

# Has Invisalign improved? A prospective follow-up study on the efficacy of tooth movement with Invisalign

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**Introduction:** The purpose of this research was to provide an update on the accuracy of tooth movement with Invisalign (Align Technology, Santa Clara, Calif). **Methods:** This prospective clinical study included 38 patients treated with Invisalign Full or Invisalign Teen. All teeth, from the central incisor to the second molar, were measured on digital models created from intraoral scans. Predicted values were determined by superimposing the initial and final ClinCheck models, and achieved values were determined by superimposing the initial ClinCheck models and the digital models from the posttreatment scans. Individual teeth were superimposed with a best-fit analysis and measured using Compare software (version 8.1; GeoDigm, Falcon Heights, Minn). The types of tooth movements studied were a mesial-distal crown tip, buccal-lingual crown tip, extrusion, intrusion, and mesial-distal rotation. **Results:** The mean accuracy of Invisalign for all tooth movements was 50%. The highest overall accuracy was achieved with a buccal-lingual crown tip (56%), whereas the lowest overall accuracy occurred with rotation (46%). The accuracies for mesial rotation of the mandibular first molar (28%), distal rotation of the maxillary canine (37%), and intrusion of the mandibular incisors (35%) were particularly low. **Conclusions:** There was a marked improvement in the overall accuracy; however, the strengths and weaknesses of tooth movement with Invisalign remained relatively the same. (*Am J Orthod Dentofacial Orthop* 2020; ■: ■-■)

In 2009, Kravitz et al<sup>1</sup> conducted the first prospective clinical study on Invisalign (Align Technology, Santa Clara, Calif) to evaluate its efficacy. Prior published data included case reports, material studies, technical articles, editorials, surveys, studies comparing Invisalign to conventional fixed appliances, and a systematic review, none of which provided scientific evidence regarding the efficacy or limitations of Invisalign.<sup>2-23</sup> Ten years after Invisalign was introduced, orthodontists were just beginning to quantify how well it moved teeth.

The landmark study by Kravitz et al<sup>1</sup> evaluated the accuracy of anterior tooth movements with Invisalign. Measurements were made by superimposing the predicted and achieved ClinCheck digital models over

the stationary premolars and molars, using ToothMeasure, Align's tooth measurement software.<sup>24</sup> The most accurate movement was lingual constriction (47%), and the least accurate movements were incisor extrusion (18%) and mandibular canine rotation (28%). The overall mean accuracy of Invisalign was 41%.

In a second study, using the same sample and methodology, Kravitz et al<sup>25</sup> specifically evaluated the influence of interproximal reduction (IPR) and ellipsoid attachments on canine rotation. The mean accuracy of this rotation with Invisalign was 36%. The authors reported that canines which received IPR achieved the highest accuracy (43%). Most importantly, the accuracy of canine rotation significantly dropped with rotational movements greater than 15°.

Since these 2 studies were published, significant contributions have been made, further evaluating the efficacy of tooth movement with Invisalign.

In 2012, Krieger et al<sup>26</sup> also evaluated anterior tooth position with Invisalign, but they studied different parameters. Rather than assessing individual tooth movements, the authors evaluated arch length, intercanine distance, overbite, overjet, and midlines by comparing initial and final plaster casts, which were measured with digital calipers. They provided a general

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conclusion that Invisalign effectively resolved anterior crowding by incisor proclination, but overbite correction was difficult to achieve.

In 2014, Simon et al<sup>27</sup> evaluated the influence of attachments and power ridges with Invisalign for 3 specific movements: incisor torque, premolar rotation, and maxillary molar distalization. Predicted digital models were superimposed over achieved digitized plaster models, using Surfacr software. The least accurate movement was premolar rotation (40%). Similar to the findings by Kravitz et al,<sup>25</sup> this accuracy significantly decreased with rotational movements greater than 15°.

In 2017, Grünheid et al<sup>28</sup> evaluated the efficacy of tooth movement with Invisalign for all teeth. The predicted and achieved digital models were superimposed with a best-fit registration, using Compare software (version 8.1; GeoDigm, Falcon Heights, Minn). Although the percent accuracy was not calculated, the movements that had the greatest difference between predicted and achieved outcomes were molar torque, mandibular incisor intrusion, and mandibular lateral, canine, and first premolar rotation.

