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# Invisalign<sup>®</sup>, an Innovative Invisible Orthodontic Appliance to Correct Malocclusions: Advantages and Limitations

**Abstract:** Tooth movement may be achieved by the use of sequential positioners made by altering tooth positions on set-up models to simulate progress of treatment. The principle is based upon Kesling's positioner concept of 1945, though its subsequent application to splint therapy was labour intensive and did not result in precise tooth movement. Invisalign<sup>®</sup> was developed by Align Technology, Inc (Santa Clara, CA, USA) in 1997 by applying 3-D imaging technology to overcome these problems, and permitting customization on a large scale. Their system offers significant advantages, but still suffers from limitations which are discussed in this article.

**Clinical Relevance:** By providing an aesthetic means of correcting malocclusions of minor to moderate severity, Invisalign<sup>®</sup> has met with high patient acceptance. Aggressive marketing of the system makes it essential that the orthodontists and dentists understand the basic mechanism whereby the system works, along with its strengths and limitations.

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## The history

Kesling's positioner was a precursor to the aligner. In 1945, Kesling foresaw the future development when he stated that:

*Major tooth movements could be accomplished with a series of positioners by changing the teeth on the setup slightly, as treatment progresses. At present this type of treatment does not seem to be practical. It remains a possibility, however, and the technique*

*for its practical application might be developed in the future.*<sup>1</sup>

The following decades were characterized by aligner-like thermoformed splints which were fabricated from different acrylics, and covered all teeth as well as the marginal parts of the alveolus. However, the utilization of these splints suffered from two disadvantages. First, they were labour intensive and second, the amount of tooth movement had to be very limited to avoid excessive tooth mobility. Sheridan, later on, broadened the use of vacuum-formed aligners after the widespread introduction of his air-rotor stripping.<sup>2</sup> By blocking out and grinding areas on the working cast, cutting windows in the appliance, thermoforming the material with special pliers, placing composite mounds on teeth and attaching elastic traction to these mounds, he managed to expand the spectrum of tooth movement. However, all this still required extensive and expensive laboratory

labour.

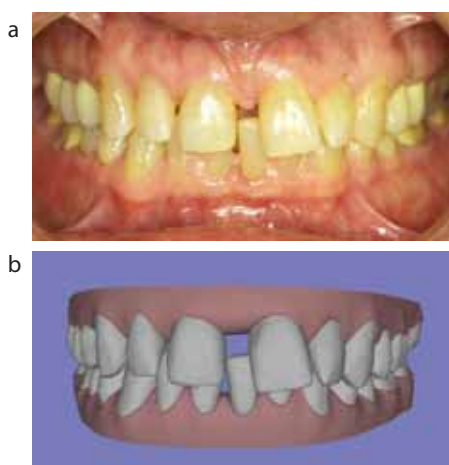
Invisalign<sup>®</sup> was launched by Align Technology, Inc (Santa Clara, CA, USA) in 1997. By applying 3-D imaging technology to the principle of moving teeth with a series of aligners, mass-customization, ie the production of individual appliances on a large scale, became reality.

## The principles of the Invisalign<sup>®</sup> system

Pre-treatment records include photographs (extra-oral: frontal [at rest/smiling] and profile; intra-oral: frontal, left/right lateral, maxillary/mandibular occlusal), and radiographs (panorex or status). In addition, Align Technology also requires accurate maxillary and mandibular impressions made in a polyvinyl siloxane material along with a bite registration.

Using CT technology, the

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**Figure 1.** (a) Intra-oral frontal view of a patient's dentition and (b) the corresponding 3D-model. (With permission from R-R Miethke. Treatment with the Invisalign system. In: *Orthodontic and Dentofacial Orthopedic Treatment* Rakosi, Graber. Stuttgart: Georg Thieme Verlag, 2009.)

impressions and the bite registration are scanned while they rotate in front of an amorphous silicon X-ray sensor. The scanning process has a precision in the 100 µm range and permits the fabrication of a 'virtual model' (Figure 1 a and b).<sup>3</sup> Proprietary software (ToothShaper®) is applied to define the facial axes of the clinical crowns, colour-code all teeth, and separate them from each other, thus simulating work done on a plaster cast with a jig saw. All teeth receive a rudimentary root and are 'worked over', whereby any imperfections or artefacts are removed. At the same time, the gingival margin is demarcated, defining the extension of the anticipated aligner onto the alveolus.

