Product review and demonstration of the Invisalign clear aligner system

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This article will report on the Invisalign (Align Technology, Santa Clara, Calif) product and highlight the features of this appliance. In addition, patients will be shown using the features discussed. Invisalign has changed the orthodontic specialty forever, *pushing* into the forefront the possibility of comprehensively treating malocclusions with clear aligners. Although now, there may be more competitors inside and outside of our practices, the name Invisalign has certainly become synonymous with clear aligner therapy, especially to the public. Invisalign has existed for over 20 years, allowing for significant investment into technology, allowing for more predictable tooth movement with Invisalign aligners. This evolution has improved the ability to treat malocclusions with a great degree of difficulty with Invisalign. Three patient studies will be reviewed, demonstrating some of the range of what is possible with the present-day appliance. (Am J Orthod Dentofacial Orthop Clin Companion2021;1:7-21)

PRODUCTS AND FEATURES

Invisalign (Align Technology, Santa Clara, Calif) is an orthodontic appliance consisting of a series of clear aligners that progressively move teeth. Invisalign, historically and currently, has the largest market share in the clear aligner segment of orthodontic treatment. The orthodontic specialty has now largely adopted clear aligners as a definitive option for patient care. However, as with any orthodontic appliance, sound judgment regarding diagnosis and treatment planning are still paramount for proper outcomes and predictable, repeatable results.[1]

Align Technology, the makers of Invisalign, was founded in 1997 by Zia Chishti while attending Stanford University. Mr Chishti conceived of the concept of clear aligner therapy to comprehensively treat malocclusions while in orthodontic treatment. Mr Chishti was provided with a set of thermoformed retainers intended to complete his treatment; however, he posited that a series of such retainers could progressively provide comprehensive tooth movement. Accordingly, he partnered with another Stanford student, Kelsey Wirth, to seek developers for his vision and project.

In 1998, Invisalign was approved by the Food and Drug Administration, and sales began in the US in 1999. With a robust marketing campaign, the appliance gained popularity among prospective patients. The use of the appliance grew quickly, especially considering general dentists were eventually allowed to use the product. According to Align Technology, in 2014, 2.4 million people around the world had been treated with Invisalign. Since then, their Web site currently states that 9 million patients have been treated with the product worldwide, and this trend shows no current signs of slowing down.

Through extensive research and development, data mining, and doctor feedback, Align Technology has introduced a multitude of improvements, allowing for more predictable outcomes for orthodontists and their patients. Currently, experienced practitioners can treat complex malocclusions via clear aligners with often comparable treatment times to fixed appliances.[2] A review of the Invisalign product, including concepts and features, will be discussed in this paper.

THE BIOMECHANICS BEHIND THE APPLIANCE

According to Align Technology, the Invisalign aligners are a comprehensive system supported by 3 proprietary innovations: SmartTrack (Align Technology) material, SmartForce features (involving attachments and activations), and SmartStage technology (Fig 1). These pillars are integrated and work in unison to deliver treatment outcomes on the basis of principles of orthodontic biomechanics. The proposed advantages of these features are described below.

SmartTrack material

SmartTrack material is a multilayer aligner material made of a copolyester and thermoplastic polyurethane. According to Align Technology, the SmartTrack material provides gentle and constant forces for orthodontic tooth movement, more constant than historic Invisalign (version

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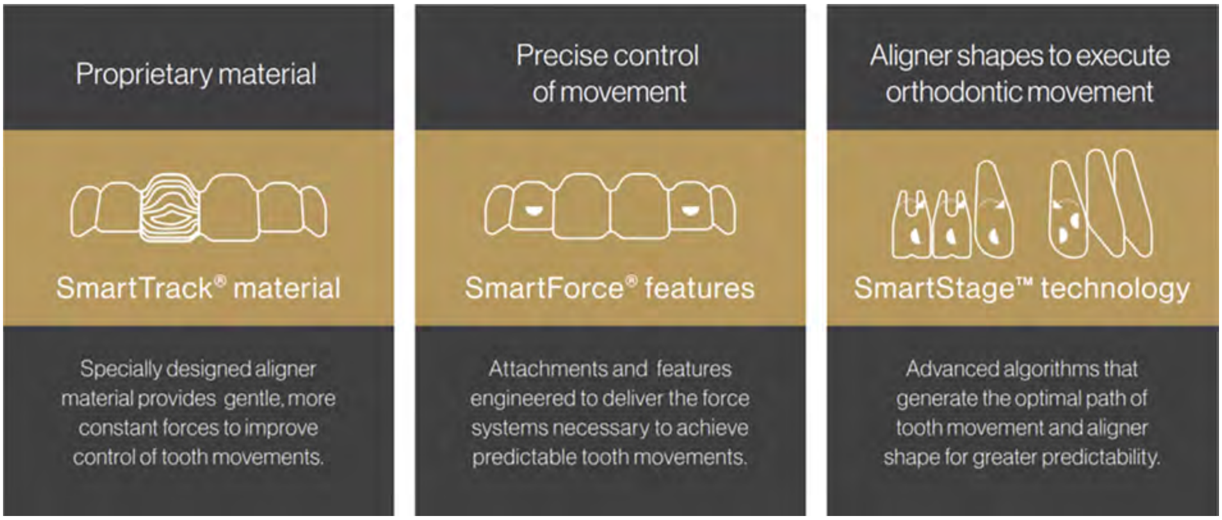

Fig 1. The 3 pillars of Invisalign: SmartTrack (Align Technology) plastic, SmartForce features, SmartStage technology.

EX30) aligners previously made from the single layer EX30 material. The newer material demonstrates a higher range of elasticity as well, more closely returning to its original shape once deformed (Fig 2). Gentle, constant forces improve control of tooth movements throughout treatment, properly eliciting a more predictable biological response from the periodontal tissues and supporting structures.

To accomplish gentle, constant forces, SmartTrack material is engineered with controlled stress relaxation and stiffness. SmartTrack material provides orthodontic forces more constantly, over a longer period than the previously used Invisalign (version EX30). In comparison, the forces applied by the Invisalign (version EX30) clear aligner material decreased more quickly with time. Both materials were tested under intraoral conditions. Furthermore, SmartTrack material is, counterintuitively for many practitioners, stiffer material than the previous Invisalign (version EX30) after several days in intraoral conditions. Therefore, the newer SmartTrack material applies a stronger signal to the teeth after several days (Fig 2).

Conventional aligner materials relax and lose a substantial percentage of energy in the initial days of aligner wear, but SmartTrack maintains more constant force over 2 weeks so that a patient may continue to wear their aligners effectively, on the basis of their doctor's recommendation. The flexible SmartTrack material also more precisely conforms to tooth morphology, attachments, and interproximal spaces to improve control of tooth movement throughout treatment.