In 2018, Charalampakis et al<sup>29</sup> evaluated the efficacy of incisor, canine, and premolar movements with Invisalign. The predicted and achieved ClinCheck models were superimposed over stationary first and second molars, using SlicerCFM software. Similar to the findings by Grünheid et al,<sup>28</sup> the least accurate movements were mandibular incisor intrusion, followed by a rotation of the maxillary canines, mandibular premolars, and mandibular canines.

Since the publication of the 2009 studies,<sup>1,25</sup> the Invisalign system has undergone significant changes. The 2 most notable are the introduction of SmartForce features (2008), such as optimized attachments, pressure zones, and customized staging, and the SmartTrack aligner material (2011), which allows for a better range of force delivery and fit. In addition, physical impressions have been largely replaced by digital scans. The purpose of this prospective clinical study is to provide an update on the accuracy of Invisalign with newer technology.

## MATERIAL AND METHODS

The study group comprised 38 patients (13 males, 25 females) with a mean age of 36 years. Twenty-nine patients received Invisalign Full and 9 received Invisalign Teen. The mean number of aligners per arch was 21 maxillary and 20 mandibular. Both arches each averaged 6 attachments and less than 1 mm of IPR. The breakdown of malocclusions was as follows: 22 Class I, 13 Class II, and 3 Class III. The average time between the initial and final scans was 8.5 months (Table I).

**Table I.** Sample demographics

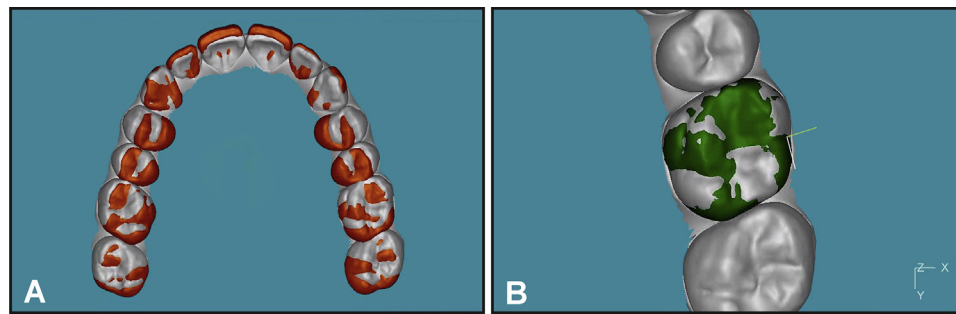
Category	n
Patients	
Male	13
Female	25
Malocclusion	
Class I	22
Class II	13
Class III	3
Type of Invisalign	
Invisalign Full	29
Invisalign Teen	9
Average number of aligners	
Maxillary	21
Mandibular	20
Frequency of attachments	
Maxillary	6
Mandibular	6
Average amount of IPR, mm	
Maxillary	<1
Mandibular	<1

The research protocol was approved by the Institutional Review Board of European University College (no. EUC-IRB-17.2.11). Invisalign treatment was provided at a single orthodontic practice in South Riding, Virginia, and the orthodontist (N.D.K.), who prescribed all ClinCheck treatment plans, was highly experienced (Tier-Level Diamond Plus Provider [formerly Top 1% Elite] with over 2500 Invisalign cases treated). Unlike the 2009 study,<sup>1</sup> overengineering of tooth moments was prescribed when deemed necessary to achieve the best result clinically.

The patients were instructed to wear their aligners for 22 hours per day and change their aligners every 10 days. At the delivery appointment, the patients understood that they were part of a research study, and honest reporting of their compliance was critical. Compliance was also verbally confirmed at each appointment. The last data collection was in November 2017.

Inclusion criteria were as follows: (1) treated with either Invisalign Full or Invisalign Teen, (2) underwent treatment in both arches, (3) completed an initial and final intraoral digital scan, and (4) confirmed good compliance throughout treatment. Exclusion criteria were as follows: (1) noncompletion in time for the study, (2) poor compliance with the aligners, and (3) oral surgery or dental restorations before the final scan. A total of 44 patients were enrolled in the study but 6 were excluded; 3 patients did not complete their treatment in time for data collection, and 3 patients had errors in their final scans.

