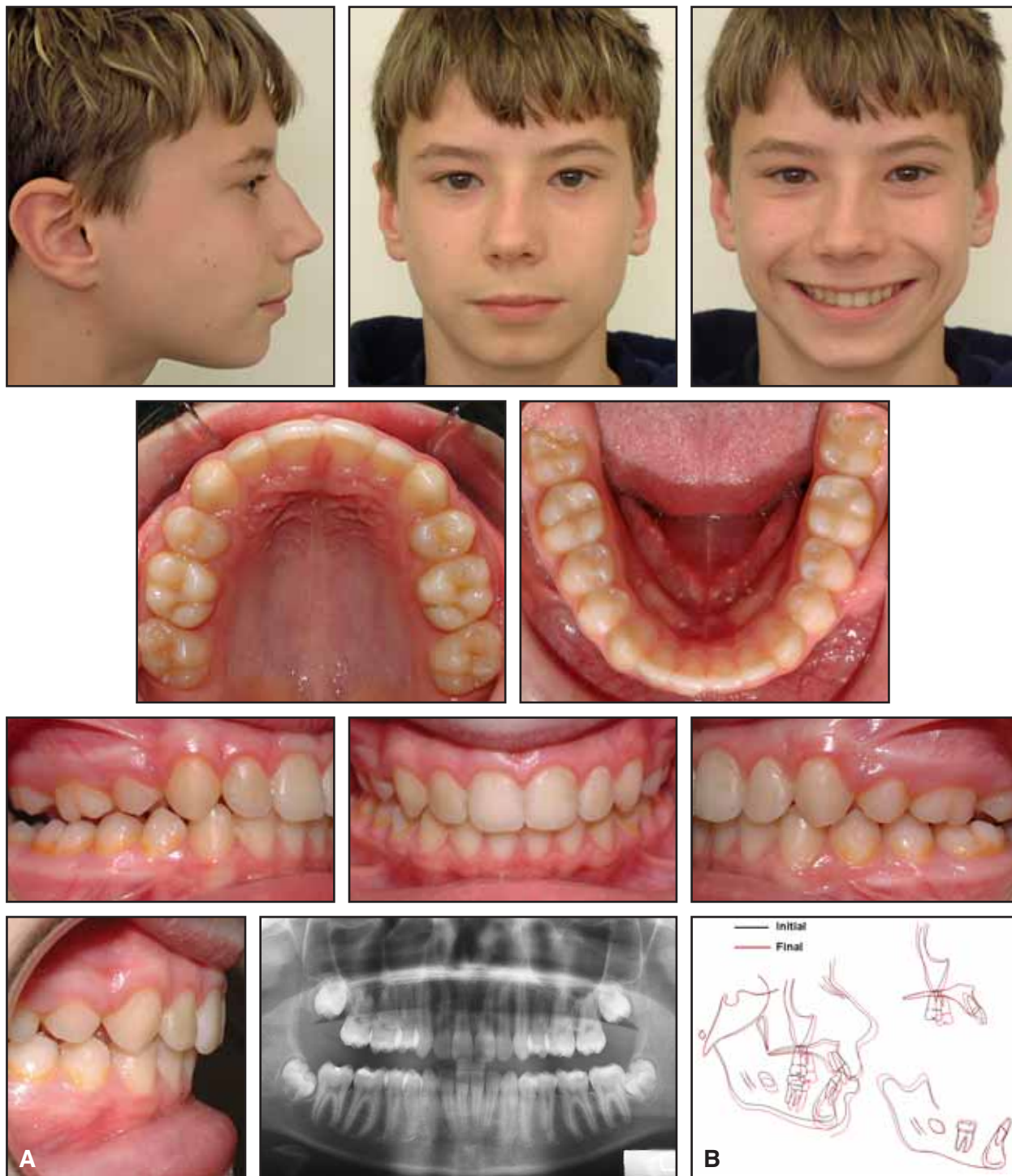


Fig. 4 Case 1. A. Patient after 14½ months of treatment. B. Superimposition of pre- and post-treatment cephalometric tracings.

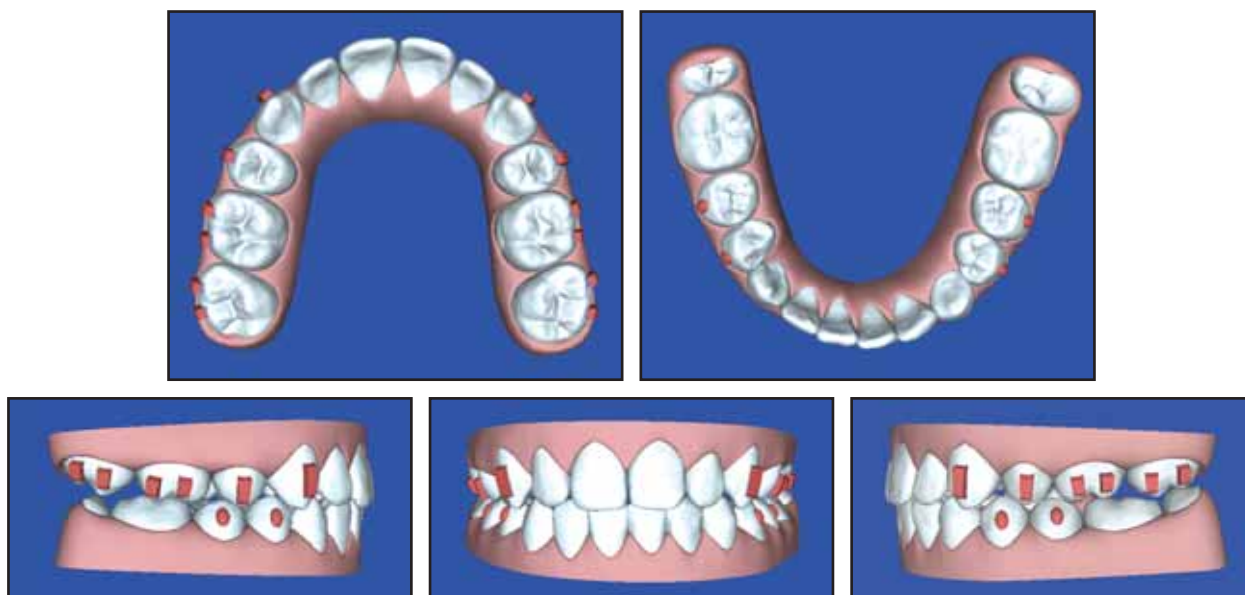


Fig. 5 Case 1. Final ClinCheck projections, matching post-treatment results.

maxillary right second premolar was lost and had to be replaced to prevent tipping (Fig. 3).

