Accuracy of clear aligners: A retrospective study of patients who needed refinement

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Introduction: The purpose of this study was to determine the accuracy of specific tooth movements with Invisalign (Align Technology, Santa Clara, Calif). **Methods:** The study sample included 20 Class I adult patients treated with Invisalign; they completed their first series of aligners and had to have a "refinement" series. Initial and predicted models were obtained from the initial ClinCheck (Align Technology). The starting point of the refinement ClinCheck was used to create the achieved models. Predicted and achieved models were superimposed over the initial ones on posterior teeth using the 3-dimensional Image Analysis open-source software Slicer CMF. Three hundred ninety-eight teeth were measured for vertical, horizontal, and rotational movements, and transverse widths were measured. The amount of predicted tooth movement was compared with the achieved amount for each movement. **Results:** Horizontal movements of all incisors seemed to be accurate, with small (0.20-0.25 mm) or insignificant differences between predicted and achieved amounts. Vertical movements and particularly intrusions of maxillary central incisors were found to be less accurate, with a median difference of 1.5 mm ($P < 0.001$). All achieved rotations were significantly smaller than those predicted, with the maxillary canines exhibiting the greatest difference of 3.05° ($P < 0.001$). **Conclusions:** The most inaccurate movements identified in this study were intrusion of the incisors and rotation of the canines. (Am J Orthod Dentofacial Orthop 2018;154:47-54)

The Invisalign appliance was introduced to the public in the late 1990s by Align Technology (Santa Clara, Calif) as a novel method of straightening teeth without braces. Since then, Invisalign has made great progress in terms of treatment planning methods, materials, and manufacturing. The company's powerful marketing has helped to increase the public's demand for clear aligners to the point where Invisalign is an essential part of any orthodontic practice today. There is much speculation regarding its future and the future of orthodontics; however, there is no strong evidence regarding the capabilities and limitations of clear aligners.

In recent years, researchers have used several methods including the American Board of Orthodontics objective grading system, Peer Assessment Rating scores, and other objective occlusal criteria to assess the quality of Invisalign treatment.[1-12] The most notable conclusions were that Invisalign is not as effective as fixed appliances for expansion,[6] it seems to cause more relapse,[5] and it is not very effective in controlling buccolingual inclination,[4,10,11] occlusal contacts,[4,10,11] occlusal relationships,[4,11] overjet,[4] and overbite.[7] Although these are relatively simple and objective methods of evaluating treatment outcomes, they have some limitations and do not explain the etiology of unsatisfactory results in depth.

A different way of evaluating the accuracy of Invisalign is 3-dimensional (3D) superimposition of predicted and achieved models. A few studies have used 3D superimpositions to measure the accuracy of different types of tooth movements, but the results have been unclear.[13-17] A major limitation of 3D superimpositions is the lack of stable anatomic structures on the predicted models, since ClinCheck (Align Technology) only contains clinical crowns and virtual gingiva. Well-conducted studies of this kind could provide valuable information for efficient treatment planning with ClinCheck. For example, if the accuracy percentage of a specific tooth movement is known, overcorrecting it by the appropriate amount or staging the movement in smaller increments may result in the desired outcome.

Previous studies have obtained valuable information, but there is still much to be learned about the biomechanics and limitations of clear aligners. According to a recent systematic review, the quality of available

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studies was not sufficient to draw evidence-based conclusions.[18] Much of what we know about Invisalign is still based on clinical experience rather than scientific evidence.[15]

In addition, the studies that used 3D superimpositions were performed before the introduction of the new aligner material called SmartTrack (Align Technology) in 2013. According to Align Technology's anecdotal research, it has superior properties compared with standard Essix materials and can exert continuous forces over a longer period of time. Despite the technological advances and changes that the Invisalign appliance has undergone, clinicians still find that a refinement stage is often necessary.

The aim of this study was to determine the accuracy of specific tooth movements with Invisalign to identify possible reasons for refinement.

MATERIAL AND METHODS

The study group comprised 20 adult patients (3 men, 17 women) with an average age of 37 years 6 months (range, 18 years 1 month to 79 years 11 months). Crowding ranged from mild (0-3 mm) in 7 subjects to moderate (3-6 mm) in 8 subjects and severe (>6 mm) in 3 subjects, and 2 patients had minor spacing. Overbites were deep in 13 subjects, but those with normal overbite (4) and anterior open bite (3) were also included. The study protocol was approved by the Institutional Review Board of Saint Louis University (number 27561). All patients received Invisalign treatment in the Department of Orthodontics at Saint Louis University or a private practice under the supervision of the same orthodontist (●●●), who is an Invisalign elite provider. The orthodontist planned all the ClinChecks according to his preferences with no restrictions on attachment placement. Aligners were changed every 2 weeks. Average treatment time was 12 months (±2.5 months). All patients started treatment in 2014 or later, after Invisalign introduced the SmartTrack material. Inclusion criteria were predefined as follows: (1) all patients received treatment in both arches, (2) all participants successfully completed an initial series of aligners and then had a "refinement" phase, because the treatment goals were not reached, (3) patient charts indicated good compliance with consistent aligner wear, (4) minimal movement of the molars in all 3 planes was planned, and (5) treatment started in 2014 or later. Exclusion criteria were (1) noncompletion of the initial series of aligners, (2) poor compliance, (3) dental restorations before refinement, (4) posterior crossbite, and (5) missing first or second molars.

Twenty-nine potential subjects were identified after searching the university's and the private orthodontist's accounts on the Invisalign doctor Web site. After review of patients' charts, 20 patients met the inclusion and exclusion criteria. Despite minimal planned movement of the molars, superimpositions of the initial and achieved models showed that the intermolar width changed by 0.81 mm (±0.57 mm) on average.

Records were gathered from the Invisalign doctor Web site. Digital models were exported from ClinCheck as stereolithography files. The initial and final models from the first ClinCheck were labelled as "initial" and "predicted." The initial models of the refinement ClinCheck were labelled as "achieved," since they depicted the actual result after aligner wear.[8]

Initial, predicted, and achieved digital models were imported in SlicerCMF (open-source, version 3.1; http://www.slicer.org). The predicted and achieved models were superimposed over the initial ones with regional superimpositions on molars that appeared relatively stable in ClinCheck. The central pits of the first and second molars were traced, and an area of equal radius around them was selected. The regions of interest were limited to the occlusal surfaces if there were attachments (Fig 1), or otherwise the whole crown was selected. Maxillary and mandibular arches were superimposed and measured separately.

Measurements were made on the initial vs predicted and initial vs achieved models to identify the magnitude and direction of the predicted and achieved movements. Predicted and achieved models were not superimposed on each other. The total number of teeth measured was 398. For every subject, 100 measurements were made (50 predicted and 50 achieved movements) for horizontal movements, vertical movements, rotations, and transverse changes as follows.

1. Horizontal displacements (parallel to the occlusal plane) were measured with the ruler tool at the middle of the incisal edges or cusp tips when the models were viewed directly from the occlusal view (Fig 2).
2. Vertical displacements were measured at the middle of the incisal edges or cusp tips (Fig 2).
3. Intercanine and interpremolar widths were measured at the canine cusp tips and the central grooves or central fossae (depending on the anatomic variation) of the second premolars (Fig 3).
4. Mesiodistal rotations were measured by tracing 2 points on the incisal edges of the incisors: the most mesial and most distal points of the canines and the labial and lingual cusp tips of the premolars. The 2 points were connected on each model with a straight line, and then the angle (yaw) between the lines was measured on the horizontal plane (Fig 4).