The digital models were deidentified and imported into Compare, a tooth measurement software program.



**Fig. A,** Determining the achieved values. Global alignment of initial ClinCheck model (*orange*) over the posttreatment model (*white*). **B,** Superimposition of a segmented tooth from the initial ClinCheck model (*green*) over the unsegmented posttreatment model (*white*) using a best-fit surface registration.

All teeth in the arch were evaluated. The total number of teeth measured was 899 (450 maxillary and 449 mandibular), which was more than twice as many as the 2009 study.<sup>1</sup> The digital models were evaluated following the protocol established by Grünheid et al.<sup>28</sup>

The initial ClinCheck model was segmented into individual teeth. To provide the predicted values, we globally aligned the initial ClinCheck model over the final ClinCheck model. Then the individual teeth from the initial model were superimposed over the equivalent teeth of the final model, using a best-fit algorithm. To provide the achieved values, we superimposed the individual teeth from the initial ClinCheck model on the digital model from the posttreatment scan (Figs, A and B).

The tooth movements measured were mesial-distal crown tip, buccal-lingual crown tip, intrusion, extrusion, and rotation. Although the software measured “torque,” in the absence of radiographs, this movement could not be confirmed and was excluded from this study. The percent accuracy was determined by the following equation: percentage of accuracy =  $100\% - \left( \frac{\text{predicted} - \text{achieved}}{\text{predicted}} \right) \times 100\%$ . The equation accounted for directionality and ensured that the percentage of accuracy never exceeded 100% for teeth that achieved movements beyond their predicted value.<sup>1</sup>

To evaluate the clinical relevance of our results, we printed and assessed the posttreatment scans of half the sample (19 patients), according to the American Board of Orthodontics (ABO) cast evaluation system.<sup>30</sup> Patients were randomly chosen using research randomizer software. Following the protocol of the 2009 study,<sup>1</sup> a modified-Discrepancy Index of the pretreatment malocclusion was calculated, excluding for cephalometrics and skeletal asymmetry scores. The posttreatment ABO scores were calculated by 2 operators; subsequently, 10 models were remeasured by the same examiner to assess intraoperator reliability.

### Statistical analysis

The statistical analysis was performed with SPSS software (version 15; IBM, Armonk, NY). Each tooth movement was measured separately. Clinical significance was set for linear movements at  $<0.25$  mm and angular movements at  $<2^\circ$ , which is approximately the amount of maximum movement on a tooth per aligner. Paired *t* tests ( $P < 0.05$ ) compared the intraarch accuracy of tooth movement by direction (ie, buccal versus lingual), and independent *t* tests compared the accuracy of tooth movement by arch (ie, maxillary vs mandibular).

### RESULTS

All predicted linear and angular movements less than 0.1 mm and  $1.0^\circ$  were eliminated from analysis to account for error in model superimposition. Acceptable sample sizes were attained for all tooth movements, except for the lingual crown tip of the maxillary first molar ( $n = 6$ ), first premolar ( $n = 3$ ) and second premolar ( $n = 7$ ), as well as the intrusion of mandibular second premolar ( $n = 8$ ).

The mean accuracy of Invisalign for all tooth movements was 50%. The highest overall accuracy was achieved with a buccal-lingual crown tip (56%). The lowest overall accuracy occurred with rotation (46%). Specifically, the most accurate movement was the labial crown tip of the maxillary lateral incisor (70%), and the least accurate movements were the mesial rotation of the mandibular first molar (28%), followed by intrusion of the maxillary (33%) and mandibular central incisors (34%) (Table II).