A study of over 1000 patients treated with Invisalign aligners made with SmartTrack material demonstrated statistically significant improvement in control of tooth movements such as rotations and extrusions ($P < 0.001$), compared with patients treated with aligners made with previous Invisalign material.[3] Furthermore, the new material was favorably rated by the patients and showed significant reductions in pain intensity, pain duration, and

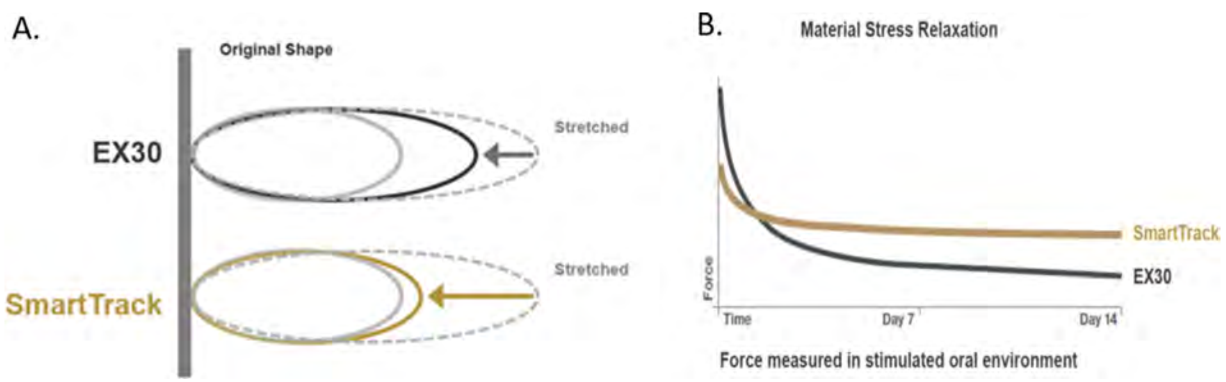

Fig 2. A, Visual demonstration of SmartTrack (Align Technology) plastic returning closer to its original shape after distortion vs the original Invisalign (version EX30; Align Technology) plastic, providing improved range and better tooth movement. **B,** Visual demonstration of the SmartTrack plastic has lower insertional force for improved comfort, yet improved delivery of force and stiffness over a longer period in a simulated oral environment over 2 weeks.

pressure on insertion. Important clinical parameters like overall comfort and impairment were also improved.[4]

When discussing any appliance, it is also important to note possible adverse reactions. Although quite rare, the most frequently reported adverse events with Invisalign have been difficulty breathing, followed by sore throat, swollen throat, swollen tongue, hives and itchiness, anaphylaxis, swollen lips, and feeling of throat closing, tight airway, airway obstruction and/or laryngospasm.[5,6] If any of these events should occur, it is recommended to stop wear of the appliance immediately and to call the vendor to discuss alternative options for the patient.

SmartForce features

Optimized attachments

These are features designed to direct and deliver the appropriate biomechanical forces needed for enhanced predictability of orthodontic tooth movement. They appear in the ClinCheck (ClinCheck Pro 6.0; Align Technology) treatment plan as optimized attachments, power ridge features, pressure points, and pressure areas. These features are automatically placed by the TREAT software in accordance with the desired movement. According to Align Technology, these features are carefully designed and engineered to deliver the correct biomechanical force systems to control the movement of each tooth. The addition of the SmartForce features, such as optimized attachments, make it possible for doctors to treat more complex problems by introducing automated, customized force systems to make more challenging tooth movements increasingly predictable.

Optimized attachments for certain movements, such as extrusion, are needed to generate enough vertical force to perform extrusion effectively. When there is no surface conducive to force application from the aligner, a surface must be created on the tooth for the appropriate force to be applied by the aligner; this is done using attachments. With Invisalign, attachment shapes, and positions, are determined by the tooth movement required in the treatment plan. SmartForce features control the movement of the root with respect to the crown. This is a very important consideration to prevent unwanted tooth movement as a side effect of forces being applied to the crown. Subsequently, the shape of the aligner is also able to selectively change to control the force system applied to the tooth. The aligner contacts both the tooth and the attachments to control the force applied to the tooth (Fig 3).

Regarding the proper use and placement of optimized attachments, doctors who use the Invisalign product need to set up their preferences on the Invisalign Doctor Site, under *Clinical Preferences* at the upper right-hand corner of the home screen. Once in the *Clinical Preferences*, doctors should then go to the *attachment interface* to allow for and to prioritize their individual preferences for placement of the optimized SmartForce attachments on particular teeth and for the certain movements they desire (Fig 4).

This customization of preferences will affect the ability of the software to trigger these features during treatment. However, it is important to note that the doctor's preferences for optimized attachments may not always be followed in the software for the following reasons: (1) movement threshold triggers attachment placement, but the feature is not available, either: because of prioritized hierarchy rules (described below) or because of conflicts with the doctor's special instructions; (2) movement thresholds trigger attachment placement, but there is not enough space/clinical crown/collision/etc; and (3) movement is below the attachment placement threshold.

Furthermore, it is also important to note that at any 1 particular time, specific teeth may not receive the desired or appropriate optimized attachment *needed for your specific treatment goals,* given the following considerations:

> Barring special instructions from the doctor, Invisalign's software will identify and place optimized attachments based on the movements prescribed by the orthodontist. This automation helps make designing treatment more efficient, but with complex movements, thresholds are often met in the software for several competing optimizations at the same time. So how exactly does the software decide between potential options?
>
> *Invisalign's software helps guide this process by using a number of algorithms to establish a decision tree for the automatic placement of optimized attachments (Fig 5). By understanding the logic behind this hierarchy, this allows the orthodontist to make better clinical choices and to switch between the different optimized attachments that are triggered by the movement requirements. If instances arise when the attachments provided based on the hierarchy are not consistent with the treatment goals, doctors can request the correct optimized attachments in lieu of what they received from their technician. This requires a written request in the comments.*
>
> *The orthodontist can also manually request any optimized attachment as long as the movement in the tooth is present in the right direction, whether or not the automatic rule or threshold is met. When deciding on the correct optimization, tooth movements should also be modified so that the movement quality is in harmony with selected attachment design. . .*[7]

SmartForce Aligner Activation

In concert with SmartForce Attachments are SmartForce Aligner Activations, which are customized thermoforming features. SmartForce Aligner Activations are a

Visual	Threshold	Maximum Velocity
SmartForce Attachments		
	5° of rotation	2°/stage
	0.5 mm of intrusion	0.25 mm/stage
 A	0.75 mm for central and lateral incisors; 0.75 mm translations from the center of resistance for canines and premolars	0.25 mm/stage