Post-treatment records showed complete closure of the upper extraction spaces and achievement of normal overjet and overbite (Fig. 4A). The slight posterior open bite on the right side is commonly seen because of intrusion caused by closure on the double thickness of the aligners. The post-treatment panoramic radiograph confirmed root parallelism adjacent to the upper extraction sites. (The pretreatment cephalometric measurements and tracings were obtained one year before the start of treatment, which explains why more growth is shown than would have been expected in 14½ months.) The reduction in overjet was most likely due to forward mandibular growth (Fig. 4B). Cephalometric analysis also showed slight flaring of the lower incisors, with no significant change in the mandibular plane angle and only slight uprighting of the upper incisors (Table 1). The final ClinCheck projections matched the post-treatment results (Fig. 5).

Two years after the end of treatment, the slight posterior open bite had closed as a result of wearing the aligners only at night, but continued

growth of the patient's nose had adversely affected the profile (Fig. 6). The panoramic radiograph showed stable root positions. Gingival inflammation and tooth staining were due to a recently developed smoking habit. Because there was inadequate space for the third molars, it was recommended that they be removed.

Case 2

A 16-year-old female presented with the chief complaint of "crooked and uneven front teeth" (Fig. 7). She had an end-on Class II canine relationship and rotated maxillary left and mandibular canines. The overbite was more than 120%. Palatal impingement and severe retroclination of the incisors were noted in both arches, and the gingival margins of the maxillary incisors were uneven because of supra-eruption of the central incisors. The panoramic radiograph showed normal roots and alveolar bone and partially erupted third molars, which were scheduled for extraction.

A total of 35 upper and 30 lower aligners were planned over 18 months of treatment, with 1mm elliptical attachments placed on all eight

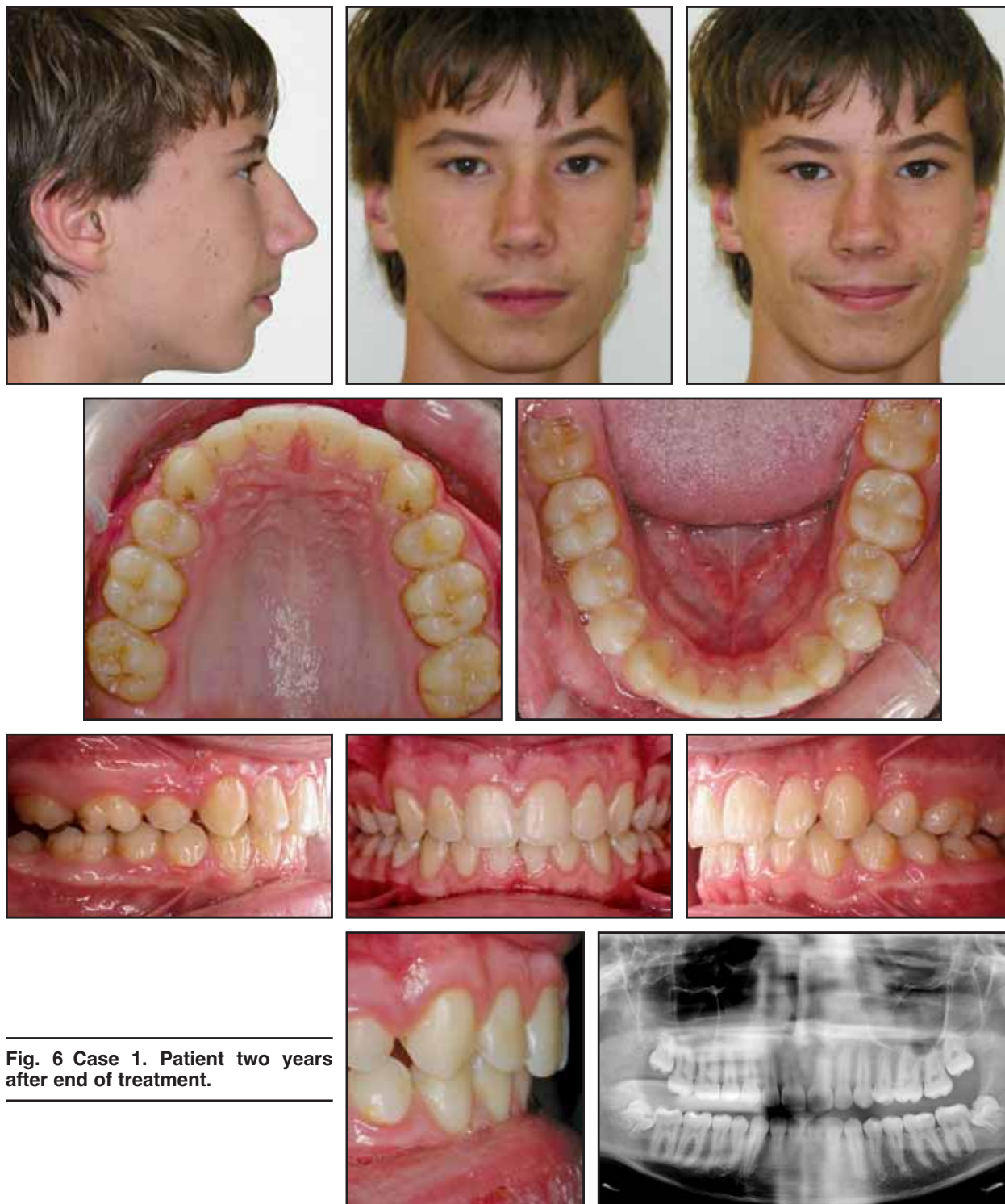


Fig. 6 Case 1. Patient two years after end of treatment.

