Invisalign: The Contact Lenses for Teeth

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Abstract

Invisalign is a series of removable clear appliances to effect tooth movement in orthodontic therapy carried through 'An Invisible' way of straightening teeth without using antiquated metallic braces and wires. It instead adopts a method of fabricating clear custom fabricated aligners designed to gradually and sequentially move teeth to their desired positions using a computer assisted technology. Also called as "Aligners" or as "Repositioners". The main aim of this study is to search the current literature regarding the Invisalign system. This systematic review will provide a more up-to-date understanding of this system, as well, an evaluation of the indications, contra-indications and case selection using Invisalign can also be conducted.

Introduction

Orthodontics is a boon to dentistry and has come a long way with more advanced techniques. Earlier the term "Orthodontics" produced the image of heavy metal wire, painful brackets, bulky head gears and the associated "Nerd factor" or "Brace face". However, with the introduction of Align Technology's Invisalign came a comfortable, esthetic, and practical alternative to traditional fixed orthodontics[1]. Improved esthetic orthodontic appliances, especially for adult patients, are highly desirable as an alternative to conventional fixed appliances. Various esthetic brackets and wires have been developed for clinical orthodontics[2].

In 1998, Align Technology (Santa Clara, Calif, USA) introduced Invisalign, a series of removable polyurethane aligners, as an esthetic alternative to fixed labial braces. The Invisalign system uses CAD/CAM stereolithographic technology to forecast treatment and fabricate many custom-made aligners from a single impression[3].

History

Invisalign® is not a 'new' concept. Sheridan and Sheridan[4] et al in 1995 reported on the techniques of interproximal tooth reduction (IPR) and aligning teeth using Clear Essix appliances. This is based on the Kesling[5] 'setup' technique (1945), 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 was required. This was uncomfortable for the patient, as well as time consuming for an orthodontist.

In 1971, Ponitz[6] introduced a similar appliance called the "invisible retainer" made on a master model that prepositioned teeth with base-plate wax. He claimed that this appliance could produce limited tooth movement.

The revolutionary aspect[7] 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[8]" (Fig. 1).

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.

Align Technology was in a legal battle with the makers of a competing product, Ortho Clear, from early 2005 until September, 2006[9]. Zia Chisti, one of the founders of Align, had started Ortho Clear to compete against Invisalign. In a complaint filed with the United States International Trade Commission (ITC) on January 11, 2006, Align alleged that Ortho Clear utilized Align's trade secrets and infringed twelve Align patents, comprising more than 200 patent claims, in the production of Ortho Clear aligners at a facility in Lahore, Pakistan. On September 27, 2006, Align Technology settled its litigation with Ortho Clear. Ortho Clear has stopped accepting new cases and discontinued its aligner business worldwide. Align acquired all disputed intellectual property.

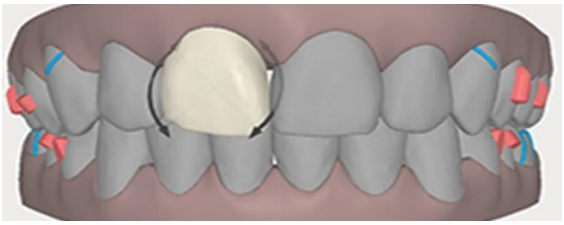

Fig. 1. Showing an image of "ClinCheck" Software

Indications:[10, 11]

1. Mildly crowded and malaligned problems (1–5 mm). Treatment that can be done with some slight lateral and/or antero-posterior expansion, with some minor interproximal tooth reduction, or by removal of a lower incisor.
2. Spacing problems (1–5 mm).
3. Deep overbite problems (Class II division 2 type malocclusions) where the overbite can be reduced by intrusion and advancement of incisors.
4. Narrow arches that can be expanded without tipping the teeth too much.
5. Relapse after using appliance therapy.
6. Minor rotations.

