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Review Article

Treatment Efficacy of Invisalign: Literature Review Update

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Purpose: Inconsistency between computer prediction and actual tooth movement in Invisalign treatment always limits clinical judgment. The objective of this review was to update the evidence on the treatment efficacy of the Invisalign appliance.

Material and Methods: Medical databases were screened for relevant peer-reviewed articles from 2000 to 2018 for the use of Invisalign as a treatment intervention. All human studies other than case reports and case series were included.

Results: A total of 25 articles (4 RCTs, 6 prospective cohort studies, 15 retrospective cohort studies) were included. Treatment outcomes have been improving over the past 17 years. Invisalign treatment achieved results comparable with those of fixed appliances in extraction cases, except for buccolingual inclination ($p<0.005$) and occlusal contacts ($p<0.001$). For specific tooth movement, the highest accuracy was for arch expansion (upper: 72.8%, lower: 87.7%) and molar distalization (87%). Rotation of rounded tooth and overbite control with aligners was unpredictable.

Conclusions: Invisalign treatment for controlling buccolingual inclination and occlusal contacts were less than ideal. None of the tooth movement was completely in line with predictions. Auxiliary or revised prescription may be needed to achieve high-quality results. Because the material, treatment design, and evaluation methods differ among studies, results should be interpreted carefully. ***(Taiwanese Journal of Orthodontics. 32(2): 68-78, 2020)***

Keywords: Invisalign; treatment efficacy; aligners

Nowadays, patients seeking orthodontic treatment want not only high-quality results as planned, but also a comfortable and esthetic treatment experience. Using fixed appliances can achieve treatment goals and fulfill patients' needs, but gum irritation and the difficulty of oral hygiene care invariably become inconvenient for patients

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and doctors. Transparent and movable appliances have been strongly promoted since Align Technology (Santa Clara, CA, USA) introduced the Invisalign system into the market in 1999 and the name of this product has since became synonymous with the technique. Using digital models derived from polyvinylsiloxane impressions or oral scanning allows computer-simulated treatment planning, which includes setting the treatment goal and designing the staging and auxiliary features. For each stage of tooth movement, a series of clear, plastic aligners are fabricated and used on compliant patients to perform the programmed tooth movement.

Lagravère et al.[1] conducted the first systematic review in 2005, and only two articles were included, with no conclusion regarding the treatment indications and limitations. In 2014, Rossini et al.[2] reviewed 11 articles and concluded that the aligner is effective in controlling anterior intrusion, posterior buccolingual inclination, and upper molar bodily movements; conversely, the aligner was ineffective in controlling anterior extrusion, anterior buccolingual inclination, and rotation of rounded teeth.

Aligner therapy has become increasingly popular, and additional studies on its treatment outcomes have been reported in recent years. Therefore the objective of this review was to update the evidence on the efficacy of Invisalign.

MATERIALS AND METHODS

Eligibility criteria

According to previous systematic reviews, articles related to our research question have been limited. Therefore, randomized controlled trials (RCTs), observational studies, and any other study design, except case reports and case series, were included in this review to expand the research materials (Table 1). All of the studies had to have focused on Invisalign appliances and evaluated the tooth movement or treatment results quantitatively.

Table 1. *Eligibility criteria for article selection.*

Inclusion criteria	Exclusion criteria
Clinical human studies Study population of all ages Use of Invisalign as a treatment intervention	Treatment combined with orthognathic surgery Patients with genetic syndrome/facial deformities/ periodontitis Case reports/case series Review articles No full text available Non-peer-reviewed articles

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Information sources, search strategy, and study selection

A systematic search of medical databases and Google Scholar was conducted on July 31, 2018. The search strategy listed in Table 2 was employed by the first author (M.H.T.) to retrieve the available peer-reviewed articles between January 2000 and July 2018. Medical subject headings were used in Medline (Ovid) to achieve the same search strategy as the other databases. Google Scholar cannot recognize truncation symbols, and the search modality is also different from medical databases, and therefore different key words were used in Google Scholar.