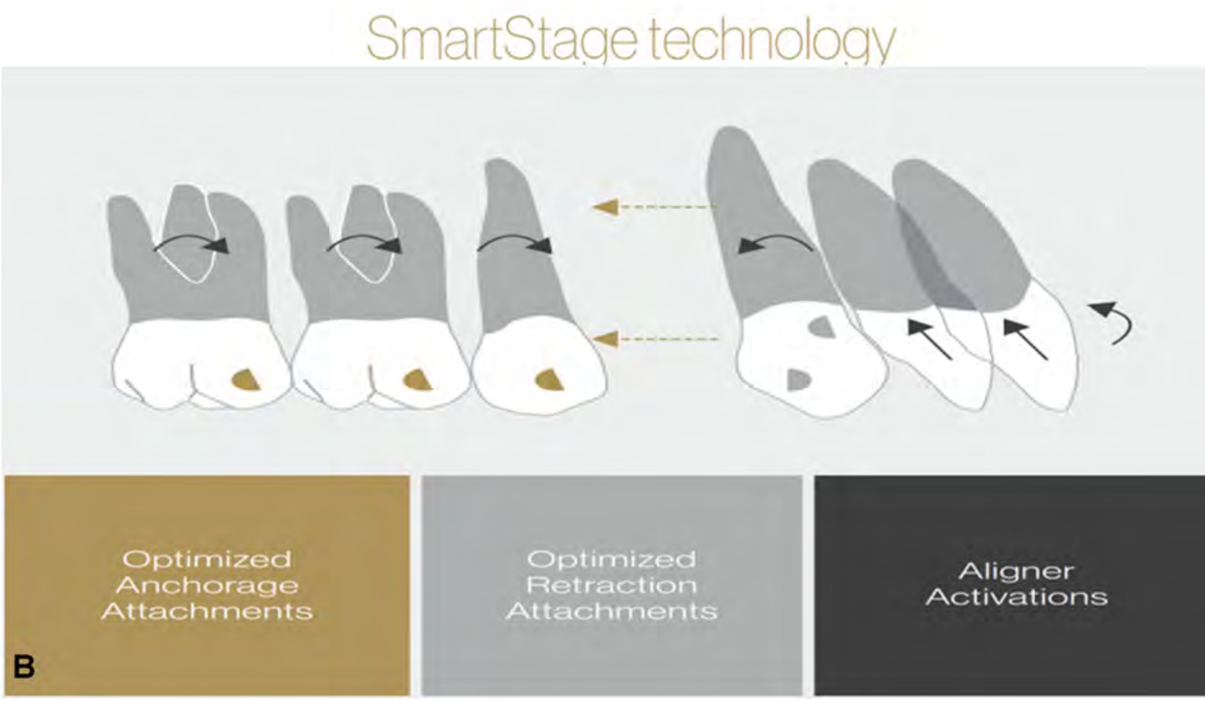

Fig 3. A, An example table demonstrating some of the available SmartForce attachments and their thresholds to trigger in the software. Different teeth have a different menu of SmartForce options; hence, it is incumbent on the practitioner to be familiar with what options are available to make sure the best attachment is being used for their patient's needs. Furthermore, the appropriate attachment may not even exist for a given tooth, whereby the doctor must add a conventional attachment on their own. **B,** Demonstration of SmartStage technology, alterations in the cadence and path of tooth movement, in addition to changes in aligner shape, to allow for improved outcomes. This specific example above is for the solution for premolar extractions.

modification to the tooth position in the aligner created during fabrication to create the necessary contact points that apply forces to the tooth. Hence, tooth movement is tailored to each patient and the needed movements, working synergistically with other SmartForce features for control of the force system. With SmartForce Aligner Activations, select areas of the aligner surface are specifically contoured to apply optimal forces to the tooth surfaces to control the location, direction, and intensity of the force to produce the desired outcome and minimize unwanted or unintended movements.

The most recent demonstration of these features is the newest set of innovations from Invisalign (version G8). This series of generational enhancements feature SmartForce