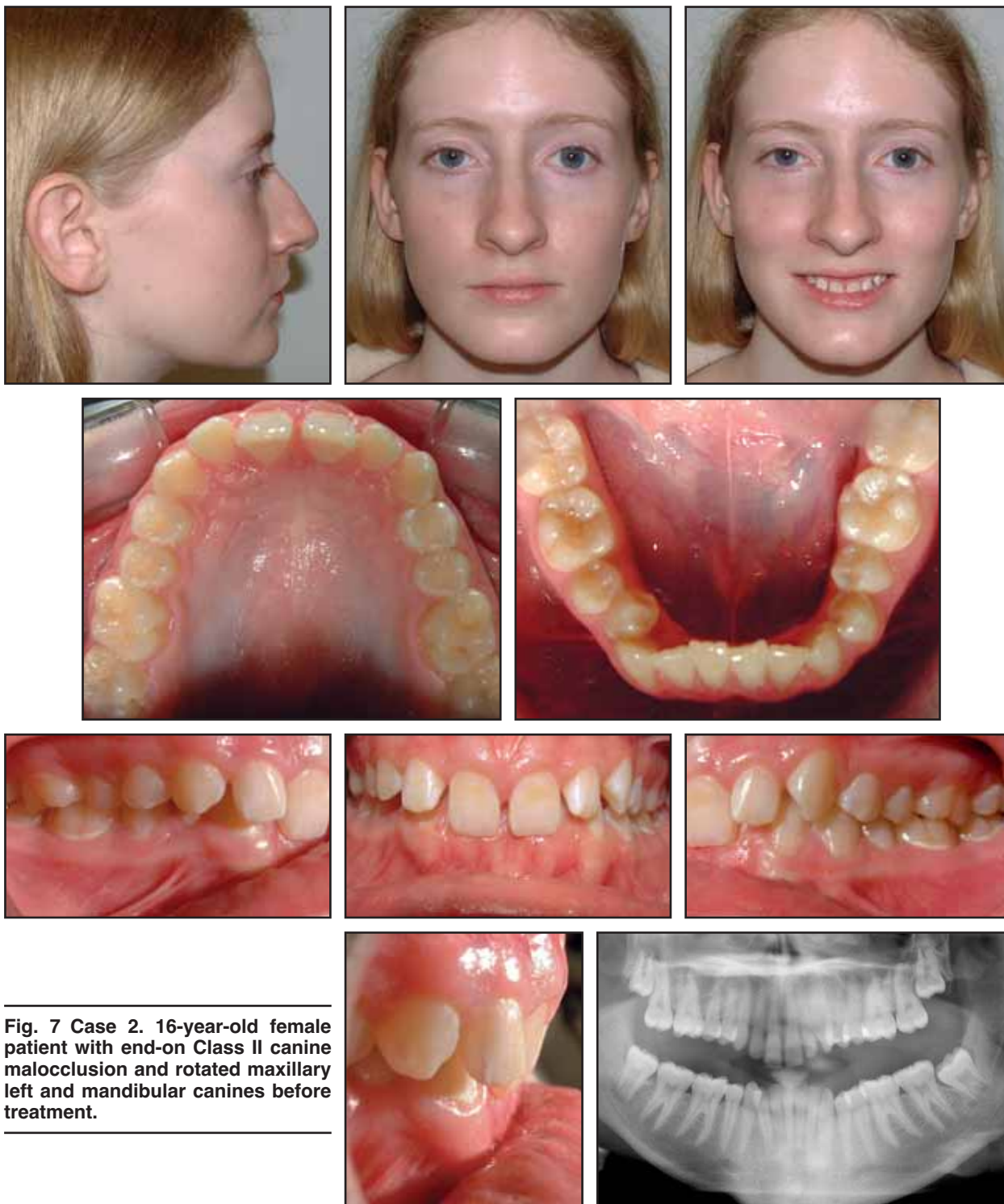


Fig. 7 Case 2. 16-year-old female patient with end-on Class II canine malocclusion and rotated maxillary left and mandibular canines before treatment.

premolars to facilitate intrusion of the incisors (Fig. 8). Treatment of this patient was begun before adoption of the new protocol, which would have called for two horizontal beveled attachments on each first premolar and 4mm or 5mm × 1mm × 2mm vertical rectangular attachments on the three rotated canines.

The upper left buccal segment was distalized about 2mm to improve the canine relationship. An upper arch Case Refinement involving four additional aligners was needed for slight additional derotation of the upper left canine, probably because no vertical rectangular attachment was placed on that tooth. In fact, the tooth was still slightly rotated after the Case Refinement.

After 18 months of treatment, records showed opening of the deep overbite, good alignment of the teeth, and leveling of the upper incisor gingival margins (Fig. 9A). The panoramic radiograph demonstrated proper root alignment, with no resorption despite the significant intrusion, and adequate healing after the extraction of all four third molars. Cephalometric analysis showed significant

TABLE 2
CASE 2 CEPHALOMETRIC DATA

	Pre-treatment	Post-Treatment
SNA	73.1°	73.0°
SNB	73.2°	73.1°
ANB	-0.1°	-0.1°
Wits appraisal	-3.3mm	-2.0mm
FMIA	87.5°	67.9°
FMA	20.0°	19.3°
IMPA	72.5°	92.9°
SN-GoGn	37.5°	36.6°
U1-SN	83.9°	93.6°
U1-NA	10.8°	20.6°
U1-NA	2.5mm	5.0mm
L1-NB	3.2°	22.6°
L1-NB	-3.4mm	3.1mm
Interincisal angle	166.1°	136.9°
Po-NB	5.1°	6.2°



Fig. 8 Case 2. Initial ClinCheck images.

