COMMENTARY

Bob Fry, DDS, MS

Complex Orthodontic Treatment Using a New Protocol for the Invisalign Appliance

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In 1997, as part of the requirement for their degree completion, two MBA students at the Stanford University School of Business devised and submitted a business plan for a new company. Their concept was a revolutionary approach to orthodontics involving the use of sets of clear, vacuum-formed retainer-like aligners to move teeth in stages, based on a computer-generated sequence of movements. In their small apartment, the two students and one PhD computer-graphics engineering student gave birth to Align Technology and the product we know as Invisalign.*

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 1999 and first described in a peer-reviewed publication in 2000.[1] Controversy remains over whether the system is appropriate for moderate-to-difficult cases.[2-5]

Early longitudinal clinical trials demonstrated successful use of Invisalign for tipping movements, incisor rotations, and closure of naturally occurring spaces.[6-10] 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.[11,12] (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.[13] 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.[22] 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.[14,15,17] 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.

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Case Selection

Many patients who request Invisalign treatment have previously undergone orthodontic treatment with fixed appliances and do not want to repeat the experience.[23] 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.[24] In addition, Spear reported that patients who require minor restorative dentistry or bleaching tend to

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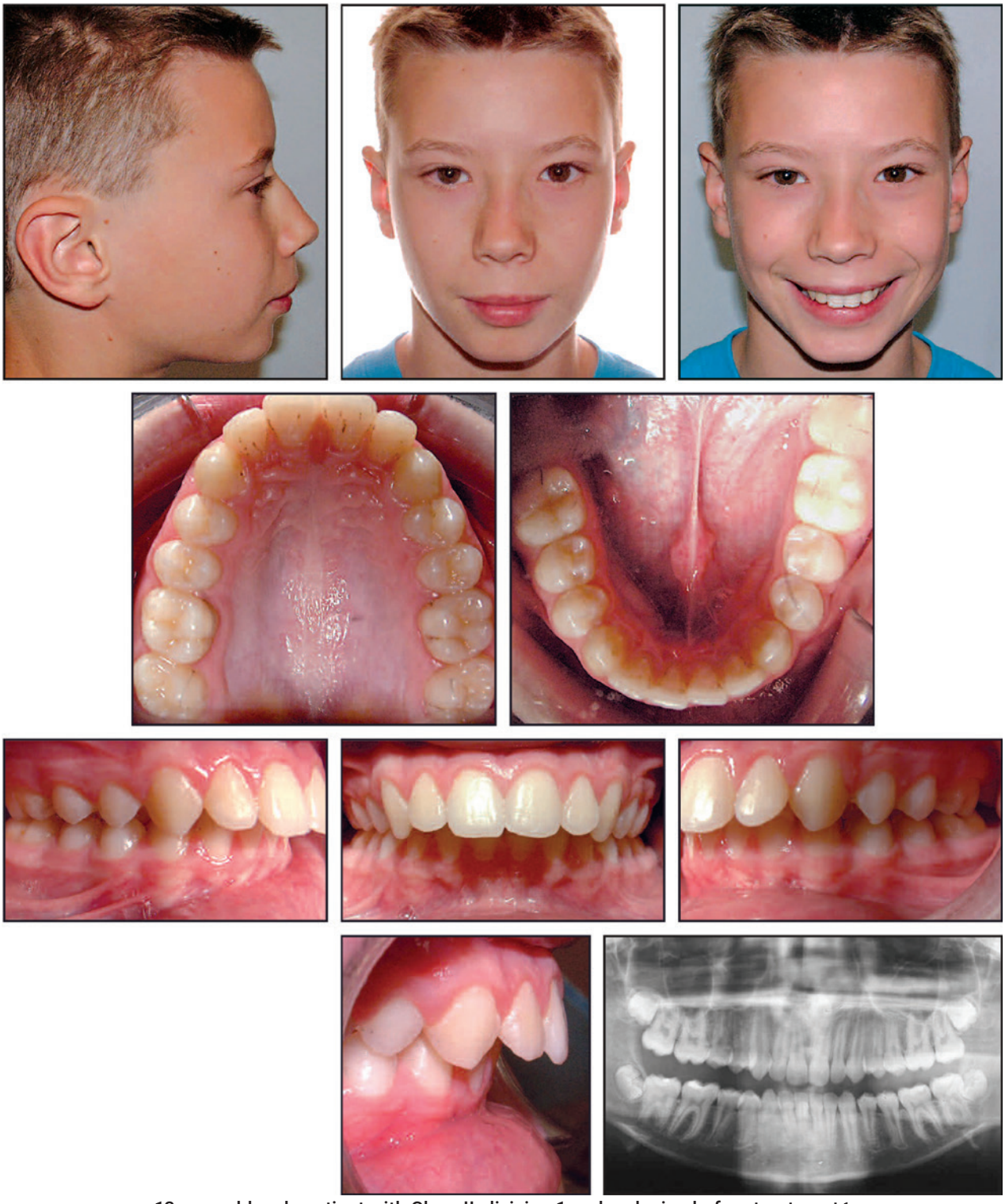


