

Cases & Commentaries in Orthodontic Technology

From the Editor

The mystery that surrounds the effectiveness of Invisalign® treatment appears to be a common conversation topic within orthodontic circles. Even a greater mystery, however, is why.

Principles of tooth movement never change, whether one uses wires made of metal or plastic, or brackets made of metal or resin. With the addition of nickel, titanium and numerous other elements, the metal orthodontic wire has changed significantly since its earlier days; and in the years to come the Invisalign plastic (tray) is likely to see the same. Similarly, the Angle design bracket now has a twin on the same base; there are ceramic varieties, self-ligating versions, and even the type that is glued onto the lingual side of the tooth. The Invisalign bracket (attachment) is certain to experience a similar evolution. While designs and materials change, the tooth remains the same; it is still supported by the periodontal ligament, the alveolar bone and the gingiva. Mechanical principles of force application and the consequent biological response, therefore, will never change.

Initially, due to uncertainties and the exercise of caution, Invisalign was applied to cases of mild to moderate complexity. The results were encouraging. The experienced practitioner now uses Invisalign to prepare cases for surgery, treat adolescents, or in cases with premolar extractions. Many of these cases are still in progress. The experienced clinician will also know difficult cases are simply “difficult,” no matter which appliance is used to treat them. Just as clinical difficulties were catalysts for newer metal bracket and wire designs, the “difficulty” will dictate the evolutionary changes in the resin attachments and plastic wire.

The collective experiences from well over 75,000 patients in private practices and university settings propel constant improvements in the system. Clinical studies are not easy; they are costly and time-consuming. Despite these barriers, however, more than 28 clinical articles have been published on this technique, half of which have appeared in peer-reviewed journals. What follows in this issue of Cases & Commentaries in Orthodontic Technology is a précis of the findings of clinical trials conducted on over 250 patients.

The first clinical study was designed to test the applicability of the appliance. It showed that the appliance was indeed effective in the treatment of generalized crowding, space closure and lower incisor extractions. Following this study, another clinical trial was launched to elucidate what stiffness of the plastic material and recommended frequency of wear were optimal. This second study included complex cases. It showed less predictable movements for extrusion, bodily translation in bicuspid extractions and round teeth. These results paved the way to a third study where different attachments were designed and tested for predictability of tooth movement. To expand on these findings, a separate study was initiated to examine bodily movement in premolar extraction cases, staging of treatment, and the combination of Invisalign with fixed appliance treatment. Another study examined the compliance and oral hygiene of the adolescent patient.

A good orthodontic outcome results from proper diagnosis, treatment strategy, bracket placement and wire bending. The first two of these do not change whether the patient is treated with the Invisalign system or not. The latter two, in the case of Invisalign, are done on the computer. The clinician's bracket (attachment) placement must be accurate in the ClinCheck, just as staging of tooth movement and types of tooth movement must be perfect. It is immaterial whether the treatment is carried out with plastic or metal wires. Essentials of care, attention to detail, continuous monitoring of progress, minimization of patient inconvenience, and all the elements of Hippocratic thought remain in place.

Predictions of the future were accurate ... the manual skills of wire manipulation are being replaced by 3D image manipulations. Perhaps, this is the “industrial revolution” of orthodontics. Manufacturing is no longer a manual task; robots make better cars, but unfortunately, bad drivers are still out there. The day is not likely to come when Invisalign can bail out the sloppy clinician.

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Applicability Study (1998)

Investigators Robert Boyd, DDS, Med;
Vicki Vlaskalic, BDS, MDS;
Mohamed Fallah, BDS, MDS

Research Site University of the Pacific

Objective To explore the applicability of the Invisalign appliance

Study Design 37 non-randomized patients were enrolled and assigned to one of three groups based on treatment time (< 6 months; 6-12 months and 13-24 months)

Findings (Continued on next page)



Figure 2. Progress reveals bodily movement of teeth into extraction site; left side anchorage segment remains untaxed. Overlap of the maxillary centrals will be resolved in later stages of treatment.