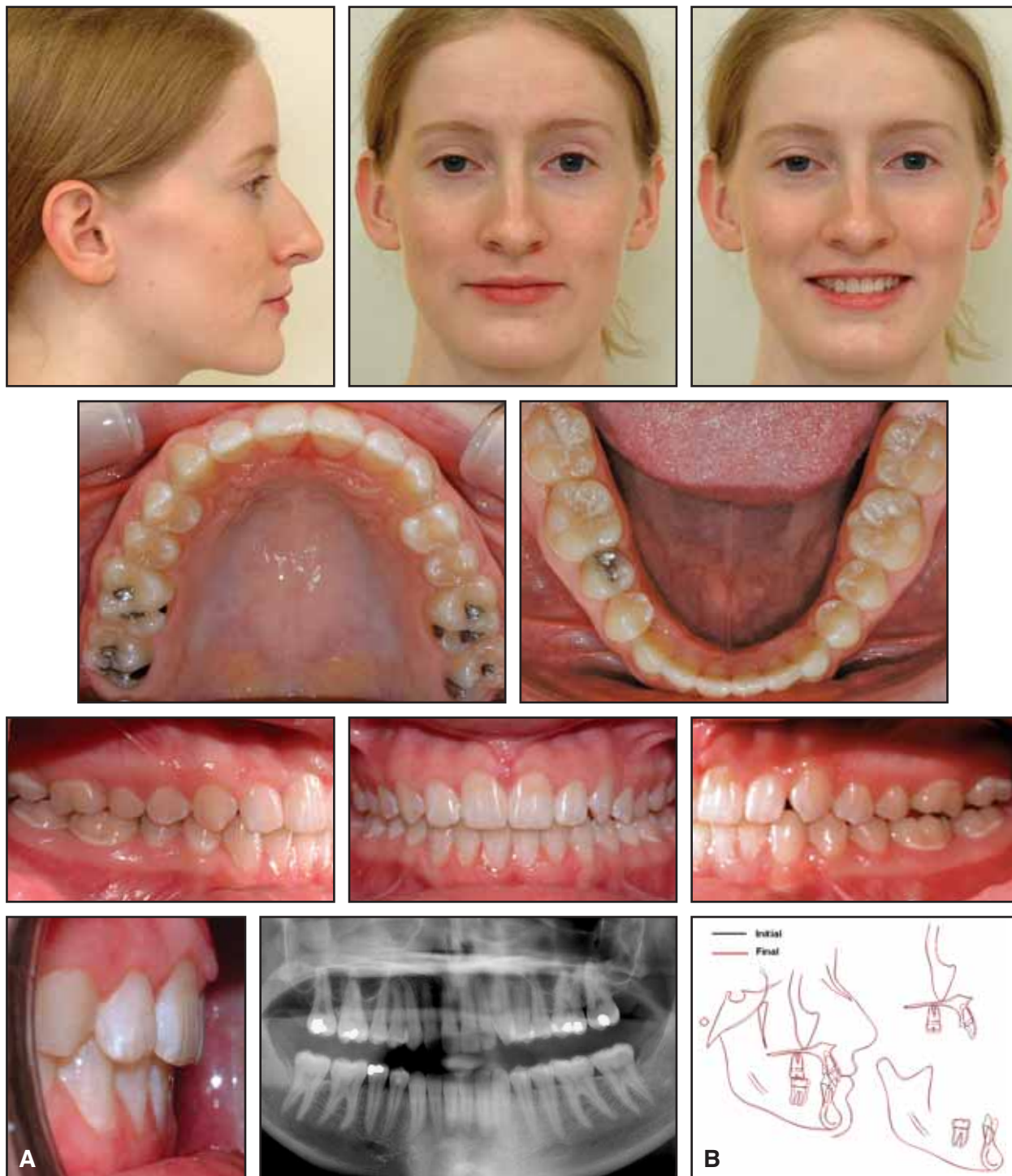


Fig. 9 Case 2. A. Patient after 21 months of treatment, including Case Refinement. **B.** Superimposition of pre- and post-treatment cephalometric tracings.

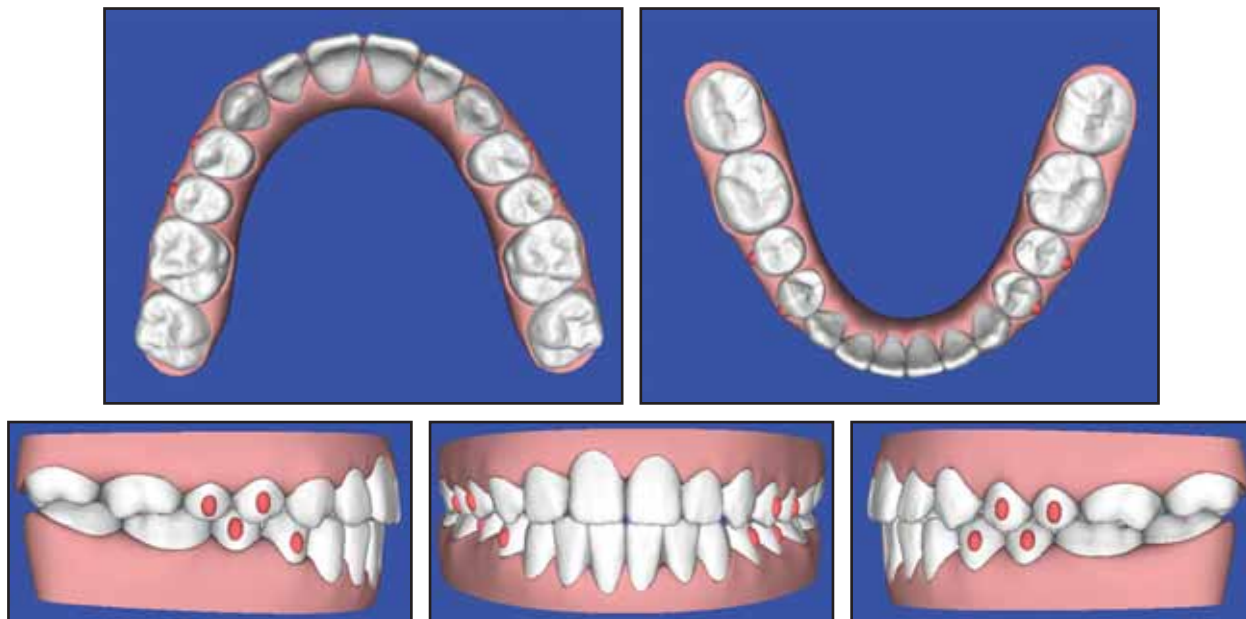


Fig. 10 Case 2. Final ClinCheck projections, matching post-treatment results.

intrusion of the upper and lower incisors, with minimal impact on the skeletal relationships (Fig. 9B, Table 2). The interincisal angle was reduced from 166° to 137°, the upper incisor to SN angle increased from 84° to 94°, and the lower incisor to mandibular plane angle increased from 72.5° to 93°. The final ClinCheck projections closely matched the post-treatment results (Fig. 10).