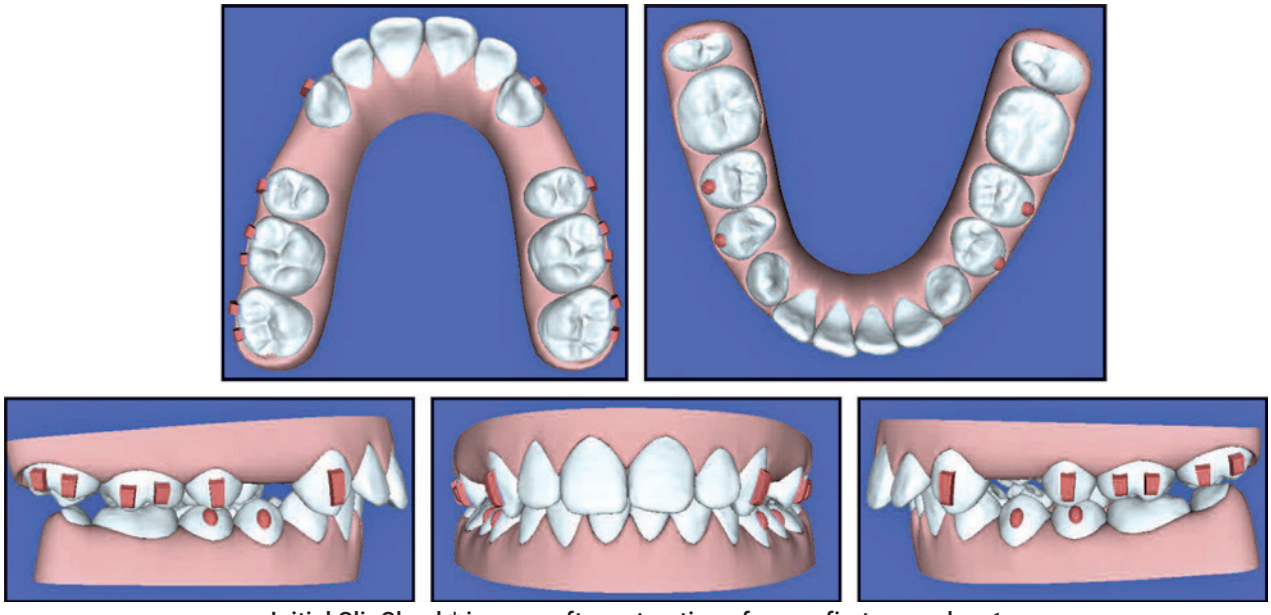
13-year-old male patient with Class II, division 1 malocclusion before treatment.[1]

Commentary: Bob Fry

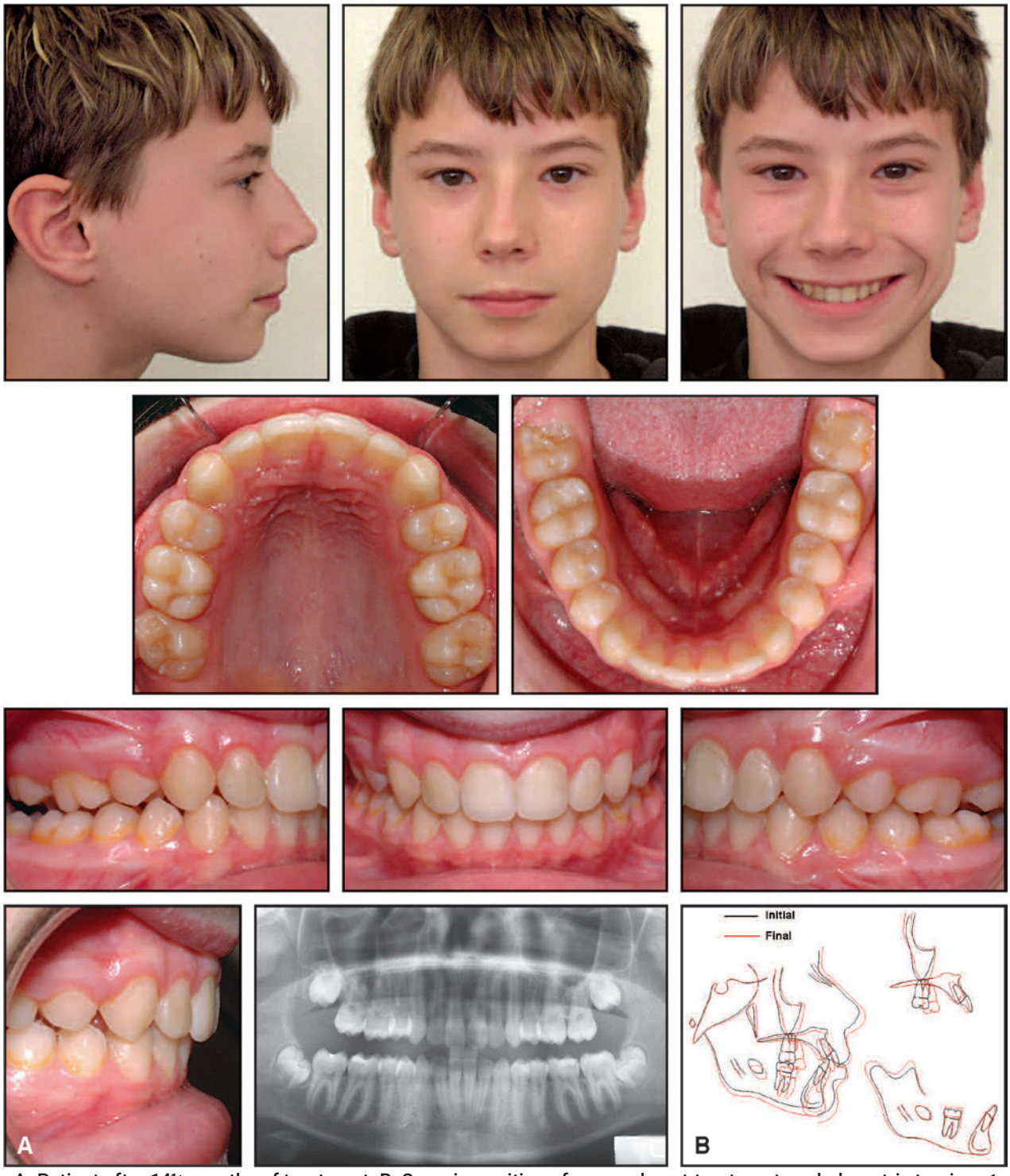
Attempting to move teeth with removable appliances was not a new concept. Most orthodontists, myself included, had tried removable appliances for simple tooth movements with marginal results. In 1998, Align was eager to find clinicians to be "alpha" testers for their new product. When I was approached, I listened politely and declined. But they were so desperate for testers that they agreed to buy me a personal computer and show me how to use it (which was the real challenge).