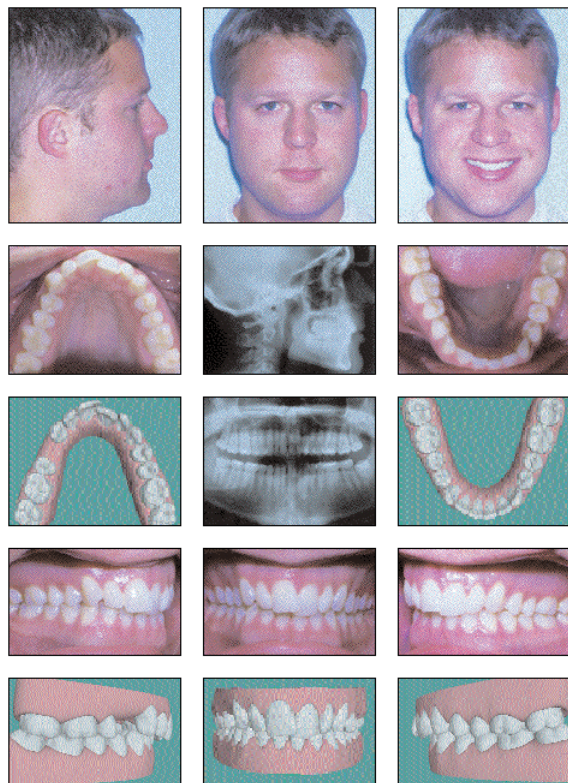


Figure 1. The pre-treatment images of this patient reveal moderate crowding, midline deviation, deep bite, and a unilateral Class II subdivision (right) malocclusion. Findings from the cephalometric and panoramic radiographs are non-contributory. Maxillary right first premolar was extracted to finish with a Class II molar relationship on the right and Class I on the left.

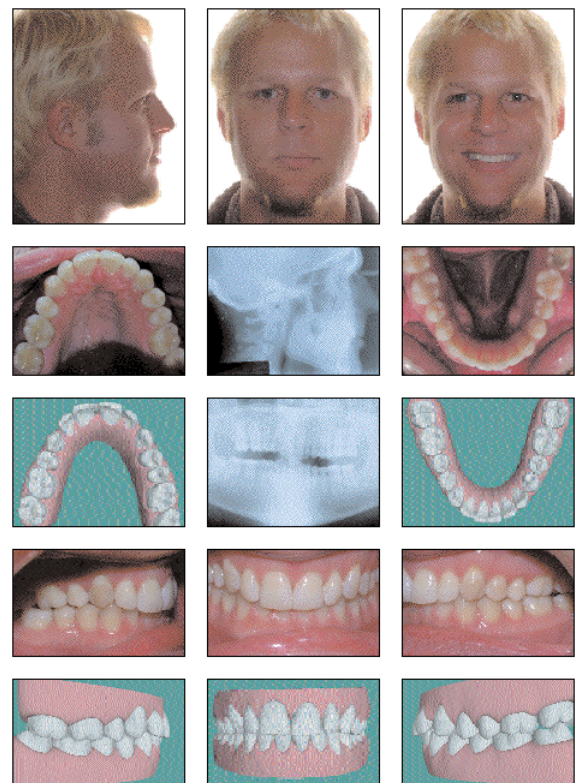


Figure 3. Final appearance of the dentition after Invisalign treatment. Note the well-aligned marginal ridges. The panoramic radiograph shows the parallel roots at the extraction site. The middles are now coincident; the crowding and deep bite have also been corrected.

Findings
(Continued)

- 1) The appliance predictably treated crowding cases; the crowding was resolved by programmed expansion, interproximal reduction, and lower incisor extraction.
- 2) The appliance was less predictable at achieving the following movements: rotation of round teeth, extrusion, and bodily movement in bicuspid extraction cases.

Frequency of Wear and Material Stiffness Study (2000)

