

Invisalign : A New Dimension To Invisible Orthodontics

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Abstract

Invisalign is a series of clear, removable teeth aligners that orthodontists use as an alternative to traditional metal dental braces. Invisalign is designed, manufactured, and marketed by Santa Clara-based medical-device company Align Technology. Invisalign is an improved copy of a technique developed by orthodontists in the early 1900s. Orthodontists used a clear polymer aligner to move the teeth by setting the teeth into a different place in the plaster model and then making a new aligner. This article describes the Invisalign technique. The technology behind Invisalign and its development is reviewed. The Invisalign clinical technique is described, and the advantages and disadvantages of using Invisalign are highlighted.

Key words: Aesthetic appliances, Invisalign, Invisible orthodontics

Introduction

Invisalign is an orthodontic technique that uses a series of clear plastic aligners to move teeth. The aligners are made from thin, see-through plastic, which fits over the buccal, lingual (palatal), and occlusal surfaces of the teeth. The aligners are worn for a minimum of 20 hours per day and are changed (and advanced) on a 2-weekly basis. Each aligner is designed to move a tooth or small group of teeth about 0.25-0.3 mm.

Invisalign is not a 'new' concept. Sheridan^{1,2} and Sheridan *et al.*^{3,4} report on the techniques of interproximal tooth reduction (IPR) and aligning teeth using clear Essix appliances. This is based on the Kesling 'set-up' technique, where teeth are 'repositioned' by cutting them individually off a model and then making appliances to move the teeth into the 'set-up' position. These techniques have been utilized with some success over many years. The drawback of these techniques is that almost every tooth movement (or movement of a number of teeth) requires a new model 'set-up' and, therefore, a new set of impressions for the patient at almost every visit. This is uncomfortable for the patient, and time and labour intensive for the orthodontist.

Align Technology, using computer-aided scanning, imaging, and manufacture technology, has just pushed this technique into the realms of everyday orthodontic practice.

The revolutionary aspect of Invisalign is the scanning in and imaging of high precision casts made from very accurate impressions. This allows the patient's teeth to be replicated as an 'on screen' 3-D model, which can be manipulated and 'virtually' corrected through a treatment plan developed by the orthodontist and translated by Invisalign using sophisticated propriety software. The clinician has the ability to view the 'virtual' models from malocclusion to correction, movement by movement, through an Internet connection program called 'ClinCheck' The

patient's treatment can be reviewed aligner-by-aligner, and corrections made before the treatment plan is validated. Changes are made through the ClinCheck system until the result achieved is to the clinician's liking. Only then are the actual aligners made and dispatched.

Review of development

As of April 2008, more than 730,000 patients have completed or are currently in treatment.⁵ Invisalign is designed, manufactured, and marketed by Santa Clara-based medical-device company Align Technology, Inc. Align says that over 35,790 doctors are trained to provide Invisalign treatment in the U.S., with 48,130 doctors worldwide.⁵ As of January 29, 2008, Align Technology has 1,307 employees worldwide, and has manufactured more than 32 million aligners.

So far, most of the research and development into Invisalign as an orthodontic technique is being conducted at a number of orthodontic departments in the USA, particularly the University of the Pacific, University of Florida, and in a number of private practices in the USA and Europe. Apart from a number of descriptive and clinical papers⁶⁻⁸ there is nothing published in the form of retrospective or prospective control studies as yet (the technique itself is possibly a little too young to produce definitive research). Trials are being undertaken at the University of Florida into the extrusive, intrusive, and rotational abilities of Invisalign aligners

Treatment Advantages & Disadvantages

Generally, Invisalign handles simple to moderate non-extraction alignments better than mild to moderate extraction corrections. This is primarily because Invisalign[®] only has a limited ability to keep teeth upright during space closure. Attachments, formed by bonding tooth coloured restorative material in a vertical 'bar' to the buccal surface of certain teeth, can give the aligners greater rotation and angulation control. This is only partially effective. As materials improve it is these 'attachments' that will allow much greater control over tooth movements.

Advantages of Invisalign are:

Ideal Aesthetics: The aligners are relatively invisible, apart from a slight sheen to the teeth in close-up. This is the biggest draw card for the patient seeking orthodontic correction and should not be under-estimated when it comes to compliance and co-operation.