Contra- Indications:[12]

1. Crowding and spacing over 5 mm• skeletal anterior-posterior discrepancies of more than 2 mm (as measured by discrepancies in cuspid relationships)
2. Centric-relation and centric-occlusion discrepancies
3. Severely rotated teeth (more than 20 degrees)
4. Open bites (anterior and posterior) that need to be closed
5. Extrusion of teeth
6. Severely tipped teeth (more than 45 degrees)
7. Teeth with short clinical crowns
8. Arches with multiple missing teeth.

Advantages:[13]

1. The most obvious advantage of the treatment is cosmetic: the aligners are completely transparent, therefore far more difficult to detect than traditional wire and bracket braces. This makes the method particularly popular among adults who want to straighten their teeth without the look of traditional metal braces, which are commonly worn by children and adolescents.
2. In addition, the aligners are marketed as being more comfortable than braces. Due to the removable nature of the device, food can be consumed without the encumbrance of metallic braces.

Disadvantages:[10, 13, 14]

1. The very fact that the aligners are removable means they are not continually correcting the teeth, thus they were largely dependent on a patient's habits and their consistency in wearing the aligners. The success of the Invisalign aligners is based on a patient's commitment to wear the aligners for a minimum of 20–22 hours per day, only removing them when they are eating, drinking, or brushing their teeth.
2. Certain teeth are slightly problematic for Invisalign aligners to rotate. For eg. Few lower premolars with round shape anatomy can be difficult for the aligners to grasp and apply a rotational force to.
3. 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 (Fig. 2). This is only partially effective. As materials improve it is these 'attachments' that will allow much greater control over tooth movements. This may improve the treatment outcome in the more difficult cases, but would increase the overall cost.
4. Limited control over root movement, such as root paralleling, gross rotation correction, tooth uprighting and tooth extrusion.
5. Limited intermaxillary correction. Obviously, severe skeletal discrepancies cannot be contemplated with Invisalign® alone. Surgery or a pre-Invisalign® functional phase would be necessary.
6. 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 A–P correction of the buccal segments—up to 2 mm— and, thereby, some dento-alveolar reduction of any maxillary incisor protrusion.
7. 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.
8. The system is also somewhat expensive, as conceded by the Align company, and can be more expensive than traditional wire and bracket systems.
9. Because the aligners are removed for eating, they could be lost. Invisalign recommends that the

patient keep the previous aligners in case this happens.

10. Unlike traditional braces, if a patient grinds or clenches his or her teeth during the day or while sleeping, the aligners can become damaged. In practice, however, this problem is very rare and a new aligner can be ordered.
11. Also, similar to traditional metal braces, aligners may cause a slight lisp at the beginning of treatment. This usually disapp-ears as the patient becomes used to the treatment.
12. The aligners are constructed of implantable-grade polyurethane, and the Align Company has acknowledged that, though extremely rare, there may be cases of allergic and toxic sensitivity reactions to Invisalign. Minor symptoms such as sore throat, cough, and nausea have been reported. In more serious cases, the FDA has received reports of systemic swelling or throat pain that has extended to the upper chest and wind passages requiring emergency medical treatment and discontinuation of the Invisalign treatment. While the Invisalign Company provides no information except the MSDS (material safety data sheet) directly to patients or orthodontists, working through the patient's orthodontist Invisalign will make the aligners with several different materials to attempt to reduce toxic or allergic sensitivity.
13. If the treatment go off track, or patients fail to keep the aligners in for the required length of time, then the next aligner in the series will not fit, and a new set of impressions and aligners will be necessary, adding to the cost.
14. While chair side time is greatly reduced, the input on treatment planning, treatment ClinCheck revisions and mid-course Clin-Check assessments can and does increase non-chair side time.