Case 3

A 55-year-old woman presented with the chief complaint of “crooked front teeth that do not touch” (Fig. 11). She had undergone successful treatment for generalized periodontitis, with follow-up periodontal maintenance visits every three months. At the start of orthodontic treatment, her periodontal health was excellent, with minimal plaque accumulations and no bleeding on gentle probing. She had extensive posterior restorations. The diagnosis was maxillary vertical excess with dental and skeletal open bite and moderate crowding in both arches. Endodontic therapy had been performed on the mandibular right second pre-

molar, and the pretreatment panoramic radiograph revealed generalized alveolar bone loss of about 20%. The maxillary left second and third molars had drifted mesially and tipped into the space left by early loss of the first molar.

The patient was advised that ideal treatment would involve Le Fort I orthognathic surgery and genioplasty with full fixed appliances. She declined this treatment, but accepted a compromise plan involving upper and lower interproximal reduction and extraction of the maxillary right first premolar, followed by clear aligner treatment to correct the midline and reduce the crowding.

A series of 37 upper and 33 lower aligners was planned. As in Case 1, 5mm × 1mm × 2mm vertical rectangular attachments were placed on the teeth adjacent to the extraction site and on the maxillary right molars (Fig. 12). In addition, 1mm elliptical attachments were placed on the mandibular premolars and on the anterior teeth as they were retracted in the upper arch and slightly proclined in the lower arch. These attachments took advantage of the natural extrusion that would occur when slow extrusive movement (half the



Fig. 11 Case 3. 55-year-old female patient with maxillary vertical excess, dental and skeletal open bite, and moderate crowding in both arches before treatment.

usual .25mm per stage) was combined with proclination and retraction movements (Fig. 13). It was decided not to upright the maxillary left second and third molars, which would have required

the use of a sectional fixed appliance.

After 31 months of treatment, the open bite was partially closed, and the maxillary premolar extraction space was completely closed (Fig. 14).

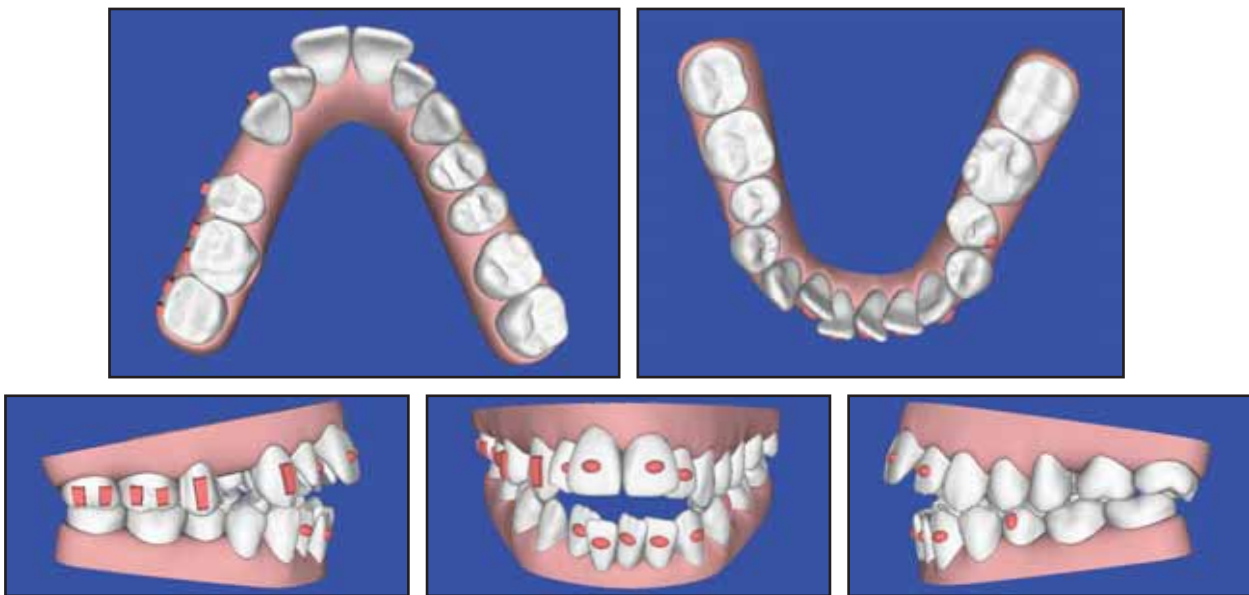


Fig. 12 Case 3. Initial ClinCheck images after extraction of maxillary right first premolar.



Fig. 13 Case 3. Partially closed open bite and completely closed maxillary right extraction space before Case Refinement.



Fig. 14 Case 3. Patient after 31 months of treatment.

Two Case Refinements were performed, using 15 upper and 12 lower aligners in the first and seven upper aligners in the second.

After 31 months of treatment, excellent facial esthetics had been achieved through the improvement in occlusion, avoidance of an increase in anterior face height, and plastic surgery involving a face lift and chin implant (Fig. 14). The open bite was closed except for the maxillary lateral incisors, which were 1mm out of occlusion. The post-treatment panoramic radiograph showed parallel roots around the upper right first premolar extraction space. The post-treatment panoramic radiograph showed parallel roots around the upper right first premolar extraction space. The midlines were not fully corrected because the patient did not want to wear interarch elastics toward the end of treatment. Final Clin-Check projections after the two Case Refinements showed the use of horizontal beveled attachments on the upper incisors to achieve the final amount of extrusion needed to correct the overbite (Fig. 15).