I was still unconvinced about participating, though, so they played their trump card. I was assured that the lead investigator for Invisalign treatment was Dr. Bob Boyd, Chairman of Orthodontics at the University of the Pacific Arthur A. Dugoni School of Dentistry. While I did not know Dr. Boyd personally at that time, I had admired his research and writings, as well as his commitment to orthodontics. He is now widely recognized as a pioneer in the specialty.[2] I later learned that he turned down a lucrative offer to become a full-time researcher for Align, preferring to stay true to his values and love of teaching. Dr. Boyd's integrity and commitment to the profession swayed me, and I agreed to help as a tester. I was certain it would not work well, however, and would not enter the mainstream of orthodontics. As my wife and staff like to remind me, "You are seldom in doubt, but often wrong!"

Since that time, I have had the joy of working with Dr. Boyd on numerous projects, including many years of service on Align's North American Clinical Advisory Board. He is very persuasive. He convinced me to join the faculty at the University of the Pacific. He taught me how to use and value clear aligners. He constantly challenged me and the entire profession to do more difficult cases with Invisalign. He also taught us how to treat those difficult cases. He paved the way by doing it first. As one example, I noted with considerable interest that Dr. Boyd



Initial ClinCheck* images after extraction of upper first premolars.[1]



A. Patient after 14½ months of treatment. B. Superimposition of pre- and post-treatment cephalometric tracings.[1]

was experimenting with one-week aligner changes as early as 2003. Even the clinical advisory board of which he is a member has only recently reached a consensus and recommended one-week aligner changes as the standard protocol.

Dr. Boyd's seminal JCO article on treating complex cases with Invisalign gave an honest assessment of the early challenges we encountered with this new approach. He freely discussed what he believed were contraindications for Invisalign treatment. (In a recent discussion, he shared with me that he believes several of these problems, such as crossbites and arch development, can now be resolved with Invisalign.) He also pointed out situations where Invisalign may be superior to fixed appliances. For instance, he was the first to demonstrate to the profession the benefits of aligners in treating anterior open bites.

The four cases shown in Dr. Boyd's article would have been considered difficult and outside the realm of possibility for most Invisalign practitioners. All four were treated to excellent results without the benefits of several subsequent, wonderful innovations from Align: SmartTrack** proprietary aligner material, SmartForce* attachments and features, power ridges for torquing, cutouts for elastics, digital scanning with iTero* vs. physical polyvinyl siloxane impressions, and more. Dr. Boyd believes all of these early patients could be treated more efficiently today, perhaps with different treatment plans. The case reproduced here, he says, could have been treated without extractions in two-thirds of the time.

This article—which appeared in JCO's 40th Anniversary Issue—had its share of skeptics and detractors in 2007, but it helped the orthodontic profession see what was possible. It was a challenge to many of us, serving as a reminder that we should not let our biases limit our vision. In terms of historical significance, it may have done for Invisalign therapy what Andrews's "six keys" did for fixed appliance treatment.

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