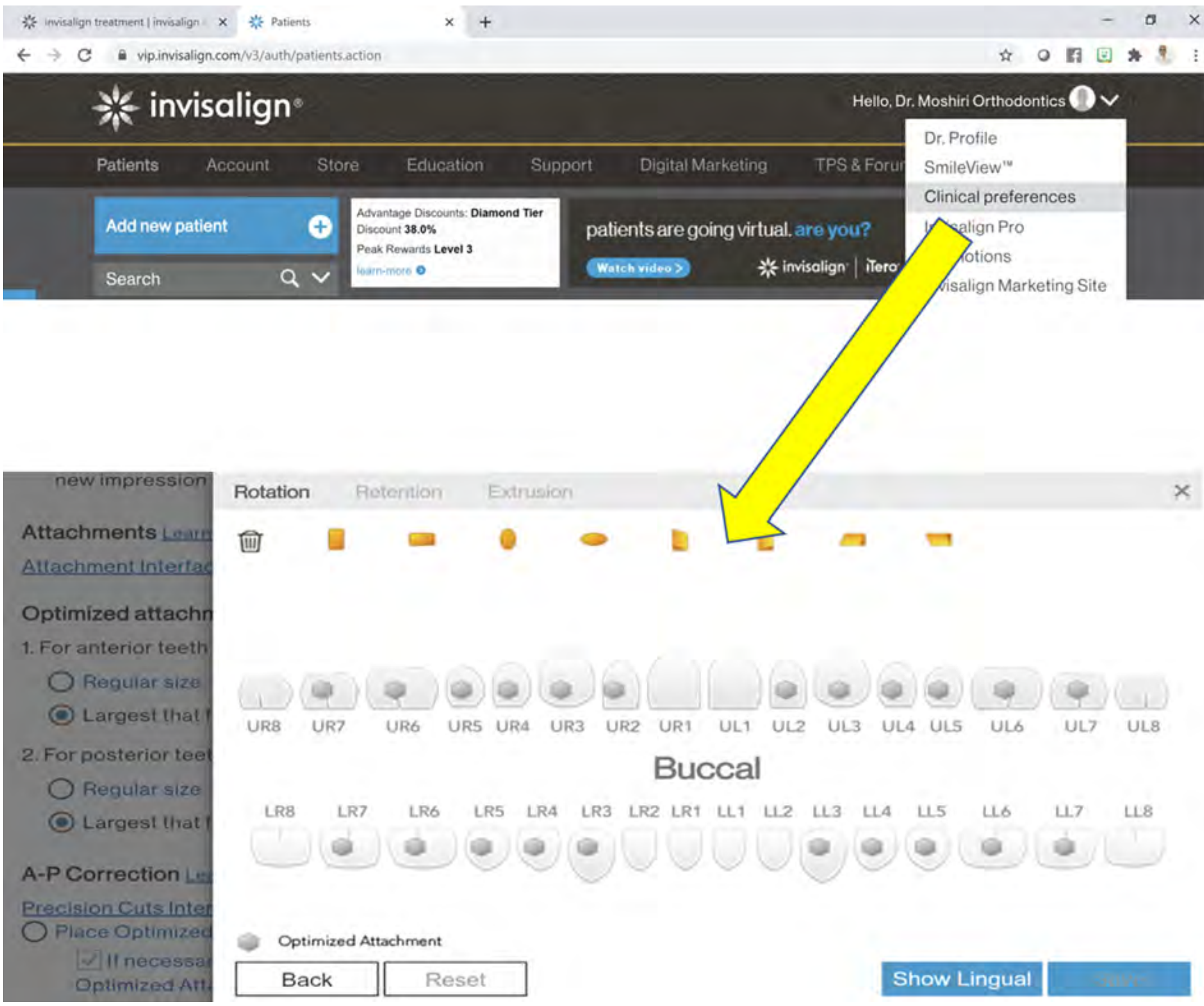

Fig 4. Demonstration of the attachment interfaces within the clinical preferences section of the Invisalign (Align Technology) doctor site, allowing doctors to set their preferences for which teeth and movements they would like optimized attachments triggered. Note. When optimized attachments are not available, conventional attachments may be used instead.

Aligner Activations to attempt sufficient and consistent activation to help get more of the desired movements from the aligners, specifically in the treatment of crowding, crossbites, and deep bites.

For crowding and crossbite in patients, Smart Force Aligner activations will further aid in posterior arch expansion by working synergistically with new optimized expansion support attachments (or optimized expansion support and rotation attachments) to reduce the potential for buccal crown tipping during posterior arch expansion.

For deepbite in patients, G8 SmartForce Aligner Activations will further support anterior intrusion with improvements in the treatment plan set-ups to level the curve of Spee.

SmartStage technology

Finally, for improved outcomes with challenging movements, SmartStage technology is used to provide an ideal progression of tooth movement to improve the predictability of proposed movements while reducing unwanted interferences during treatment which may result from unwanted tooth movement. SmartStage technology implements algorithms that determine how the teeth will be staged to move, which teeth move, and when.

An example of SmartStage technology can be seen in first premolar extraction space closure treatments (Fig 3). The canines initially move into the extraction site before moving the incisors en masse, encircling the cuspids with a full wrap of plastic. Initiation of SmartStage technology enhances control of tooth movements during extraction space closure. The initial movement of the canines increases the probability of attaining maximum anchorage in treatment. This staging also allows for better control of bodily root movements and is less taxing on the steepening of the curve of Spee (a common side effect of significant en masse, nonstaged space closure in aligners).

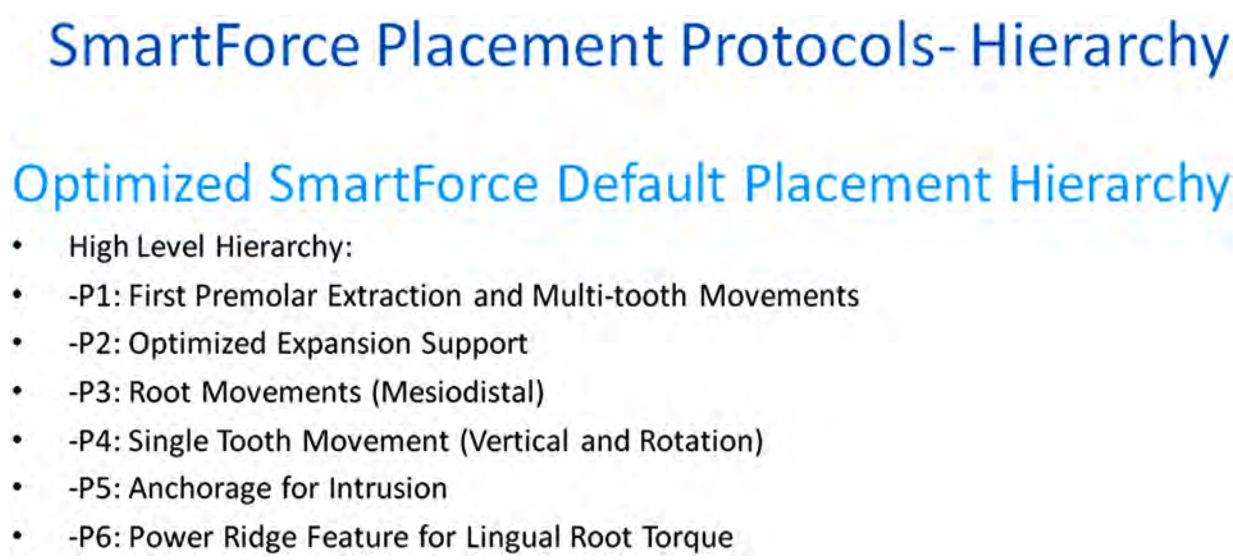

Fig 5. Optimized SmartForce default placement hierarchy as of Generation 8. This table shows the hierarchy of decision-making by the software on the basis of the movements present. In difficult scenarios when multiple orders of movements are considered challenging, the treating doctor may need to request different attachments to achieve more predictable movements by requesting a change from the technician.

INVISALIGN AS A FORCE VS DISPLACEMENT-DRIVEN SYSTEM

The Invisalign appliance system features innovations that make the appliance a force-driven vs displacement-driven clear aligner system via its automation. Under normal circumstances, when proprietary features are lacking as previously mentioned, clear aligners function as a displacement-driven system. In a displacement-driven system, the aligner is formed on the basis of the next intended intraoral position of the tooth. The aligner is then placed over the teeth in their current state, and the teeth then hopefully move or displace to their next positions. A displacement-driven system is one in which the next position of the tooth is programmed in the treatment plan, and the doctor clinically assumes that the tooth will find its way there. However, a displacement system may not engineer the correct forces into the aligner shape, which in turn may lead to an increase in unwanted tooth movements.

Conversely, in a force-driven system, the aligner is formed in a shape that is intended to impart specific forces to the crown that will result in the desired movement of the tooth and root. A force-driven system uses biomechanical principles to apply the correct forces that move the tooth. Hence, the shape of the aligner capable of producing these forces is not necessarily always the shape of the tooth. The force system required to move the tooth and subsequently the shape of the aligner is determined by the principles of biomechanics applied to and learned from model testing.

By applying the correct force systems to control tooth movement, the fundamental concepts of biomechanics in orthodontics and control of the force system are the functions that move teeth. Hence, the appliance is designed so that it applies the force system—it contacts the teeth in multiple locations and applies force at those locations to control the movement of both the root and the crown. In applying proper force systems, one may achieve more predictable tooth movement (Fig 6).