One year after the end of treatment, further closure of the open bite had occurred, with interincisal contact of all anterior teeth (Fig. 16A). New crowns were placed on the upper right molars to

TABLE 3
CASE 3 CEPHALOMETRIC DATA

	Pre-treatment	Post-Treatment
SNA	73.5°	73.5°
SNB	69.1°	69.0°
ANB	4.4°	4.5°
Wits appraisal	-0.4mm	-1.4mm
FMIA	52.0°	54.4°
FMA	49.6°	49.1°
IMPA	78.4°	76.5°
SN-GoGn	59.6°	59.3°
U1-SN	98.6°	88.0°
U1-NA	25.1°	14.5°
U1-NA	6.3mm	1.9mm
L1-NB	27.1°	24.7°
L1-NB	7.3mm	7.0mm
Interincisal angle	123.4°	136.2°
Po-NB	2.5°	5.7°

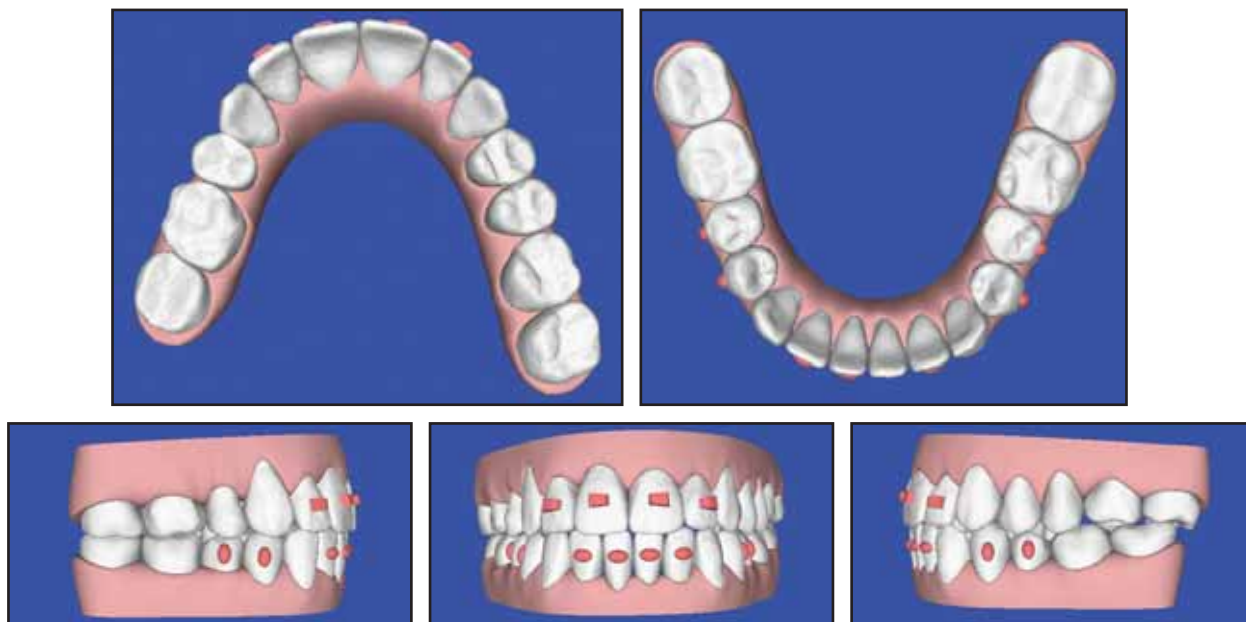


Fig. 15 Case 3. Final ClinCheck projections after second Case Refinement.



Fig. 16 Case 3. A. Patient one year after end of treatment. **B.** Superimposition of pretreatment and 15-month-post-treatment cephalometric tracings.

improve their esthetics. The patient had worn the retainers only at night for the preceding nine months, confirming the stability of the open-bite correction. Slight rotation of the maxillary lateral incisor and mandibular central incisor had occurred during the night-only retainer wear, and the midlines remained off by 1mm. Comparison of the pretreatment and 15-month-post-treatment cephalometric tracings showed that the overall skeletal structures and the mandibular plane angle had remained remarkably similar throughout treatment, considering the closure of a substantial open bite (Fig. 16B, Table 3). The upper incisors were uprighted nearly 11° and the lower incisors 2°.

Case 4

A 32-year-old male presented with a Class II, division 1 malocclusion, a 3mm overbite and 7mm overjet, and the chief complaint of “worsened overbite and crowded front teeth” (Fig. 17). Moderate crowding was noted in both arches, but the periodontal tissues were healthy. The patient had undergone previous orthodontic treatment as an adolescent after the extraction of all four first premolars. The pretreatment panoramic radiograph showed parallel roots in all four extraction sites. The third molars had also been extracted, and the alveolar bone height was good, although many of the roots showed multiple dilacerations.

An initial series of 43 upper and 14 lower aligners was planned over 25 months of treatment, using elliptical attachments on the maxillary second premolars and first molars and mandibular second premolars for appliance retention (Fig. 18). The Class II correction was achieved in ClinCheck with interproximal reduction, combined with a simulation of interarch movement using the surgical movement tool. After the interproximal reduction in the upper anterior segment, treatment involved 14 months of wearing 4oz Class II elastics from clear buttons on the upper canines to metal buttons on the lower first molars. The aligners were cut back about 2mm gingivally to accommodate the buttons.

A Case Refinement with 10 lower aligners was needed to complete the treatment, primarily

**TABLE 4
CASE 4 CEPHALOMETRIC DATA**

	Pre-treatment	Post-Treatment
SNA	81.1°	81.7°
SNB	74.0°	74.6°
ANB	7.1°	7.1°
Wits appraisal	5.5mm	4.9mm
FMIA	51.5°	53.5°
FMA	25.3°	26.0°
IMPA	103.2°	100.0°
SN-GoGn	33.0°	33.8°
U1-SN	98.6°	97.0°
U1-NA	17.5°	15.3°
U1-NA	3.8mm	1.5mm
L1-NB	30.0°	28.4°
L1-NB	10.2mm	9.6mm
Interincisal angle	125.2°	129.2°
Po-NB	0.0°	0.0°

because a 1mm vertical rectangular attachment was not initially placed on the rotated lower right canine. The Case Refinement used such an attachment to successfully derotate the tooth (Fig. 19A).