Fig. 2: Showing vertical Bar to the buccal surface for greater rotation and angulation control

Various Studies Conducted:

1. A comparison of treatment impacts between invisalign and fixed appliance therapy during the first seven days of treatment was done by Kevin Blaine Miller (2006)[15] and the results showed that:
2. The fixed appliance group reported a more intense decrease in overall quality of life and more a more intense increase in pain beginning at day one and extending through day seven.
3. The fixed appliance group reported a more intense decrease in functional, psycho-social and pain-related aspects of their daily lives.
4. Clinically, aligners avoid many of the side effects of traditional fixed appliances[16], for example the effects on the gums and support-ing tissues[17].
5. M.G. Taylor[17] performed a study to determine the effect of orthodontic tooth movement on periodontal soft tissue using Invisalign®. As part of a clinical trial on measuring tooth movement using Invisalign® on 100 subjects, soft-tissue reaction was checked using papillary bleeding score (PBS) and periodontal pocket depth (PD) at baseline and end of treatment. Periodontal tissue health as measured by papillary bleeding score and periodontal pocket depth improved with use of Invisalign® aligners during orthodontic treatment.
6. Fixed appliances are known to cause the roots of teeth to shorten for most patients[18], whereas with invisalign, patients "graduate" to a new set of aligners in their treatment series approximately every two weeks. The aligners give less force per week and less pain than do fixed appliances. Fixed appliances are adjusted approximately every six weeks and apply greater forces[15].
7. Demineralisation or tooth decay occurs in up to 50% of patients[19] with fixed appliance treatment because they cannot be removed for eating and cleaning. Aligners should be removed to eat, drink, to clean the teeth, or to have them checked by the clinician. Because you remove the aligners, you are not limited to what you eat. (It is acceptable to wear aligners while drinking water.)
8. Computerized treatment planning is compul-sory as part of the Invisalign protocol. As with other forms of orthodontic treatments that incorporate a computerized plan, this allows the prospective patient to review the projected smile design, learn how long the treatment is likely to take, compare different plans, and make a more educated decision about whether or not to use Invisalign.
9. Invisalign treatments have been claimed to be quicker than traditional orthodontics. A large-scale study of 408 patients with traditional appliances in Indiana took an average of 35.92 months with a maximum of 96 months[20], while Invisalign takes between 12–18 months [10,16]. In an another study[21], Invisalign was shown to be faster and achieve straighter teeth than alternatives but relapsed to ultimately get similar results to the traditional appliances examined. The study was considered by the authors,

however, to be too small for many conclusions to be statistically significant. Furthermore, this general concept that Invisal-ign is faster has been challenged by the Invisalign review which points out that there are other appliance systems that take half the time, for example by incorporating surgery or temporary implants that insert into the patient's bone, to accelerate the procedure[13].

10. It is non cytotoxic.

Technique[22-25]

1. **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. 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 is preferable. 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.

3. **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 10–14 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', the process can be completed 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. Each aligner is programmed to move a tooth or a small group of teeth 0.25 to 0.33 mm every 14 days.

4. **Aligner application**

1. Around 4–6 weeks later, the full set of aligners, from start to finish is delivered (Fig. 3).
2. A patient start-up and care kit accompanies this (Fig. 4). The manufac-ture process is the final computer aided technology. The 3-D 'models' of each step in the realignment are transformed into hard copy models through a process of laser build up. These models are then used to make the pressure formed aligners (Fig. 4).
3. On the first visit, fit the initial aligners, checking for fit and comfort. Any inter-proximal reduction (IPR) is started, depending on the schedule delivered by Align Technology, and the patient is given the necessary wearing and cleaning instructions. The patient to return 2–3 weeks later for the first check.
4. At visit 2, see if 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 week's 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.

Fig. 3: Showing patient start-up and care kit with full set of aligners

Fig. 4: Showing pressure formed Aligners

Conclusion

Invisalign appliance can provide an excellent esthetic during treatment, ease of use, comfort of wear, and superior oral hygiene[10]. It is an effective appliance for minor space closure, lingual constriction, and correction of anterior rotations and marginal ridge height discrepancies. However, Invisalign also has some limitations of achieving the similar results as by conventional fixed orthodontic appliances. Further research and refinement of the design is still required for the further development of this worthwhile treatment.

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Source of Support: Nil

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