With regards to directionality, mesial rotation of the maxillary canine (52%) was significantly more accurate than distal rotation (37%), the lingual crown tip of the maxillary second molar (61%) was significantly more accurate than the buccal crown tip (35%), extrusion of

**Table II.** Percentage of accuracy of tooth movements

Tooth	Mesial		Distal		Buccal		Lingual		Intrusion		Extrusion		Mesial rotation		Distal rotation	
	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min
Central incisor	57.5	47.8	49.8	45.5	54.2	52.8	57.4	64.0	33.4	33.9	56.4*	44.5	61.1	51.3	54.9	43.1
Lateral incisor	47.3	38.5	47.3	51.5	69.9	61.4	54.4	57.4	44.6	36.7	53.7	47.1	54.6	52.6	48.7	41.8
Canine	52.5	53.7	43.8	47.5	58.8	67.9	57.6	54.8	53.3	51.3	42.2	50.6	51.5*	55.2	37.2	45.8
First premolar	43.3	45.4	57.1	57.2	66.3	61.1	56.5	57.9	48.4	63.1	51.3	44.5	50.9	43.1	50.0	47.9
Second premolar	64.7	53.6	54.2	62.5	60.5	69.7 <sup>†</sup>	51.8	51.8	45.5	56.1	38.3	52.5	39.2	44.8	44.7	49.8
First molar	47.8	52.6	58.4	59.2	58.3	53.6	47.2	48.0	35.1	41.2	37.6	45.2	42.9	27.8	43.2	35.4
Second molar	55.4	50.2	62.9 <sup>†</sup>	50.4	34.8	36.4	61.3*	46.0	50.3	51.3*	41.5	37.1	42.5	40.4	40.7	33.6
Total	52.7	48.8	53.4	53.4	57.6	57.6	55.2	54.3	44.4	47.7	45.9	45.9	49.0	45.0	45.6	42.5

\*Statistically significant difference in directionality; <sup>†</sup>Statistically significant difference between arches.

the maxillary central incisor (56%) was significantly more accurate than intrusion (33%), and intrusion of the mandibular second molar (51%) was significantly more accurate than extrusion (37%).

With regards to accuracy between arches, the distal crown tip of the maxillary second molar (63%) was significantly more accurate than the mandibular second molar (50%), and the buccal crown tip of the mandibular second premolar (70%) was significantly more accurate than the maxillary second premolar (61%). Overall, there was little difference in accuracy between maxillary and mandibular teeth, which was also found in the 2009 study.<sup>1</sup>

The modified-Discrepancy Index score for the randomly chosen sample was 17. When the posttreatment intraoral scans were 3-dimensional-printed and graded using the ABO cast evaluation system, 74% (14 of 19) achieved a passing score.

## DISCUSSION

In the 2009 study by Kravitz et al<sup>1</sup> evaluating the efficacy of anterior tooth movement with Invisalign, the authors reported an overall mean accuracy of 41%. The most accurate tooth movement was lingual constriction, whereas the least accurate tooth movements were incisor extrusion, followed by a mandibular canine rotation. Our current study aimed to determine whether the accuracy of Invisalign had improved with newer technology and greater operator experience.

In our study, the mean accuracy of Invisalign for all tooth movements was 50%. This finding is a notable increase from the 2009 study,<sup>1</sup> but even more remarkable considering that the posterior teeth were included, and the tooth movements were more extensive. Despite its improved accuracy, the strengths and weaknesses of tooth movement with Invisalign remained relatively the same.

The most accurate tooth movement was the buccal-lingual crown tip (56%). These results are logical, given

that the aligner material primarily flexes in a buccal-lingual direction. Furthermore, aligners move teeth by pushing, and the buccal and lingual aspects of the crown provide the largest surface area to push. The improved accuracy in incisor buccal crown tip could be attributed to the more flexible SmartForce aligner material, as well as the power ridges, which were used in 71% of the sample. However, the second molars struggled with buccal crown tip (36%), likely because of poor aligner grip around the shorter terminal crown and the decreased forces on the terminal tooth within the aligner.

The least accurate tooth movement was rotation (46%), and this movement was particularly challenging for canines, premolars, and molars. Similar findings were observed by Simon et al<sup>27</sup> and Charalampakis et al.<sup>29</sup> Although the SmartTrack features automatically placed optimized attachments for rotational movements greater than 5°, rounded teeth still struggled to grip the aligners. Despite the relatively low accuracy of rotation, its improvement for the maxillary incisors and canines is encouraging.