Cephalometric analysis and superimposition of pre- and post-treatment cephalometric tracings showed a 3mm distal bodily movement of the upper central incisor as measured from the apex, accompanied by upper and lower incisor intrusion to open the bite (Fig. 19B, Table 4). All skeletal and other dental measurements remained stable. The final ClinCheck projections were an excellent match with the post-treatment results (Fig. 20).

Discussion

Patient cooperation is a critical factor in achieving success with Invisalign treatment. The aligners should be worn at least 20 hours per day, seven days a week. The patients shown here, who had moderate-to-severe malocclusions, were all highly compliant with their aligner wear and there-



Fig. 17 Case 4. 32-year-old male patient with Class II, division 1 malocclusion before treatment.

fore had good treatment outcomes. Still, successful clear aligner treatment requires considerable clinical experience with other orthodontic methods, proper implementation of diagnosis and treatment planning, and a thorough knowledge of biomechanics. These skills form the basis for reviewing the staging process with the ClinCheck software before treatment.

Tipping was often a problem in premolar extraction cases during the early years of Invisalign treatment. The new protocol, using 1mm rectangular attachments, has allowed more upper premolar extraction patients to be treated exclusively with aligners. Nearly all patients needing lower extractions still require completion of treatment with fixed appliances, because the spaces are more difficult to close. In any case, if the teeth tip more than 5° from the vertical axis during space closure, fixed appliances will probably be needed to upright them. Although Invisalign can hold teeth upright during the closure of upper extraction spaces, it cannot upright teeth adjacent to an extraction space once they have developed clinically significant tipping. If tipping exceeds 10°, the clinician should

either incorporate a fixed appliance segment to upright the tipped teeth or convert to full fixed appliances to finish treatment. The bottom line is that Invisalign treatment involving premolar extractions is still in the experimental stage, and Align Technology does not currently recommend Invisalign for these cases.

Conclusion

Clinicians who tried Invisalign in the first few years after its introduction, but abandoned it because of shortcomings such as unpredictable tooth movement, may have more success with the improved protocol. As this article demonstrates, the new Invisalign protocol can be used successfully in a variety of complex cases, including malocclusions with deep and open bites, moderate-to-severe overjet, and upper premolar extractions. Three of the four patients shown here required only one series of aligners or one Case Refinement, with no midcourse corrections. Only the complex Case 3 required two Case Refinements. Further testing is needed by other clinicians to determine

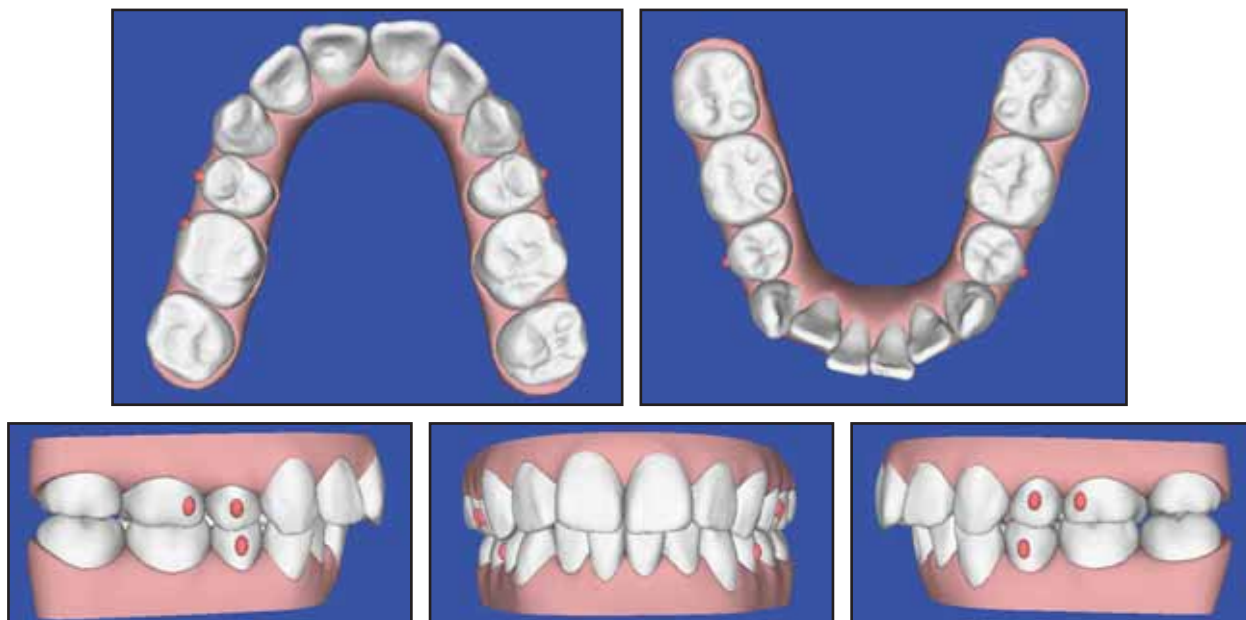


Fig. 18 Case 4. Initial ClinCheck images.