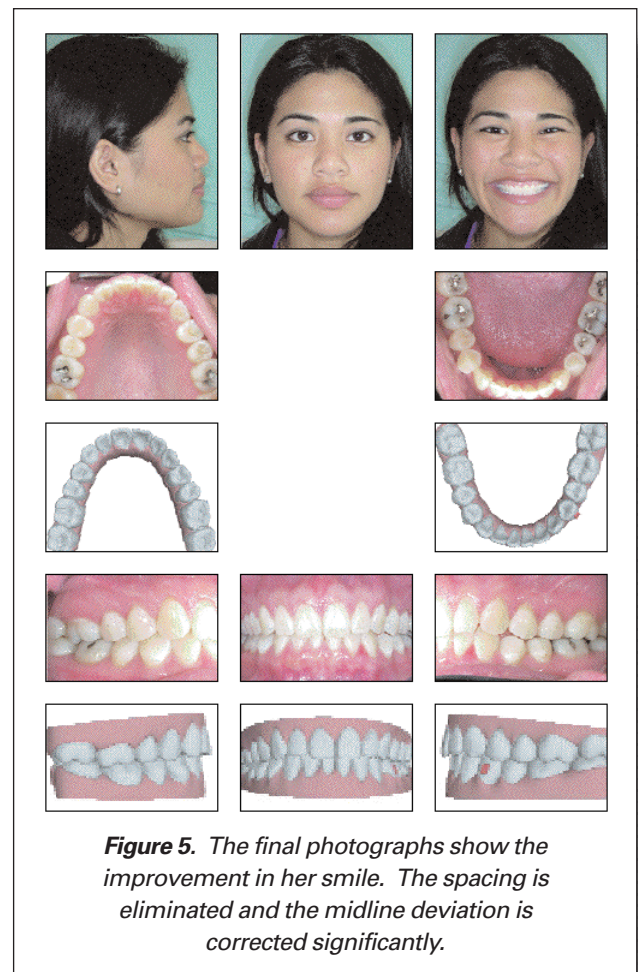
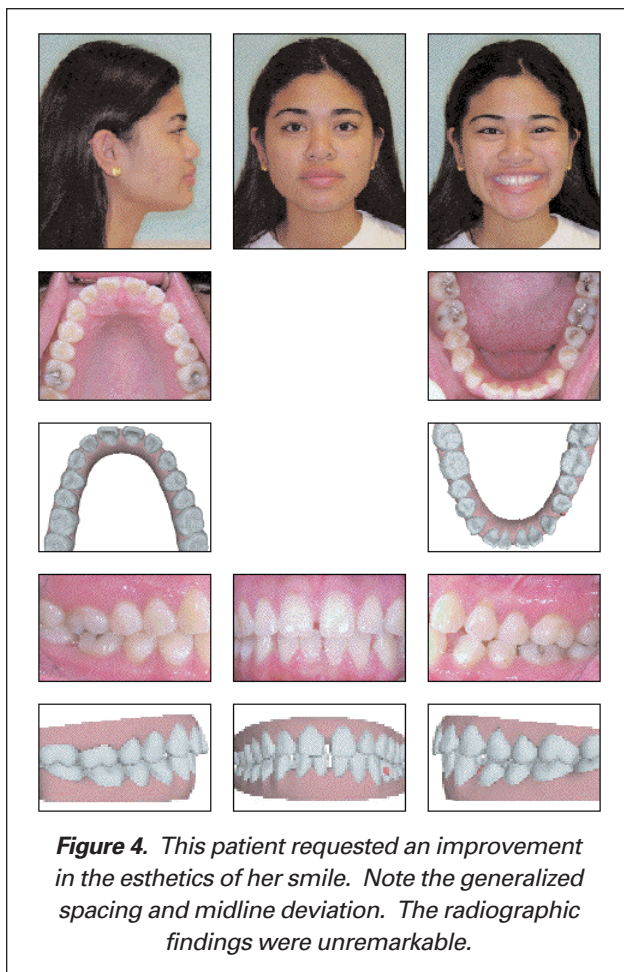
Investigators Gregory King, DMD, DMSc; Anne-Marie Bollen, DDS, PhD, MS;
Greg Huang, DMD, MSD, MPH

Research Site University of Washington

Objective To test different change frequencies (1 week vs. 2 week) and material stiffness (hard vs. soft) to determine optimal treatment regime.

Study Design For this randomized study, 51 patients were enrolled and divided based on the total unweighted Peer Assessment Rating (PAR) score (low PAR < 15; high PAR ≥ 15). Based on these selection criteria, at least 50% of the patients were complex cases that would have been considered beyond the Invisalign case selection criteria at that time. The patients were also divided into extraction and non-extraction cases.

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Study Design

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This resulted in 42% (N=21) requiring two or more bicuspid extractions, 10% (N=5) requiring one incisor and/or one other tooth extraction, and 6% (N=3) requiring lower incisor extraction only. The regimen was changed if the following situations presented: 1. unmanageable pain, 2. lack of appliance fit, or 3. inability to achieve the orthodontic treatment goal. In these cases, patients were switched to the hard material and a two-week wear regimen, or fixed appliances.

Findings

- 1) The two-week aligner wear and hard material led to a higher degree of success and completion rate than other regimens. Due to the small sample sizes, these differences were not statistically significant. These findings are consistent with the current commercially recommended protocol.
- 2) A high rate of regimen change was necessary in the bicuspid extraction cases regardless of material or frequency of change of aligners.