CASE PRESENTATIONS

Patient example 1

Diagnosis and etiology

A 36-year-old female patient presented with a chief complaint of mandibular anterior crowding (Fig 7). She had a history of orthodontics with maxillary premolar extraction and a lack of long-term retention compliance. She had severe crowding of the mandibular arch, with Class I molar and Class III canine relationships bilaterally. The initial cephalometric analysis showed a Class I skeletal relationship, acceptable maxillary incisor inclination with flared mandibular incisor inclinations, and a high angle tendency.

Treatment objectives

The treatment objectives were to (1) address the patient's chief complaint of mandibular crowding, (2) establish proper overbite and overjet, and (3) establish Class I canine relationship.

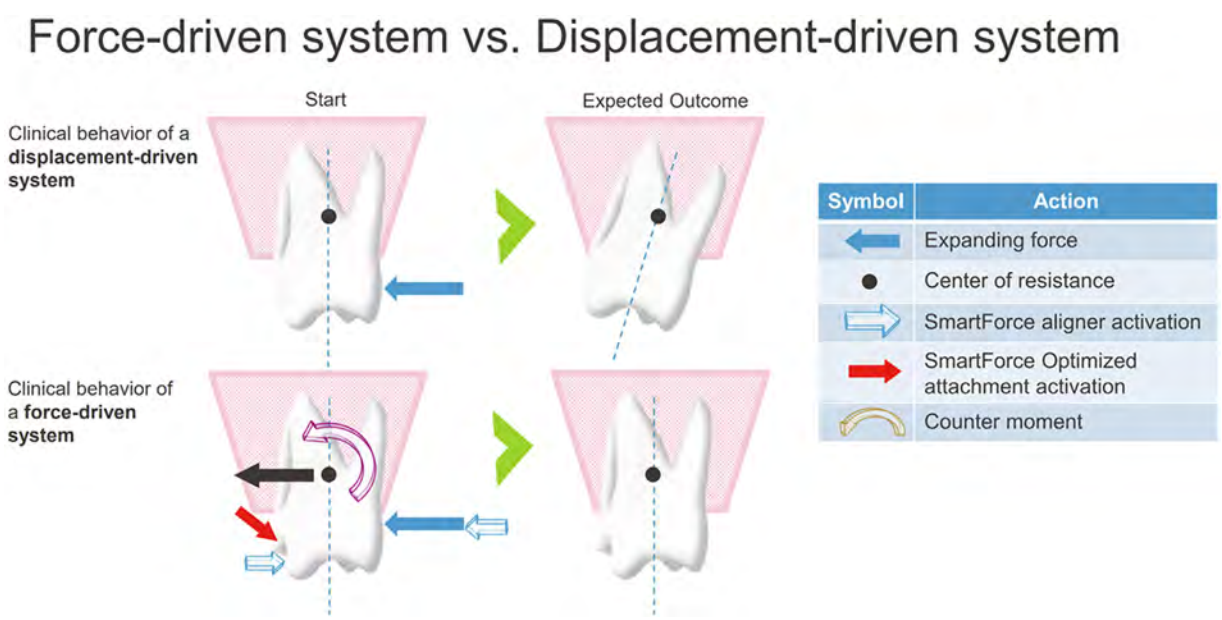

Fig 6. Force-driven vs displacement-driven demonstration. SmartForce attachments and Smartforce activations allow for more predictable tooth movement by considering root movements with respect to the movements of the crown, minimizing unwanted side effects of tooth movement via the synergistic interactions of these features.

Fig 7. Patient 1: pretreatment composite photographs.

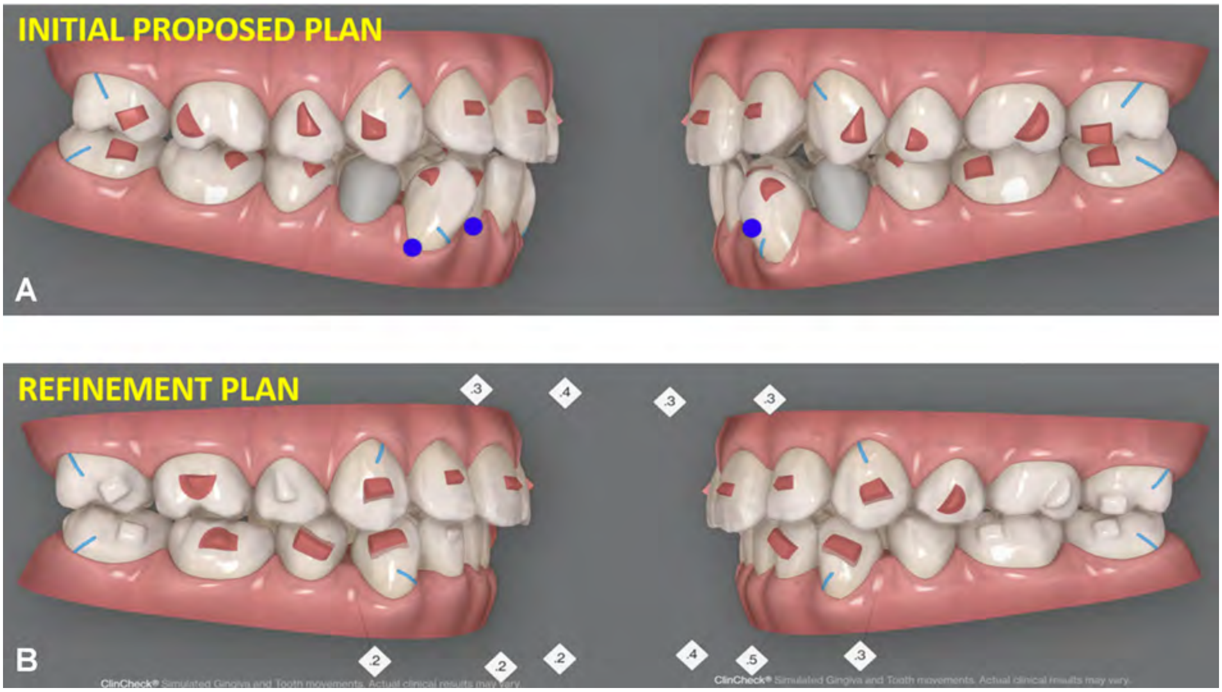

Fig 8. A, Patient 1: ClinCheck (Align Technology, Santa Clara, Calif) representation at Stage 1, demonstrating G6 attachments for premolar extraction on the mandibular arch. Optimized attachments were also used for maxillary extrusion and for individual tooth movements as needed. **B,** Patient 1: Initial stage of refinement ClinCheck, showing attachments added as needed to detail remaining movements for leveling of the lower curve of Spee and extrusion of maxillary incisors. The interproximal reduction was added to address black triangles, along with *fake IPR* to tighten contact in extraction sites.

Treatment progress

G6 SmartForce attachments for moderate anchorage and root movement were chosen and kept as the priority on the mandibular arch, with SmartForce staging to close the extraction sites (Fig 8). Sixty aligners were used in the first set of aligners, with Class III elastics worn at night time only with 0.25-in, 4.5 oz elastics.