If the virtual image is not sufficiently distinct to delineate the gingival margin accurately, the intra-oral photographs supplied as part of the preparatory phase are used to assist in this process, and in other situations of uncertainty. After defining the boundary between the teeth and the soft tissue, virtual gingivae are draped over the alveolar processes, further enhancing the visual representation.<sup>4</sup> Following this, the virtual model of the maxilla and mandible are orientated towards each other in centric occlusion by the application of another software tool (ToothShaper® AutoBite). Basically, this program applies algorithms to maximize the tooth-to-tooth contacts. Using yet another software package (Treat®),

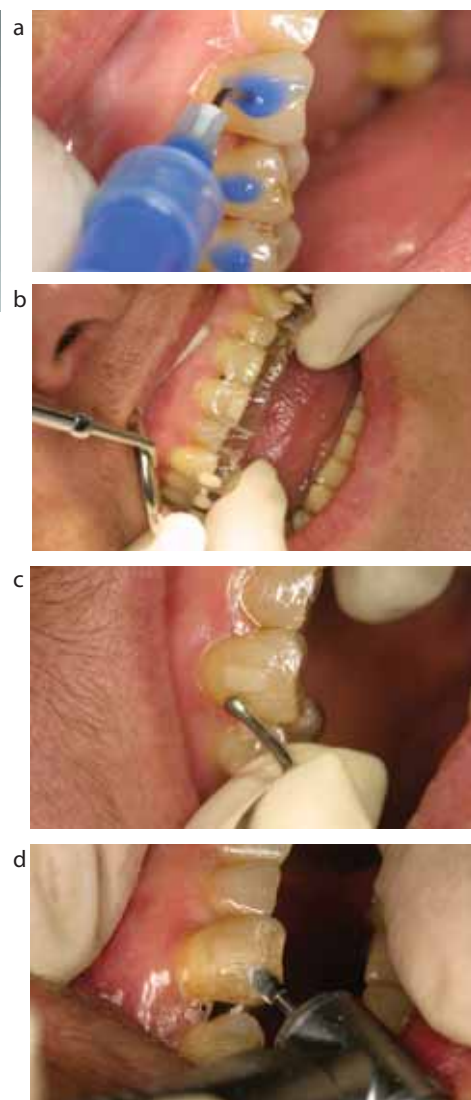


**Figure 2.** Example of an aligner for the maxillary dentition. (With permission from R-R Miethke. Treatment with the Invisalign system. In: *Orthodontic and Dentofacial Orthopedic Treatment* Rakosi, Graber. Stuttgart: Georg Thieme Verlag, 2009.)

individual teeth are then aligned according to the orthodontist's prescription at an optimal rate, ie each treatment stage will move selected teeth by no more than 0.2 mm. This manipulation is controlled by a 'widget' which enables movements of a virtual tooth in all three planes of space.

The formulated therapy is then returned to the orthodontist in virtual form for evaluation by means of ClinCheck® software. Once approved, Fab® software will convert the virtual model of each treatment stage into a plastic model by using a process known as stereolithography. An aligner is thermoformed onto each plastic cast using 0.75 mm thick foils of polyurethane with methylene diphenyl di-isocyanate and 1,6 hexanediol (Ex 40™) (Figure 2).<sup>5</sup> The aligner is then robotically marked, cut and removed from the cast. The final stages consist of tumbling, polishing, disinfecting and packaging the appliance for delivery to the orthodontist.