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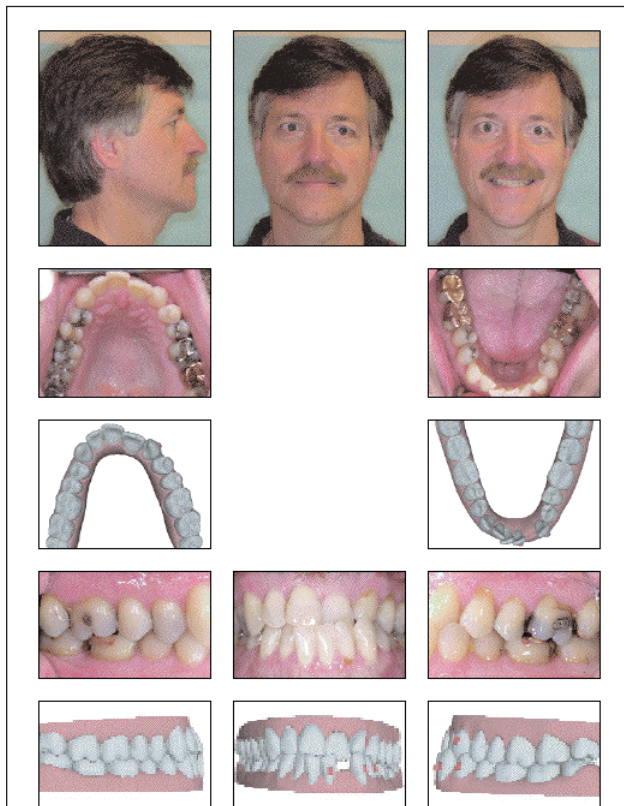


Figure 6. This patient presented with a Class III malocclusion, edge-to-edge bite, severe crowding in the lower arch and moderate crowding in the upper. Also, the maxillary left lateral was missing. In the transverse dimension it can be seen that the anterior teeth are in Crossbite and the midlines are significantly off. There were no radiographic findings to contradict orthodontic treatment.

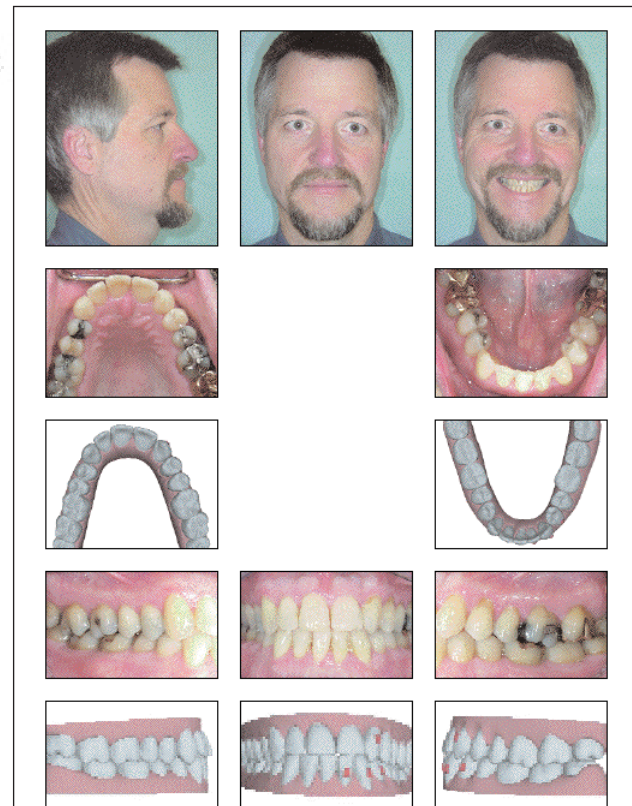


Figure 7. As these final clinical images show, extraction of one lower incisor balanced the absence of the maxillary lateral very well. Crowding and crossbite are eliminated. Both the canines and molars are Class I. Patient's enthusiasm to smile is apparent in the facial photographs.

Attachment Evaluation for Extrusion, Rotation and Intrusion (2000)

Investigators Tim Wheeler, DMD, PhD; Calogero Dolce, DDS, PhD; Marie Taylor, RDH Research Site University of Florida

Objective To evaluate different attachment designs for their optimal use and design. Their effectiveness to rotate round teeth and extrusive and intrusive movements were also evaluated. A secondary set of objectives was to evaluate periodontal health, caries and decalcification, root resorption, and TMJ changes.