The patient had 1 refinement set of aligners to finish and detail with an additional 10 months of treatment (Fig 8). Specifically, refinement was to focus on leveling the curve of Spee on the mandibular arch further, improve arch coordination, and finish space closure distal to the mandibular canines. Interproximal reduction (IPR) was added to detail black triangles, in addition to *fake IPR* (IPR added virtually that is not performed clinically) to overtreat the contacts/space closure distal to the mandibular canines.

Vivera retainers were recommended to be worn for 6 months full-time and then to nighttime for a lifetime.

Treatment results

Posttreatment photographs depict that the facial profile did not change and was favorable with treatment (Fig 9). Good interdigitation and a Class I canine were achieved per the objectives. Pretreatment and posttreatment panoramic x-ray comparisons demonstrate successful closure of the extraction sites (Fig 10).

Cranial base superimposition of the cephalograms demonstrated uprighting and extrusion of the maxillary and mandibular incisors with treatment (Fig 10).

Patient example 2

Diagnosis and etiology

A 20-year-old male presented with a chief complaint of an anterior crossbite. The patient had minimal crowding of the maxillary and mandibular arches with a Class III skeletal malocclusion (Fig 11).

Treatment objectives

The treatment objectives for the patient were to (1) correct his anterior crossbite, (2) establish proper overbite and overjet, and (3) establish Class I molar and canines. Orthognathic surgery was the treatment planned for an ideal outcome with Invisalign for presurgical orthodontic decompensation and postsurgical detailing.

Fig 9. Patient 1: final composite photographs, including final stage center representation of the final stage of initial ClinCheck (Align Technology, Santa Clara, Calif) for comparison.

Treatment progress

Initial instructions were provided to the technician (Fig 11). The instructions, combined with the prescription form and proposed movements, allowed for the algorithms of the TREAT software to determine the force systems needed for tooth movement. The initial digital treatment plan required changing the priority of the attachments on the buccal segments to anchorage attachments instead of individual rotation/root movement attachments (Fig 12). Optimized retention attachments are a lower priority within the software's hierarchy (Fig 6). Hence, the doctor needs to manually request the technician to change the attachments when desired if the priority is for anchorage to level the curve of Spee vs individual tooth movement (ie,

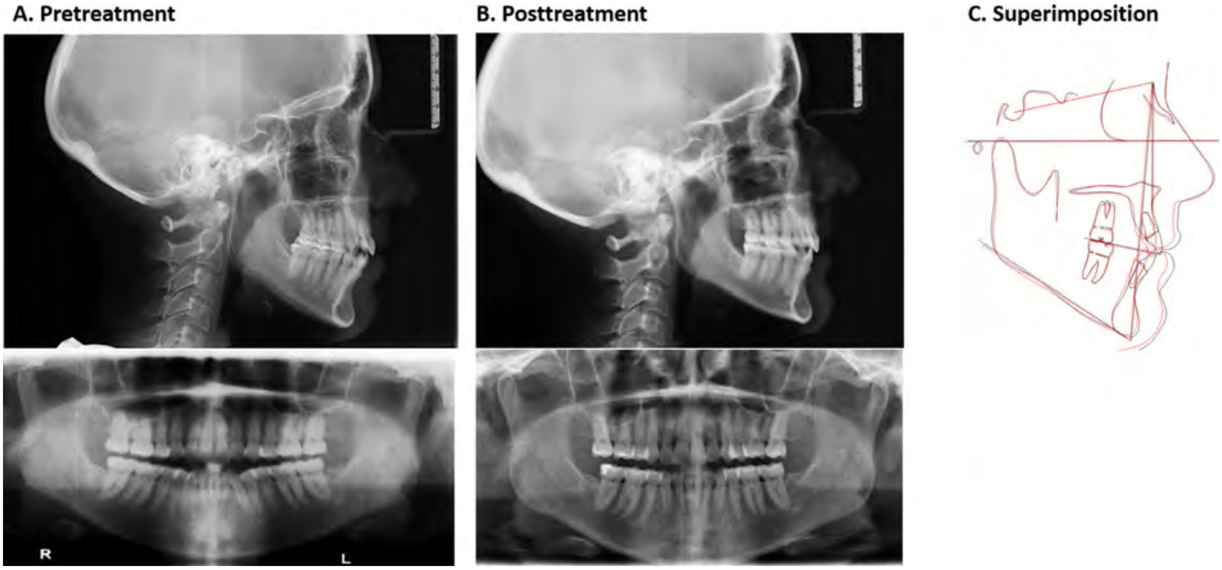

Fig 10. Patient 1: summary of x-ray comparisons, including superimposition of lateral cephalograms. A. Pretreatment. B. Posttreatment. C. Superimposition.

Fig 11. Patient 2: pretreatment composite photographs, including an example of initial instructions to Invisalign (Align Technology) technician.

rotation/root tip). In surgical patients treated with aligners, addressing the curve of Spee properly limits potential postsurgical interferences and should be a priority to facilitate postsurgical detailing when possible. Thirty-eight aligners changed weekly, were used in the first set of aligners.

Virtual surgical planning was used to treatment plan surgical movements, and 3-dimensional surgical splints were fabricated. Two temporary anchorage devices (TADs) per quadrant were placed at the time of surgery to use for both intermaxillary fixations at the time of surgery and intermaxillary elastics postsurgically. Elastics were used to guide occlusion and healing. Once the patient could open comfortably enough at 2 months, refinement scans were taken, and TADs were subsequently removed (Fig 13).

The patient had 1 refinement after surgery with 24 aligners total, mainly to eliminate interferences that were preventing settling of the buccal segments, in addition to providing continued elastic wear for arch coordination. The patient had 19 months of total treatment time, with 6 additional months of retention with a Vivera retainer.

Treatment results

Posttreatment photographs showed a favorable profile change with treatment. Good interdigitation and a Class I canine were achieved per the objectives (Fig 14).

The cranial base superimposition of the cephalograms showed that the maxilla came down and forward with advancement, allowing for clockwise rotation of the mandible, further improving the Class III skeletal relationship (Fig 15).

Patient example 3

Diagnosis and etiology

A 37-year-old female presented with no history of orthodontics. Her chief complaint was to address her open bite and to improve her overall function in preparation for future prosthodontic rehabilitation of her missing dentition. The patient demonstrated a Class III molar and canine relationship, with an open bite tendency and minimal crowding of the maxillary and mandibular arches (Fig 16).