Treatment with the Invisalign® system ultimately requires the use of 'attachments' akin to fixed appliance brackets. These small, custom-made composite shapes are bonded onto specific teeth in a manner similar to brackets (Figures 3 a–d). Attachments serve three main purposes: assistance with difficult movements, the augmentation of retention and support for auxiliary functions. They are fabricated intra-orally using a shell template which is a 0.25 mm thick 'aligner' with strategically placed concavities. These concavities are loaded with a micro-filled, light-cured composite material which affords resistance to wear and displacement during function, ie seating and removal of the appliance. The patient is instructed to wear the



**Figure 3.** (a–d) Aligner attachment fabrication. (a) Application of etching gel on the respective teeth. (b) Insertion of a special very thin and flexible tray the concavities of which are filled with tooth-coloured acrylic composite. (c) Adaptation of the tray for defined shaping of the attachment. (d) Fine shaping of the composite body with a ball-end bur. (With permission from R-R Miethke. Treatment with the Invisalign system. In: *Orthodontic and Dentofacial Orthopedic Treatment* Rakosi, Graber. Stuttgart: Georg Thieme Verlag, 2009.)

aligners continuously except when brushing, eating or drinking sugary beverages or those likely to stain.

## Providing space

Treatment with the Invisalign®



**Figure 4.** Example of maximum enamel removal between teeth LR3, LR4, LR5, LR6 and LR7.

system often requires the acquisition of space for tooth alignment by performing interproximal enamel reduction (IPR; Figure 4) or expansion of the dental arches. Extractions are rarely necessary in order to reach this end. IPR is the method of choice since it allows creating the exact amount of required space. Invisalign® patients are often those who have undergone previous orthodontic therapy and hence their crowding is seldom extreme. IPR creates small spaces necessitating only minimal tooth movements. Extractions in adult patients with a certain degree of attachment loss, on the other hand, often result in unavoidable open gingival embrasures.<sup>6-9</sup> Careful IPR is found to limit the development of such black triangles and, when compared with extractions, meets with better acceptance by most patients. However, contra-indications to this procedure include crowns of small dimension, square crown configuration, existing hypersensitivity, and root proximity. Poor oral hygiene is not an absolute contra-indication if the procedure is followed by the correct polishing sequence. Overall, though, the fact that IPR involves the removal of irreplaceable tooth structure must not be overlooked.<sup>10</sup>

Lateral expansion of the dental arches is an alternative to IPR and has the added advantage of eliminating unaesthetic

buccal corridors.<sup>11-14</sup> However, non-skeletal dento-alveolar expansion carries with it the risk of gingival recession and relapse. Therefore only a maximum of two to three millimetres of increase in arch width per quadrant can be achieved, which may not be sufficient in certain conditions.<sup>15, 16</sup>

Since aligners are unable to produce bodily movement of teeth to any significant extent, extractions should be considered as a last resort. Premolar extractions are seldom indicated in Invisalign® patients, as the mild to moderate lack of space cannot justify the extraction of two premolars (assuming a mesiodistal dimension in the 7.0 mm range each). Even if the resulting extraction spaces could be closed with aligners, paralleling the roots of all teeth would still present a challenge, particularly in the mandibular arch.<sup>17</sup> Hönn and Göz in 2006 reported on a patient treated with the Invisalign® system in combination with the extraction of four first premolars.<sup>18</sup> Even though the patient was satisfied and the results deemed acceptable, the panoramic radiograph revealed that the second premolars and canines were not upright in any of the quadrants. This has implications for both stability and the patient's periodontal health. The same root divergence was obvious in a separate patient presentation.<sup>19</sup> The use of fixed orthodontic appliances to upright the adjacent teeth after finishing treatment with aligners was proposed. However, this would prolong the treatment by up to 40 months on average.<sup>17</sup>

Overall, extractions can produce desired results when indicated, particularly when the patient is highly co-operative, the operator is experienced and the treatment includes the use of adequate attachments. An example has been reported by Miller and his co-workers.<sup>20</sup>

### Advantages of the Invisalign® system

In contrast to fixed orthodontic appliances, Invisalign® aligners permit unimpeded oral hygiene measures to be carried out,<sup>21, 22</sup> thus reducing the incidence of demineralization and periodontal disease. Unlike treatment with fixed appliances, treatment with clear, removable aligners appears to have no adverse effect upon gingival health.<sup>23</sup> This is of particular significance when treatment is being considered in the presence of pre-existing

periodontal disease, as was demonstrated by Turatti and co-authors in 2006 in a periodontally compromised adult patient whose incisors were intruded.<sup>24</sup>