Ease of use for the Patient: The aligners are easy to insert and remove, and can be done reasonably discretely just out of view of company.

Comfort of Wear: Wearing time and compliance is not a problem. Speech is usually only affected for around 24 hours.

Simplicity of care and better Oral Hygiene: Aligners need no special treatment. Brushing with a toothbrush and toothpaste at tooth cleaning times is all that is needed. After all the aligners only need last 2 weeks. Oral

hygiene is much easier for the patient, with no appliances in place when cleaning is undertaken, thereby giving much improved oral health throughout treatment. This is particularly important for periodontally compromised patients.

Disadvantages of Invisalign are:

1. Limited control over root movement, such as root paralleling, gross rotation correction, tooth uprighting and tooth extrusion. The attachments, which Align recommend and place on the teeth during treatment set-up, are used for increasing aligner retention and tooth control. Currently, the design of these attachments is fairly crudetooth-coloured composite in oval shaped 'blobs' are indirectly bonded to the surfaces of selected teeth selected by Align, using a clear plastic template provided.

We are told that as the computer software technology becomes more sophisticated and the aligner material is improved, attachments will be refined and developed to aid difficult types of tooth movement. If this is the case, Invisalign will be able to tackle more complex problems, such as extraction based corrections.

2. Limited intermaxillary correction. Obviously, severe skeletal discrepancies cannot be contemplated with Invisalign alone. Surgery or a pre-Invisalign functional phase would be necessary. The use of Class II elastics to buttons bonded to the buccal aspects of the aligners has been tried but retention of aligners when wearing elastics is a limiting factor.

Treatment planning does allow for some sagittal AP correction of the buccal segments up to 2 mm and, thereby, some dento-alveolar reduction of any maxillary incisor protrusion.

3. Lack of operator control. As the aligners are made in total, from treatment start to treatment completion, the clinician has no ability to alter the appliance during the course of treatment. If treatment goes off track, then new impressions are needed and the case is 'rebooted' through the ClinCheck mechanism (as though one was starting treatment from scratch). This can be costly, even though an add-on 'insurance' payment can be elected before case submission to cover the reboot. As much as this lack of operator control can be perceived as a disadvantage, it is the nature of the Invisalign challenge that the clinician gains the ability to plan treatment prospectively and, once this is achieved, the lack of control becomes less of an issue.

Scientific Studies

In a systematic review of the literature, published in the Journal of the American Dental Association in 2005,⁹ Drs. Manual Lagravere and Carlos Flores-Mir were unable to draw strong conclusions about the effectiveness of the Invisalign system. They

pointed to the need for randomized clinical trials.⁹ Since this paper, more studies about the clinical effectiveness have been published; for example in the UK, Dr Paul Humber has analyzed 100 back-to-back Invisalign cases. Assessing the patients after two sets of aligners, he found that 94% of the dentitions had achieved the objectives set.¹⁰ In the USA, Akhlaghi and colleagues compared treatment with the invisalign system with treatment with conventional braces and concluded that "conventional fixed appliances achieved better results in the treatment of Class I mild crowding malocclusions".¹¹ In a comparison of outcomes between the two approaches, Kuncio et al.¹² reported that the Invisalign group displayed greater relapse saying "the mean alignment of the Invisalign group was superior to the Braces group before and after the retention phase, but these differences were not statistically significant. Therefore, even though the Invisalign cases relapsed more, they appear to have the same, if not better, overall alignment scores." In a larger study¹³ Djeu and colleagues had similar findings to Akhlaghi above and concluded that "Invisalign was especially deficient in its ability to correct large anteroposterior discrepancies and occlusal contacts". They felt that "The strengths of Invisalign were its ability to close spaces and correct anterior rotations and marginal ridge heights." They added "Invisalign patients finished 4 months sooner than those with fixed appliances on average."

Cost

The treatment price is often more than traditional braces. Treatment price is set by the dentist or orthodontist, although the cost of treatment varies considerably by doctor. Doctor fees are usually determined by complexity and length of treatment. In the U.S., treatments range in price from \$3,000 to \$9,000, depending on geographic location. For example, in northwest Ohio, the case of a patient with a mild overbite and several teeth that needed to be turned cost \$5,580.00 in 2008 (for a 13-month treatment). Braces would have cost \$5,225.00 (if the express treatment were available, it would have been \$4,300). It is important to remember that costs vary from case to case. In Europe, the treatment price ranges from €3,000 to €7,800, depending on case complexity and length while Australia provides a price ranging from \$5000 to \$9000.

