

FEATURES SECTION

Current Products and Practice Invisalign®: early experiences

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Abstract

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This article describes the Invisalign® technique. It is based on the author's personal experience of over 60 cases started in the private practice setting. 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.

Introduction

This article is a personal perspective of a relatively 'new' orthodontic technique, called Invisalign®, which the author has been using for just over a year, and of the ground breaking technology behind the development of this technique.

My first view of Invisalign® was about 4 years ago when Align Technology, Santa Clara, California, USA, introduced the concept into the USA. 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®' (Figure 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.

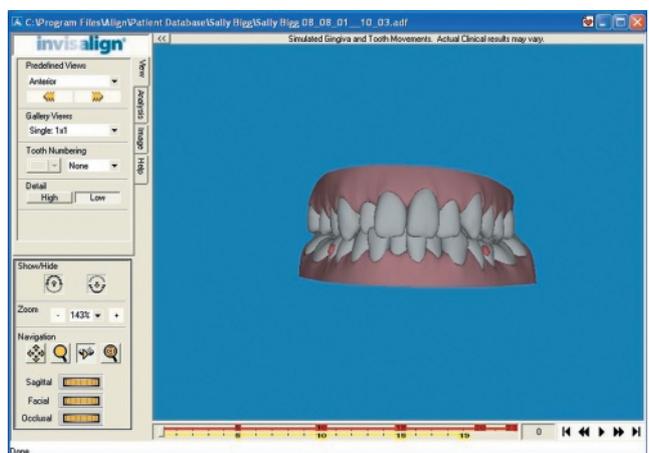


Fig. 1 Screen capture of 'ClinCheck', the Internet connection program for planning Invisalign® cases.

Review of development

Figures from Invisalign® show that there are some 40,000 patients having Invisalign® treatment in the USA and Canada, and there have been around 6000 orthodontists in the USA trained to deliver Invisalign® treatment. These figures will increase dramatically over the next few years with the introduction of Invisalign® into Europe and the rest of the world.

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 papers⁵⁻⁷ 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.

Techniques and 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 and rejig 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 10–14 days later, the patient’s ‘virtual models’ appear in 3-D, on your domain page (Figure 1). 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 4–6 weeks later, the full set of aligners, from start to finish (Figure 2), 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 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.

On the first visit, I fit the initial aligners, checking for fit



Fig. 2 Box of aligners and attachment template for one patient.

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. I like the patient to return 2–3 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.

Treatment advantages, disadvantages, and limitations

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 (Figure 3), 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.

The most common types of malocclusion I am currently treating with Invisalign® are:



Fig. 3 Composite attachments bonded indirectly to the teeth to aid aligner retention and improve tooth control.

- 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.
- Spacing problems (1–5 mm).
- Deep overbite problems (Class II division 2 type malocclusions) where the overbite can be reduced by intrusion and advancement of incisors.
- Narrow arches that can be expanded without tipping the teeth too much.

Certain aspects are more difficult to handle:

- Crowding and spacing over 5 mm.
- Skeletal antero-posterior discrepancies (as measured by cuspid relationships from Class I) of more than 2 mm.
- Centric relation and centric occlusion discrepancies.
- Severely rotated teeth (more than 20 degrees).
- Open bites (anterior and posterior) that need to be closed.
- Extrusion of teeth.
- Severely tipped teeth (more than 45 degrees).
- Teeth with short clinical crowns.
- Arches with multiple missing teeth.

Although some aspects of malocclusions are difficult to handle with Invisalign®, this does not preclude the use of Invisalign® completely, since there is an option to undertake combination treatment. Invisalign® can be used to correct problems up to a point and then treatment is completed using conventional appliances (or vice versa). Alternatively, it is possible to treat one arch with Invisalign® and the other with conventional appliances.

This may improve the treatment outcome in the more difficult cases, but would increase the overall cost.

The advantages of Invisalign® over conventional appliances 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 underestimated 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*: after 61 treatment starts, I am pleasantly surprised that wearing time and compliance is not a problem. Speech is usually only affected for around 24 hours.
- *Simplicity of care and better oral hygiene*: the 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 crude—tooth-coloured composite in oval shaped 'blobs' (Figure 3) 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 A–P 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.

How to get involved with Invisalign®

At this time, Invisalign® is only open to those orthodontists who have completed an Invisalign® course. These are held in the UK on a monthly basis and can be accessed by contacting www.invisalign.co.uk, Invisalign UK on 01908843606, or Lee Robertshaw on 07939257286

Once registered, Align Technology will set up your personal Invisalign® domain (VIP) site, which you access through the Internet. This VIP site is password protected.

Invisalign UK runs PR and advertising campaigns to promote Invisalign® to the public. Enquiries by the public are passed to a call centre, which are then filtered to a practitioner identified by postal location. My experience is that informing and educating your referring general practitioners into the Invisalign® process, and its advantages and disadvantages, soon produces a flow of patients asking about suitability.

Invisalign UK Customer service is excellent and with the increasing spread of Invisalign® treatments there is a constant evolving source of orthodontists who can assist those at the entry level of Invisalign® treatment.

The cost of Invisalign® production varies from 1500.00 to 2300.00 Euros, depending on the number of aligners needed for treatment. While chairside time is greatly reduced, the input on treatment planning, treatment ClinCheck® revisions and mid-course ClinCheck® assessments can and does increase non-chairside time.

Invisalign® also allows for refinement aligners, which can be added at the end of the scheduled treatment procedure, to finish off any tooth movement not fully expressed. This is usually needed if over-corrections are not accurately planned during the treatment-planning phase. It also happens because there is a slight flex in the aligner material that sometimes does not allow for full expression of the desired tooth movement. Refinement has to be elected prior to manufacture. No additional impressions are needed, but a refinement form outlining the desired extension tooth movements and photographs are submitted to Align Technology.

The ability to re-start a treatment (reboot) that has gone off course is also available. Reasons may be poor patient compliance with wear, inadequate or incomplete IPR so that tooth movements do not take place, or poorly-designed treatment plans. New impressions are needed, as well as photographs, and a reboot cost is charged unless 'insured' against prior to Invisalign® treatment acceptance.

Conclusions

Invisalign® should be put in perspective. As a technique, it 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.

I believe that the individual case should merit offering Invisalign® as a treatment option, rather than trying to fit Invisalign® treatment to the case.

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 move-

ment, 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.

Postscript

Les Joffe is a specialist orthodontist in Harley Street, London, and a director of OrthoWorld, an orthodontic corporate in the UK. OrthoWorld initially held exclusive rights to using Invisalign® as the company helped introduce Invisalign® into the UK in July 2001. Since March 2002, Invisalign® has been available to any orthodontist who attends a recognized course. Les Joffe has no financial interest in Invisalign® or Align Technology.

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