The Invisalign® system eliminates the appearance of labial fixed appliances and, in contrast to lingual fixed appliances, interferes to a minimal degree with tongue movements and speech.<sup>25, 26</sup> This makes it the treatment chosen mostly by adult female patients who are not prepared to accept the appearance of fixed appliances or their effect upon speech. Rosvall and co-workers<sup>27</sup> assessed the attractiveness, acceptability and value of various orthodontic appliances by showing adults relevant digital images. The study revealed the following in order of decreasing appeal:

- Alternative appliances (a clear tray simulating Invisalign® aligners);
- Ceramic bracket appliances;
- Ceramic self-ligating bracket appliances;
- Hybrid self-ligating stainless steel/ceramic bracket appliances; and
- Self-ligating stainless steel bracket appliances.

They also found that adults were willing to pay an additional fee for alternative appliances, such as clear tray aligners and lingual braces.<sup>27</sup>

During periodical removal of the aligners for eating, drinking and cleaning of both the teeth and the appliance, the periodontal ligament is given a chance to recover thus, in theory, causing less discomfort. Nedwed and Miethke demonstrated this after analysing questionnaires completed by 54 consecutive Invisalign® patients.<sup>28</sup> The questionnaire aimed to survey the following parameters: adaptation time, occurrence and duration of pain, speech impairment, lingual and mucosal irritation, temporomandibular joint (TMJ) symptoms, and the patient's assessment of the success of therapy and the calibre of information provided at the initiation of treatment. The results of their study showed high acceptance of aligners. The adaptation time of one week was considered negligible by most patients. Some patients experienced mild pain for 2-3 days and/or slight mucosal irritation. Speech impairment did not appear to be a problem. None of the patients complained about TMJ pain, but 8% reported clicking which had been present prior to the start of therapy. At the time of the interview, 89% of patients surveyed were satisfied with the progress of their treatment. All patients considered themselves well, or very well informed about



the procedure.

Miller *et al* compared, in a prospective study, the quality of life in 60 adult patients treated with Invisalign® aligners (n=33) to that in patients with fixed appliances (n=27) during the first week following insertion.<sup>29</sup> The sample used a daily diary to record any pain and any functional or psychosocial impact sustained as a result of their treatment. It was found that adults treated with aligners experienced less pain and fewer negative consequences than did those treated with fixed appliances.

Therapy with aligners should carry a reduced risk of root resorption by virtue of the fact that teeth are moved by no more than 0.2 mm at a time, which hints at a relatively low force. This assumption was investigated by Barbagallo and his co-workers in a prospective, randomized clinical trial using microcomputed tomography.<sup>30</sup> The investigators used ClearSmile® appliances (ClearSmile, Woollongong, Australia), which are similar in concept to the Invisalign® system. Comparisons were made between the splint forces, heavy and light conventional (cantilever) forces and no force application (control). The control teeth had few resorption cavities, whereas the light-force loaded teeth had approximately five times more and the ClearSmile® appliance treated teeth almost six times more. The heavy-force loaded teeth, however, showed around nine times more resorption craters than the control teeth. In this context, it should be taken into consideration that the ClearSmile® aligner moved the respective teeth 0.5 mm, a distance more than twice as much as that achieved with Invisalign® aligners. Finally, it should be mentioned that Brezniak and Wasserstein reported on a patient with severe root resorption following treatment with the Invisalign® system.<sup>31</sup>

Align Technology has developed a software tool to evaluate treatment outcomes in three dimensions.<sup>4,32</sup> When used in a recent prospective study, Kravitz *et al* found that, on average, only 41% of the programmed tooth movements were actually accomplished with the Invisalign® system.<sup>33</sup> The most reliable movement was lingual constriction (47.1%), and the least reliable was extrusion (29.6%).

Further advantages of the Invisalign® system include reduced chair time, fewer emergencies, and minimal armamentarium requirements. Moreover, Invisalign® can be used even in patients presenting with multiple artificial tooth

surfaces where bonding poses a challenge.