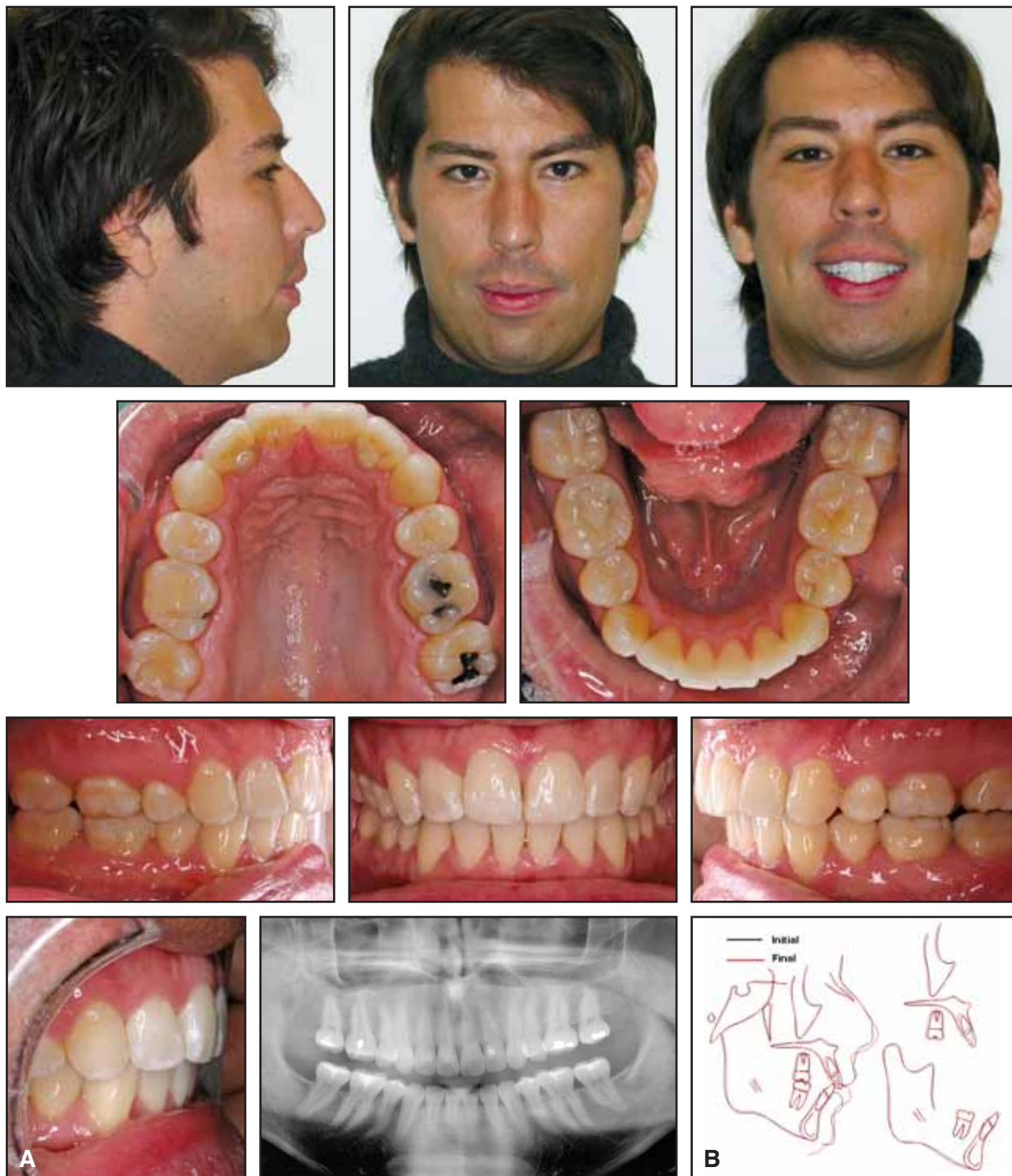


Fig. 19 Case 4. A. Patient after 31 months of treatment, including Case Refinement. B. Superimposition of pre- and post-treatment cephalometric tracings.

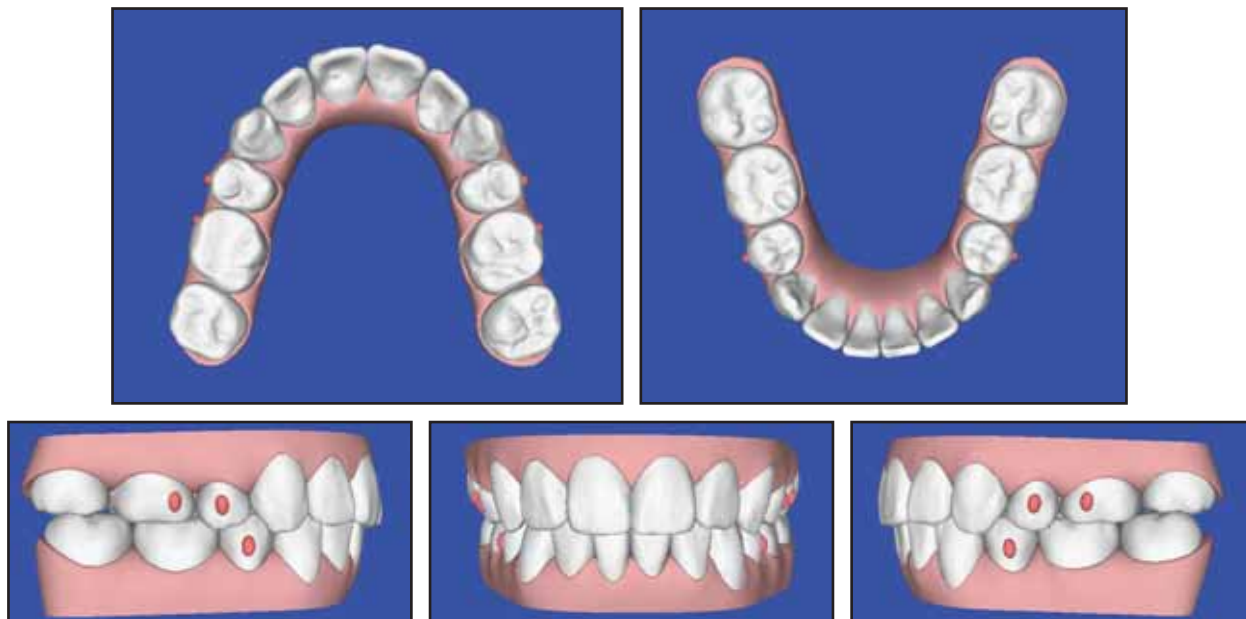


Fig. 20 Case 4. Final ClinCheck projections, showing excellent match with post-treatment results.

whether similar outcomes can be obtained in comparable cases.

Understanding the ClinCheck staging process is crucial for good results. Orthodontists will increase their chances of success with the Invisalign system if they take the time to acquire appropriate standardized instruction before using this relatively new form of treatment. They should also gain significant clinical experience in the treatment of mild malocclusions before attempting to treat more complex cases.

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