Interestingly, the direction of rotation influenced the accuracy of the maxillary canine. Distal rotation (37%) was significantly less accurate than mesial rotation (52%). In 2009, Kravitz et al<sup>25</sup> reported that IPR improved the accuracy of canine rotation and theorized that interproximal contact or binding was a major determinant for nontracking. Our results appear to provide some support. The larger distal contact area and the mechanical challenges of providing IPR on the distal aspect of the maxillary canine could explain the lower accuracy.

One of the most promising findings of this study was the improvement in the accuracy of maxillary incisor extrusion. In the 2009 study,<sup>1</sup> extrusive movement of the incisors had the lowest accuracy. The authors advocated combining extrusion with more predictable movements such as lingual crown tip, which they termed *relative extrusion* (resultant extrusion), in contrast to

true extrusion in a vertical plane. A plausible explanation for the improvement in our study may be from the use of optimized extrusion attachments. Extrusion of the maxillary incisors (55%) had the highest accuracy, whereas extrusion of the maxillary and mandibular molars (40%) had the lowest accuracy.

By contrast, incisor intrusion remained a challenge and did not improve from the 2009 study, even with the G5 enhancements. The low accuracy of mandibular incisor intrusion (35%) was similar to the results reported by Grünheid et al<sup>28</sup> and Charalampakis et al.<sup>29</sup> One explanation for the lower accuracy of mandibular incisor intrusion may be the lack of posterior anchorage. According to the SmartForce protocol, anchorage (or aligner lift off) is near the last consideration for the software. In contrast, the accuracy of second molar intrusion (51%) was relatively high.

The higher accuracy of incisor extrusion and molar intrusion and low accuracy of incisor intrusion and molar extrusion suggests that Invisalign is more effective in bite closure, rather than bite opening. Khosravi et al<sup>31</sup> reported that only 1.5 mm of overbite improvement could be expected with Invisalign, which is half of the amount typically achieved with fixed appliances. Perhaps deepbite malocclusions that require true mandibular intrusion and posterior extrusion would benefit from “hybrid mechanics” of maxillary Invisalign with mandibular fixed appliances. Nonetheless, when the results of this study were evaluated to determine their clinical significance, 74% of randomly chosen patients had passing ABO scores. This relatively high percentage is encouraging when interpreting the results of the study. In the 2009 study,<sup>1</sup> pretreatment overjet significantly affected the accuracy of the labial-lingual movement. Our results showed a higher accuracy of individual tooth movement despite treating cases of greater complexity. Undoubtedly, the Invisalign system is improving.

The primary limitation with any study using predicted digital models is that ClinCheck is merely a graphic depiction of force systems, rather than a predictor of final tooth position.<sup>32</sup> In other words, the prescribed final tooth position on ClinCheck may not be the desired final tooth position. For example, mandibular incisor intrusion achieved a relatively low accuracy, but likely received the greatest amount of overengineering. Therefore, a 50% accuracy of predicted tooth movement does not mean 50% effective from a clinical perspective.

Other notable limitations include those that rely on patient compliance, such as wearing the aligners as prescribed and using intraoral elastics as instructed, not to mention the inaccuracies associated with patient

self-reporting. There are also doctor-associated limitations because of inaccuracies and imprecision when placing attachments and performing IPR.

Finally, there is tremendous variation and general disagreement on attachment design, tooth-movement sequencing, and extent of overengineering programmed into ClinCheck plans among orthodontists. This study relies on clinical decisions by one orthodontic provider.

## CONCLUSIONS

1. The overall mean accuracy of Invisalign was 50%. Although this was a marked improvement from the 2009 study, the strengths and weaknesses of tooth movement with Invisalign remained relatively the same.
2. The highest accuracy was achieved with a buccal-lingual crown tip (56%).
3. The lowest accuracy occurred with rotation (46%), and this movement was difficult for the canines, premolars, and molars.
4. Maxillary incisor extrusion improved, but incisor intrusion remained a challenge.
5. The percent accuracy determined by a best-fit analysis on a predicted ClinCheck digital model may underestimate the product's overall clinical efficacy.
6. As such, the actual number of 50% accuracy may be less important than the confirmation that the Invisalign appliance is improving but still struggles with specific types of tooth movements.

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