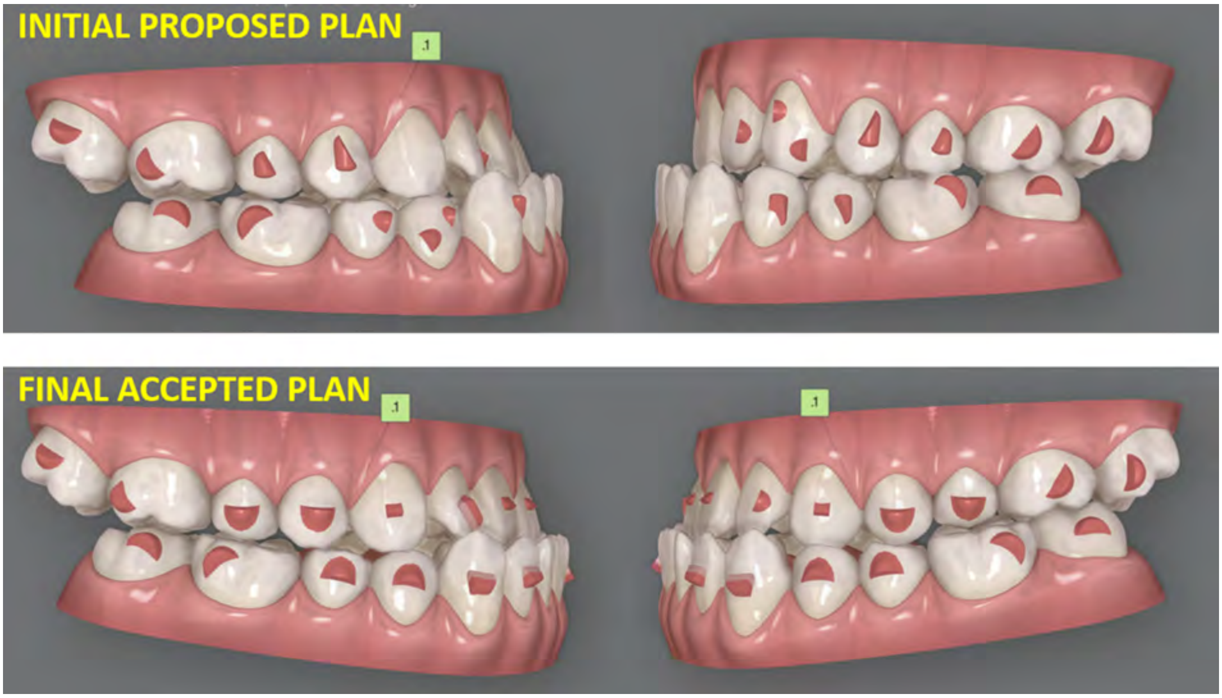

Fig 12. A demonstration of changes made to an initial ClinCheck (Align Technology, Santa Clara, Calif) treatment plan vs an accepted treatment plan. Alterations were made to optimized attachments on the mandibular premolars to address a preference toward anchorage to level the lower curve of Spee vs attachments initially proposed to address individual tooth movements.

Treatment objectives

The treatment objectives for the patient were to (1) correct her anterior crossbite, (2) establish proper overbite and overjet, and (3) establish Class I molar and canines. Invisalign with mandibular temporary anchorages was chosen as the treatment.

Treatment progress

The ClinCheck was modified to focus on extrusion of the maxillary incisors, along with anchorage/retention of precision cuts for elastic wear to prevent lifting of the aligner for Class III interdental elastics, from the maxillary 7s to mandibular 3s (Fig 16). Precision cuts were also

Fig 13. Postsurgical records demonstrating photographs, panoramic radiograph, and the first stage of the refinement ClinCheck (Align Technology) plan 2 months postsurgery.

Fig 14. Patient 2: final composite photographs, including final stage center representation of final stage of initial ClinCheck (Align Technology) for comparison.

added for distalization elastics from buccal shelf TAD anchorage to the mandibular fours. The patient had the TAD on the left side become loose and fail during treatment, which was then subsequently converted to a skeletal anchorage plate. Fifty aligners were provided in the first set. At the end of this first set, the patient was informed that a previously treated root canal was failing on the mandibular left first molar, at which point the patient opted to extract this tooth for future implant replacement.

The patient had 1 refinement with 19 aligners total, mainly to eliminate interferences which were preventing

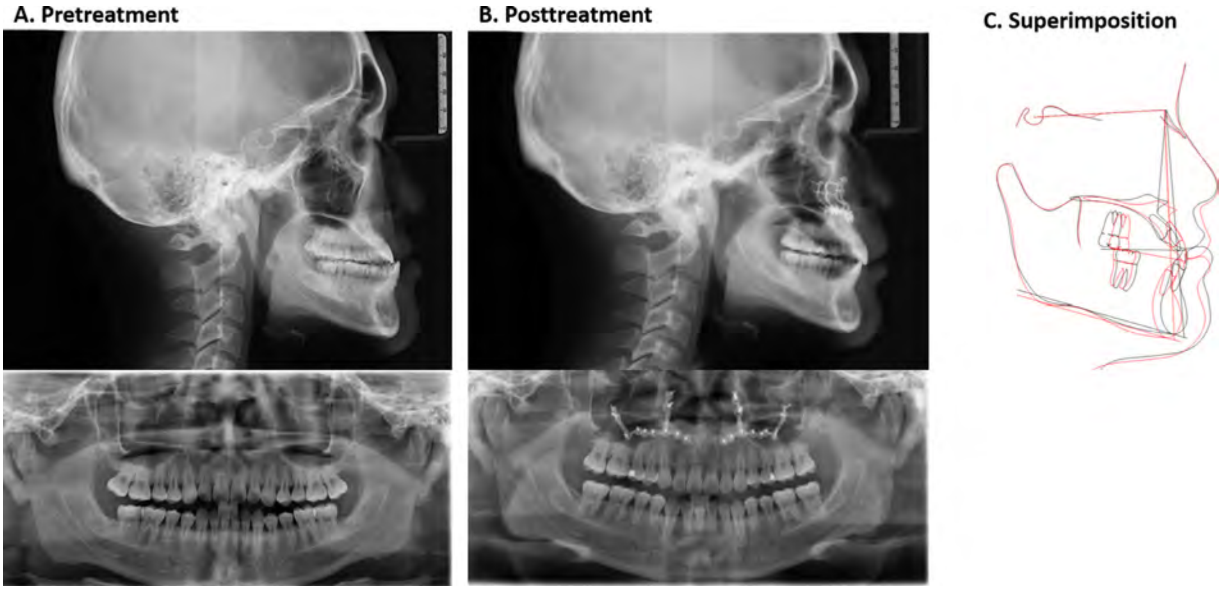

Fig 15. Patient 2: summary of x-ray comparisons, including superimposition of lateral cephalograms. A. Pretreatment. B. Posttreatment. C. Superimposition.