The title and abstract of retrieved records were imported into reference management software (Endnote X8, Clarivate Analytics, Philadelphia, PA, USA). After deduplication, references were screened and assessed in accordance with the inclusion and exclusion criteria.

Risk of bias in individual studies

The risk of bias of observational studies was assessed using questions extracted from the Research Triangle Institute item bank.[3] Twenty-nine questions in 11 domains developed for evaluating observational studies were customized to obtain 11 items, which were applied in this review. The responses to each question were yes, no, partial, cannot determine, and not applicable. Cannot determine and partial were considered to indicate an unclear risk of bias. Overall bias in an individual study was covered in the last question of the assessment, and a study with more than one item rated as unclear or high risk could not be rated as having a low risk of bias. RCTs were evaluated using Risk of Bias 2.0 which was developed for randomized trials.[4] The scoring process was completed by two investigators (M.H.T. and S.H.C.) independently, and any conflict was discussed with the other authors to reach consensus.

Table 2. *Search strategies.*

Database	Search strategy
PubMed/Scopus/Embase Medline/Cochrane Library	(orthodont* OR Clear OR sequential removable) aligner* OR Invisalign and (effect* OR effic* OR outcom* OR Predict* OR tooth movemen*)
Google Scholar	(Invisalign efficacy outcome)

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RESULTS

Study selection and characteristics

After the abstracts and full texts were reviewed, 25 articles (4 RCTs, 6 prospective cohort studies, 15 retrospective cohort studies) were identified for inclusion in the review.

The studies we retrieved showed high heterogeneity, including three studies on treatment efficacy with different aligner stiffnesses and wearing protocols[5-7], six studies comparing Invisalign treatment with fixed appliances,[8-13] nine studies comparing actual tooth movement with predictions,[14-22] two studies on outcomes with different treatment strategies,[23, 24] three retrospective studies on the treatment effects of Invisalign,[25-27] and two studies on treatment efficacy in patients with different amounts of crowding or overbite.[28, 29] The comparison group and outcome measures of each study were also varied which were summarized in Table 3 and Table 4. Most of the studies in our review offered insufficient information on the intervention.

Risk of bias of studies

The risk of bias assessment for observational studies is summarized in Figure 1 and details of the evaluation are shown in Supplemental Table 1. Because of the retrospective nature of more than half of the studies (15 studies, 71.4%), one-arm study design (13 studies, 61.9%), and unclear description of the treatment details (18 studies, 85.7%), more than 90% of the articles showed partial or high risk of overall bias. For the RCTs, the assessment results are shown in Table 5, with four studies also raising concerns about the risk of bias.

Table 3. *Comparison group of each study in the review.*

Comparison	Number of studies
Invisalign treatment with fixed appliances	6[8-13]
Actual tooth movement with predictions	9[14-22]
Outcomes of different treatment strategies	2[23, 24]
Before and after study of Invisalign treatment	8[5-7, 25-29]

Table 4. *Outcome measures of each study in the review.*

Outcome measures	Number of studies
Measurements of various OTM from digital/ plaster models	6[14-16, 20, 22, 23]
ABO-OGS/ PAR changes	7[5, 6, 8, 10, 13, 18, 25]
Inclination changes measured from X-ray, CT, or models	5[7, 11, 12, 17, 28]
Arch width changes measured from digital/ plaster models	5[9, 11, 19, 21, 28]
Cephalometrical changes of arch distalization	2[24, 26]
Cephalometrical changes in vertical dimension	2[27, 29]

ABO-OGS: American Board of Orthodontics Objective Grading System
PAR: Peer Assessment Rating