### Limitations of the Invisalign® system

A significant limitation of the Invisalign® system is the inability to alter the course of treatment once the set of aligners has been fabricated. If the final therapy outcome is unsatisfactory, the clinician may need to resort to the use of auxiliary devices (eg fixed appliances), or request the fabrication of additional aligners.<sup>34</sup>

From the patient's perspective, aesthetics and the duration of treatment are foremost priorities.<sup>35</sup> While the Invisalign® system is aesthetically pleasing, it requires basically the same treatment time as other types of orthodontic appliances. Corticotomy has been proposed as a means of shortening treatment time. In the Accelerated Osteogenic Orthodontics (AOO) approach (Trademark of Wilckodontics, Inc, Peach St, Erie, PA, USA) the bone around all teeth is subjected to corticotomy.<sup>36</sup> Owen has suggested combining the Invisalign® system with AOO in order to achieve both aesthetics and speed.<sup>35</sup> He started aligner application ten days after corticotomy, and completed treatment within eight weeks by changing the aligners every three days.

The basic constituent of Invisalign® aligners, polyurethane, is not an inert material. It is affected by heat, moisture, and prolonged contact with enzymes. Consequently, aligners retrieved from the oral cavity demonstrate substantial morphological variation involving abrasion at the cusp tips, adsorption of desquamated cells, and localized calcification of the biofilm. In addition, the posterior parts of the appliance were found to increase in hardness, a feature likely caused by cold work of the material during mastication.<sup>37</sup> In another publication, it became apparent that thermocycling and repeated loading both decrease force delivery.<sup>38</sup>

Treatment outcomes with fixed appliances are, in general, superior to those achieved by utilizing the Invisalign® system.<sup>39</sup> In particular, the Invisalign® system is unable to correct large anteroposterior skeletal discrepancies and to achieve optimal occlusal contacts. In addition, treatment stability was reported as being less than that resulting from fixed appliance therapy.<sup>40</sup> This conclusion, however, was based on a retrospective cohort study. A systematic review carried out in 2005 did not substantiate this statement.<sup>41</sup>

### Severity and type of malocclusion as a limitation to treatment with Invisalign®

Patients who opt to receive orthodontic treatment with the Invisalign® system are typically adults whose main complaints are the following: crowding, spacing, incisor flaring, or supra- and infra- positions.<sup>26,42</sup> Joffe listed symptoms that typically respond well to treatment with Invisalign® and others in which improvement is difficult to achieve when using the system on its own.<sup>43</sup>

### Malocclusions/symptoms responsive to treatment with the Invisalign® system

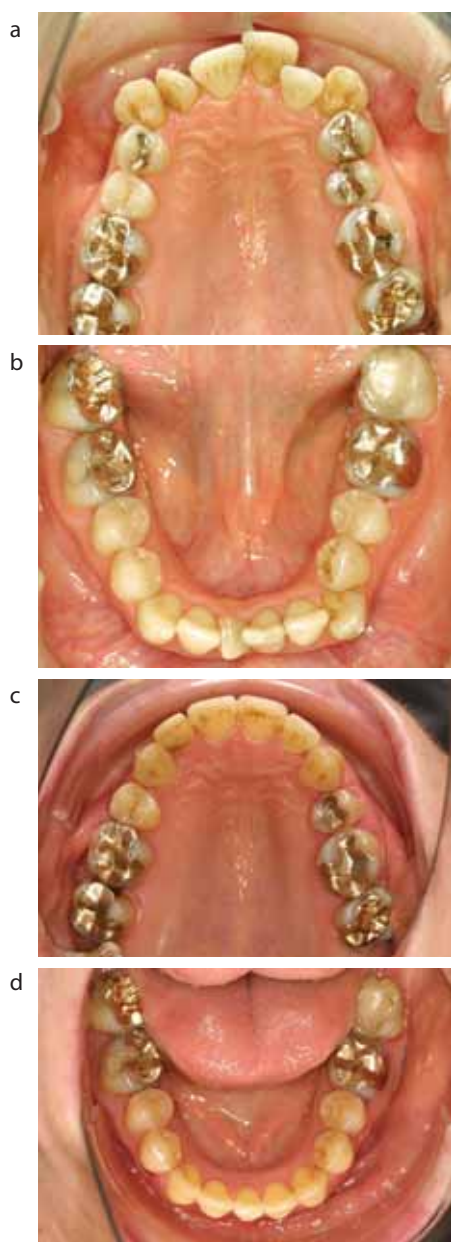
- Crowding ≤ 5 mm;
- Spacing ≤ 5 mm;
- Deep bites (Class II Division 2: correction by intrusion and protrusion of the incisors);
- Constricted arches (correction avoiding unacceptable buccal tipping).