Study Design 100 patients were enrolled and randomly assigned to one of 6 groups: 5 different attachment groups and 1 control group with no attachments; one stratification variable was needed for lower incisor extraction. Data (impressions, bleeding scores, pocket depth, craniomandibular index, caries/decalcification index, root resorption, and pre- and post-treatment radiographs) were collected at baseline 3, 6, 12 and 18 months into treatment. To increase the statistical power and reduce the number of strata and variables, bicuspid extractions were excluded.

Findings (Continued on next page)

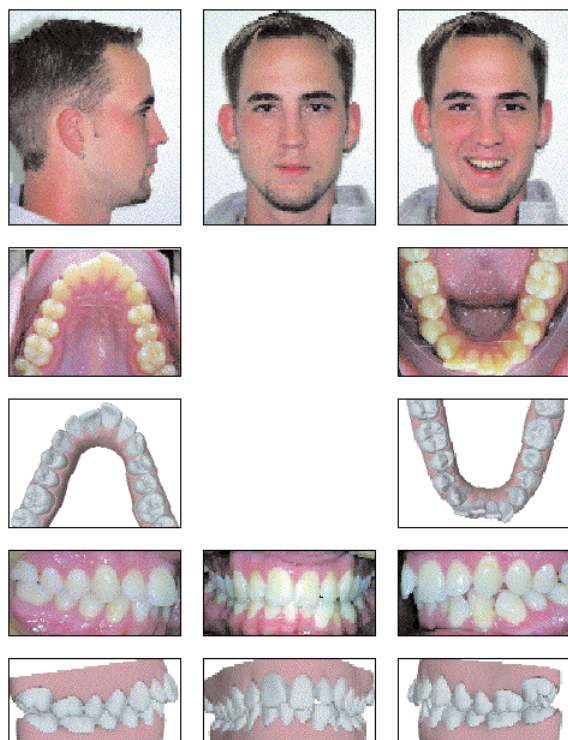


Figure 8. This patient presented with a Class I malocclusion with upper and lower crowding and buccal crossbite of the second molars. The treatment plan involved upper and lower interproximal reduction to alleviate the crowding along with anterior proclination. The buccal crossbite was to be corrected through lingual crown tipping of the upper second molars.

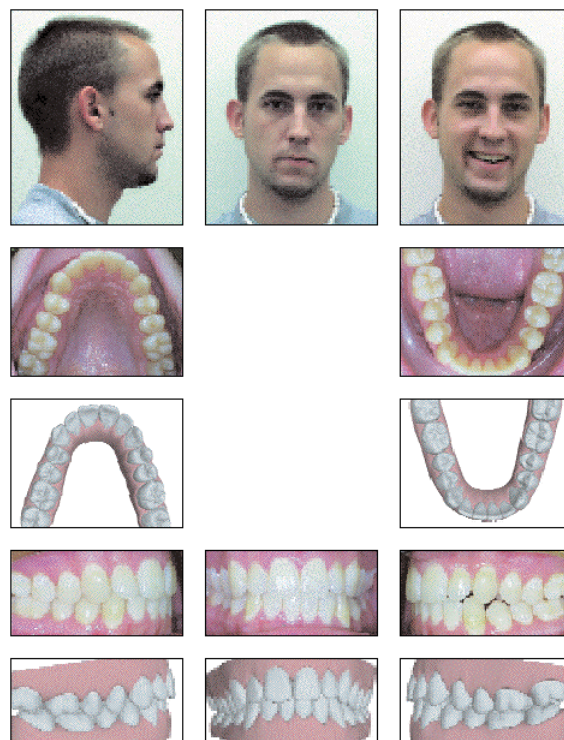


Figure 9. The final photos show the alleviation of the crowding and the excellent alignment achieved. The Class I molar relationship has been maintained and the buccal crossbite has been corrected.

Findings
(Continued)

- 1) Periodontal tissue health as measured by papillary bleeding score and periodontal pocket depth improved with the use of Invisalign aligners during orthodontic treatment. (Poster Presentation #1483, AADR San Antonio, 2003).
- 2) Data are still too preliminary to identify optimal attachment designs. Preliminary experience suggests that critical evaluation of ClinCheck is imperative. Also noted, clinician's experience is related to greater predictability of tooth movement.
- 3) Progress data demonstrate that monitoring and relieving the tight interproximal contacts around crowded and rotated teeth increase the probability of achieving proper alignment.