Fig 16. Patient 3: pretreatment composite photographs, including a screenshot of the initial stage of ClinCheck (Align Technology), demonstrating a focus on attachments for maxillary anterior extrusion to improve the patient's open bite and smile consonance, along with precision cuts for Class III elastics from mandibular 4s to retromolar TSADs, and interarch elastics (maxillary 7s to mandibular 3s).

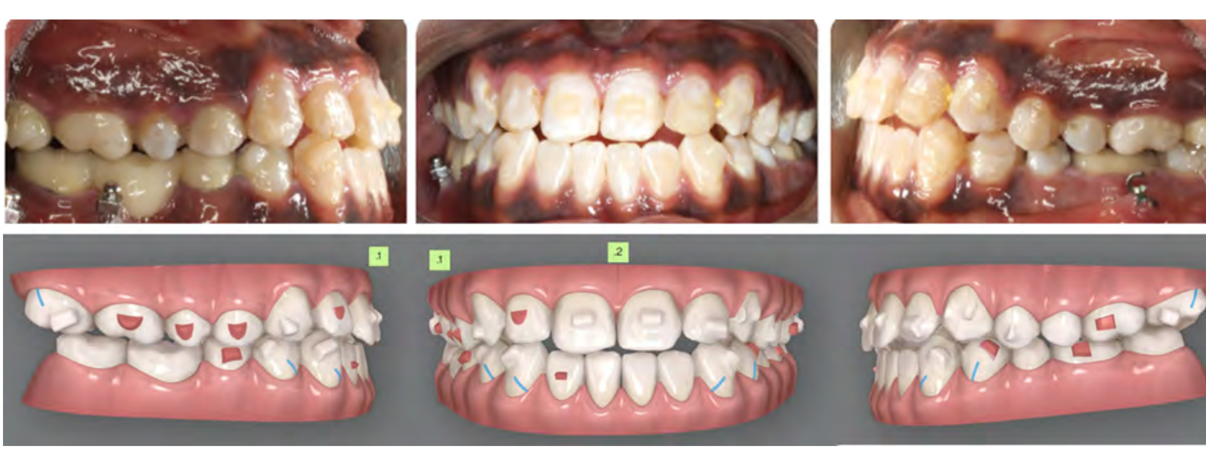

Fig 17. Demonstration of intraoral photographs at the last stage of the initial set of trays, along with the first stage of the refinement ClinCheck (Align Technology, Santa Clara, Calif).

Fig 18. Patient 3: final composite photographs, including final stage center representation of final stage of initial ClinCheck (Align Technology, Santa Clara, Calif) for comparison.

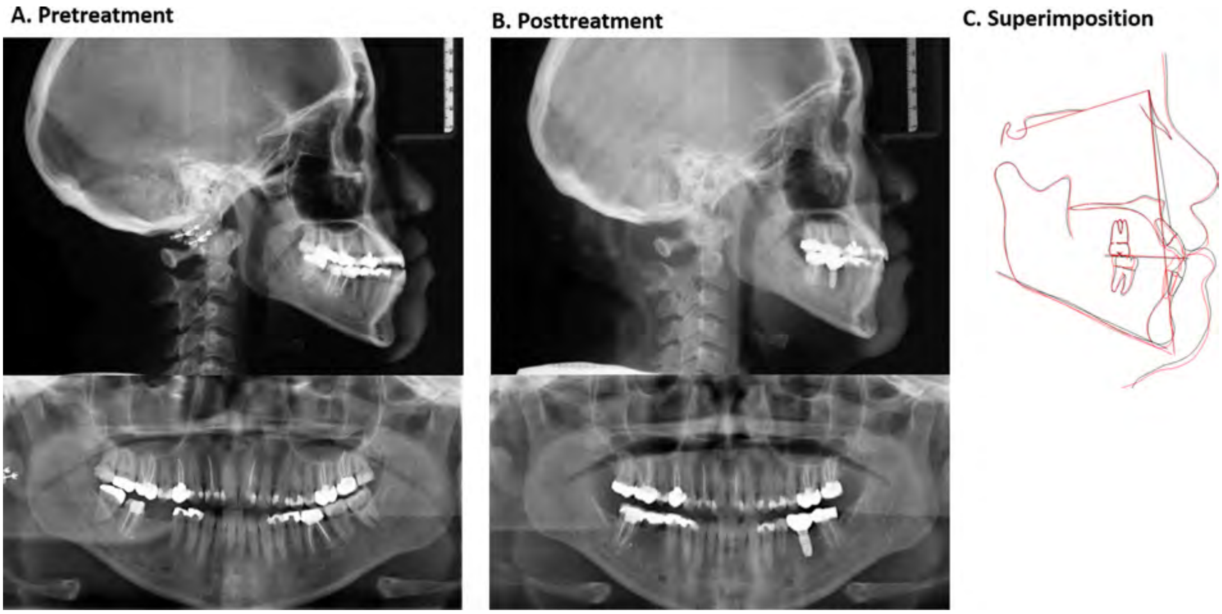

Fig 19. Patient 3: summary of x-ray comparisons, including superimposition of lateral cephalograms. A. Pretreatment. B. Posttreatment. C. Superimposition.

settling of the buccal segments, in addition to more extrusion of the maxillary incisors to improve her overbite, smile arc, and reduce her recently improved overjet (Fig 17). The patient had 19 months of total treatment time, with 6 additional months of retention with Vivera retainers.

Treatment results

Posttreatment photographs showed minimal profile change with treatment. Good interdigitation and Class I canines were achieved per the objectives (Fig 18).

Cranial base superimposition of the cephalograms showed distal and extrusive movement of the mandibular molars, hence improving the Class III skeletal relationship. The patient experienced extrusion of the maxillary and mandibular incisors to establish an ideal overbite relationship (Fig 19).

CONCLUSIONS

The principle of design for the Invisalign system is to determine the movement first via the doctor's instructions and prescription form, then to determine the required force system, and finally to design the appliance. To achieve the desired tooth movement, the force system to be applied to the tooth must be determined, and then the appliance designed to produce that force system. The ClinCheck treatment plan shows the initial position of the teeth and the final position at the end of treatment. The software then determines the type of movement the tooth must undergo during treatment to achieve the proposed path of movement. On the basis of biomechanics, the force systems needed to accomplish these movements are then determined. To apply the force systems, the 3 pillars of the Invisalign system are used for appliance design to control the tooth movement throughout the treatment. Appliance design includes attachments, changes to the shape of the aligner with plastic activations and reliefs, and algorithms to determine the staging of movements. It is then up to the treating doctor to evaluate the proposed force systems and to determine if they are truly appropriate for their patient. Often, changes will be needed to properly customize the proposed force systems to further improve outcomes (ie, adding anchorage, changing out an optimized attachment in lieu of another, adding IPR, etc), given that the software will never understand biology or the individual goals of treatment for any given patient.

Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.xaor.2021.02.003.

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