### Malocclusions/symptoms less responsive to treatment with the Invisalign® system

- Crowding or spacing > 5 mm;
- Anteroposterior skeletal discrepancies >2mm;
- Centric relation/centric occlusion discrepancies;
- Severe rotations (> 20°);
- Open bites (anterior and posterior);
- Extrusion of teeth;
- Severe hypodontia/oligodontia;
- Uprighting of severely tipped teeth (> 45°).

Joffe also pointed out that difficulties arise if teeth have too short clinical crowns.

Clements and co-workers demonstrated the validity of this listing. They assessed the improvement achieved by the Invisalign® system in 51 patients that were classified according to their pre-treatment peer assessment rating (PAR) scores, and the need for extractions.<sup>23</sup> All patients were randomized into one of four treatment protocols: one or two week activation with aligners made out of soft plastic, and one or two week activation with aligners made out of hard plastic. The results showed no significant differences between the four groups. Anterior alignment was the most responsive component, whereas buccal occlusion improved the least. When analysed by type of extraction, incisor extraction sites were closed to a significantly greater extent than either maxillary or mandibular premolar extraction sites (Figure



**Figure 5.** Example of a patient at the beginning (**a, b**) and at the end (**c, d**) of treatment after extraction of the maxillary first premolars and the mandibular right central incisor. The result was mainly accomplished with Invisalign® therapy, though some other invisible devices were temporarily also employed. (With permission from R-R Miethke. Treatment with the Invisalign system. In: *Orthodontic and Dentofacial Orthopedic Treatment* Rakosi, Graber. Stuttgart: Georg Thieme Verlag, 2009.)

5a–d). Similarly, Bollen and co-workers reported that patients with a two week activation regimen, no extractions, and a low initial

PAR score were more likely to achieve their desired treatment outcome with one series of aligners.<sup>44</sup>

Joffe emphasized that, although some malocclusions and symptoms are not entirely corrected by use of the Invisalign® system alone, this does not preclude its application in combination with other treatment modalities.<sup>43</sup> Giancotti and Ronchin, for example, bonded temporarily lingual and labial buttons to close the space of a missing mandibular first molar with elastics.<sup>45</sup> More recently, Invisalign® has been used in patients in whom orthognathic surgery was indicated to correct a complex skeletal malocclusion.<sup>46,47</sup> These patients additionally underwent treatment with segmental fixed or full-fixed appliances prior to and following surgery. Treatment using Invisalign® aligners has also been combined with the usage of mini-screws and lingual brackets.<sup>48</sup>

In 2007, Boyd suggested a completely new protocol to improve the treatment of more complex malocclusions.<sup>49</sup> This protocol was adopted by Align Technology and has since then been applied to all treatment plans. It remains to be seen how much this innovation will generally reflect on the effectiveness of the system.

## Conclusion

The Invisalign® system has been established as an option for the correction of malocclusions in patients who demand a minimally visible, non-speech impairing treatment modality. It is particularly well suited to patients who function in the public arena. Additional advantages include unhindered oral hygiene, a reduction in iatrogenic discomfort, favourable acceptance, and high satisfaction with treatment outcomes by both patients and clinicians. Nevertheless, it has its limitations, particularly in the management of severe skeletal malocclusions. Several clinical reports seem to indicate that the limitations of the system can be overcome to some degree by applying clinical expertise and the use of adjunct orthodontic therapies.

Very few prospective clinical trials can be found in the literature. Most publications are anecdotal commentaries and clinical reports. Hence, indications for, and limitations of, this form of treatment, as well as the predictability of outcome, are not supported by scientific evidence. Randomized prospective clinical trials are required to

evaluate the efficacy of the appliance and its effects upon individual teeth, the overall occlusion, and the supporting structures.

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