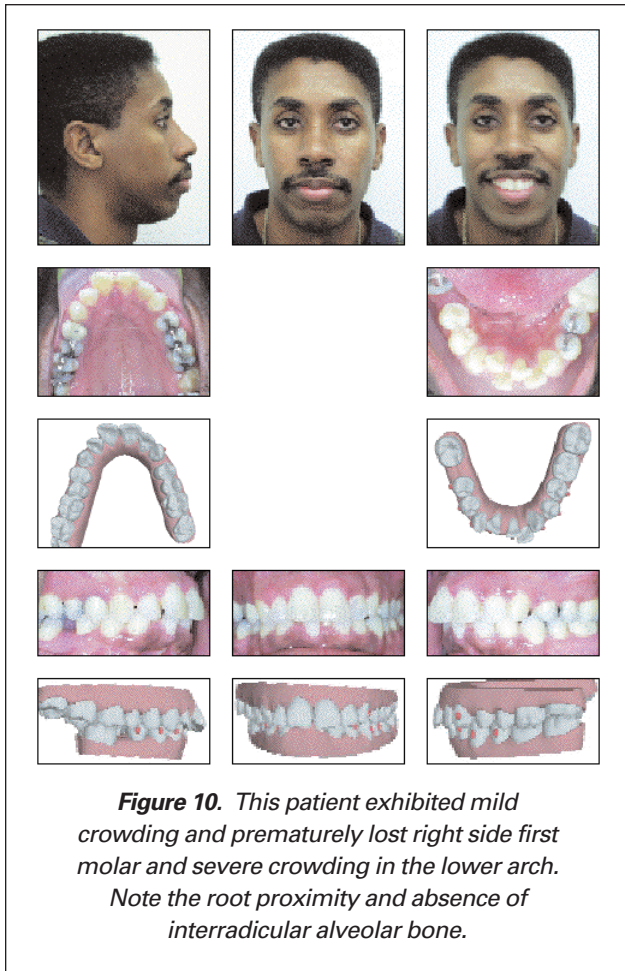


Figure 10. This patient exhibited mild crowding and prematurely lost right side first molar and severe crowding in the lower arch. Note the root proximity and absence of interradicular alveolar bone.

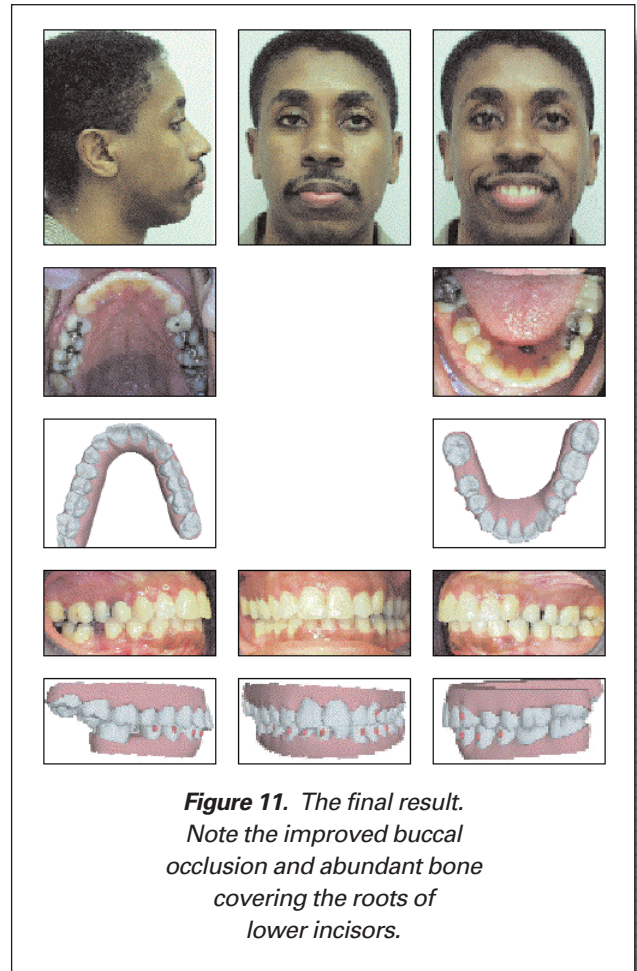


Figure 11. The final result. Note the improved buccal occlusion and abundant bone covering the roots of lower incisors.



**TO VIEW THE CLINCHECK ANIMATED
IMAGES DEPICTING THESE CASES...**

visit www.myinvisalign.com/studies and click on
"Dr. Boyd's Case", "Dr. King's Case" or "Dr. Wheeler's Case."