Techniques & Technology

The technology that allows Invisalign to be a viable orthodontic technique is three-fold.

Collection of High Quality Pre-treatment Records

It is essential to take high quality pre-treatment records study models, pan-oral and cephalometric X-rays, and photographs. The same assessment, diagnosis, and treatment planning is undertaken for Invisalign as it is for conventional orthodontics. These records (apart from the study models) are sent to Align Technology. Digital X-rays and photographs are an advantage, as they can be transmitted 'on-line', but paper copies are

equally acceptable.

A high quality set of impressions is crucial. The impressions can be taken in a polyvinyl silicone material, such as Aquasil (Dentsply, Weybridge, UK), which is a single-phase impression technique, or Pentamix 2 (ESPE Dental AG, Seefeld, Germany), a dual-phase impression technique. Alternatively, it is possible to use a polyether material, such as Impregum (ESPE Dental AG, Seefeld, Germany), which is a single-phase impression technique. My preference is Impregum, syringed around the teeth using a full syringe for each side of the upper and the lower, and completing the impression using a rigid plastic tray. It helps enormously if one of your assistants retracts the cheeks with lip retractors and you isolate the tongue. A silicone bite material is also needed to record maximum intercuspation. The orthodontist's input into this technology is the 'prospective' treatment planning. Unlike conventional orthodontics, in which we review treatment as it progresses, Invisalign asks us to 'visualize' the completed result, so we can convey our intentions in the treatment planning process. A slightly different way of looking at things than our traditional method is required.

Interactive Treatment Planning with Align Technology

Once the assessment and diagnosis is completed, you log onto the Invisalign website, where you enter your own personal domain, which is set up following the completion of training. Here, the comprehensive treatment planning form is completed, step-by-step, and submitted either on-line or in paper form. At this point, the impressions and records are sent to Align Technology in hard copy form for those not submitted on-line.

About 1014 days later, the patient's 'virtual models' appear in 3-D, on your domain page. The treatment plan has been translated into tooth movements, and you can view this 'virtual correction' stage by stage and from any angle. If there is anything you are not happy with, you can ask for alterations. This process is called ClinCheck and alterations to the treatment plan are unlimited. Once you are happy with the 'virtual treatment', you complete the process by confirming that Align can go ahead and manufacture the aligners.

This whole treatment planning process is made possible by Invisalign casting the impressions and scanning them into their computer software. The software 'individualizes' each tooth, so they can be individually repositioned, and the software relates the upper and lower teeth together so that co-ordination is kept between arches. The software is propriety to Align Technology and forms the essential core to the Invisalign process.

Aligner Application

Around 46 weeks later, the full set of aligners, from start to finish, is delivered to you. A patient start-up and care kit accompanies this.

The manufacture process is the final computer aided technology. The 3-D 'models' of each step in the re-alignment are

transformed into hard copy models through a process of laser build up. These models are then used to make the pressure formed aligners.

On the first visit, I fit the initial aligners, checking for fit and comfort. Any interproximal reduction (IPR) is started, depending on the schedule delivered by Align Technology, and the patient is given the necessary wearing and cleaning instructions. I like the patient to return 23 weeks later for the first check.

At visit 2, I hope to see that the patient is comfortable and happy using the aligners on a full-time basis. IPR is checked using floss and continued if needed. We fit aligner 2 and give aligner 3 to the patient so they can replace aligner 2 after two weeks use. Thus, the patient is seen every 4 weeks. A typical Invisalign treatment will take around 25 aligners and 50 weeks of treatment, but can vary from 10 to 50 aligners, depending on the severity of the problem.

All of this information is presented to the clinician through a comprehensive training scheme, which you are required to take before becoming registered as an Invisalign user.

Conclusions

As a technique, Invisalign is just an additional part of the armamentarium of the orthodontist. It is an aesthetic technique that can be used to treat simple to moderate alignment cases, especially in the adult. Invisalign as a technique, is with us to stay. Much will depend on the research and development that can be generated to improve aligner control over tooth movement, and our understanding of treatment and ability to plan prospectively. Further research is required in this field, preferably in the form of prospective randomized controlled trials.

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