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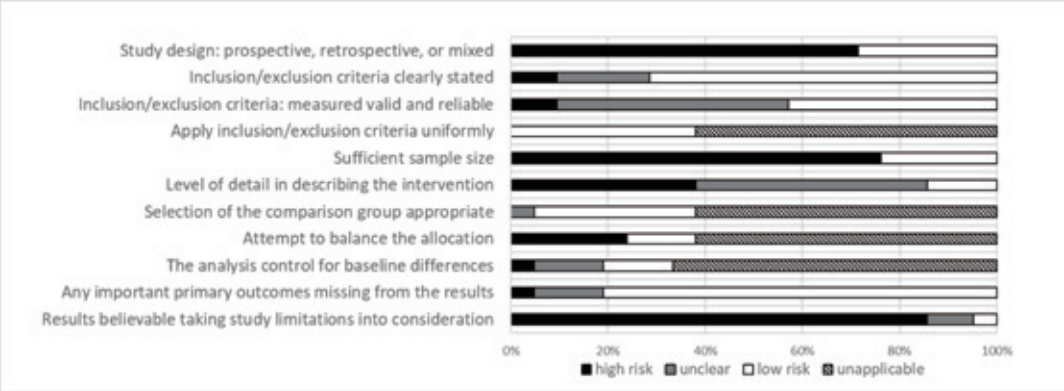

Figure 1. *Risk of bias summarized for the observational studies.*

Table 5. *Risk of bias summerized for randomised clinical trials.*

	Bias arising from the ramdomizati onprocess	Bias due to deviations from intended interventions	Bias due to missing outcome data	Bias in measurement of the outcome	Bias in selection of the reported results	Overall bias
Bollen et al. [5]	?	?	-	-	-	?
Clements et al. [6]	?	?	-	-	-	?
Li et al. [10]	-	?	-	-	-	?
Hennessy et al. [12]	-	?	-	-	?	?

+: high risk; -: low risk; ?: some concern

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Supplemental Table 1. *Customized Research Triangle Institute item bank evaluation for observational studies.*

Reference	Year	Domains and question number in each domain										
		A.	B.				C.	D.		E.	F.	G.
		1	2.	3.	4.	6.	7.	9.	10.	20.	24.	28
Djeu et al. [8]	2005	+	?	?	-	-	?	-	-	-	-	+
Baldwin et al. [7]	2008	-	-	?	/	+	?	/	/	/	-	+
Kravitz et al. [14]	2008	-	?	?	-	+	-	-	+	+	-	+
Kravitz et al. [15]	2009	-	-	-	/	-	-	/	/	/	-	-
Pavoni et al. [9]	2011	-	-	-	-	+	+	-	+	?	?	+
Krieger et al. [16]	2012	+	-	-	/	+	?	/	/	/	-	+
Castroflorio et al. [17]	2013	-	?	+	/	+	+	/	/	/	+	+
Kassas et al. [25]	2013	+	?	-	/	+	+	/	/	/	-	+
Simon et al. [23]	2014	+	-	-	/	+	?	-	+	/	-	+
Buschang et al. [18]	2015	+	+	+	/	+	+	/	/	/	-	+
Duncan et al. [28]	2016	+	-	?	-	+	+	-	-	-	-	+
Garino et al. [24]	2016	-	-	-	-	+	?	-	-	-	?	+
Ravera et al. [26]	2016	+	-	-	/	+	?	/	/	/	?	+
Grünheid et al. [11]	2016	+	+	?	-	+	+	?	+	?	-	+
Solano-Mendoza et al. [19]	2017	+	-	?	-	+	?	/	/	/	-	+
Charalampakis et al. [22]	2017	+	-	-	/	+	?	/	/	/	-	+
Grünheid et al. [20]	2017	+	-	?	/	+	?	/	/	/	-	+
Houle et al. [21]	2017	+	-	?	/	-	-	/	/	/	-	?
Khosravi et al. [29]	2017	+	-	?	/	+	?	/	/	/	-	+
Gu et al. [13]	2017	+	-	?	-	-	+	-	+	?	-	+
Moshiri et al. [27]	2017	+	-	-	/	-	+	/	/	/	-	?

+: high risk; -: low risk; ?: unclear/partial risk; /: not applicable

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DISCUSSION

Lack of consensus in most research protocols reflects the rapid advancement of materials and biomechanical features of appliance designs. In 2008, Align Technology introduced the first force-driven feature, the Power Ridge, which is a small deformation on the aligner for generating moments on incisors. Several other features have been subsequently announced, including optimized attachments and specific treatment protocols. The previous aligner material EX30 has also been replaced by SmartTrack. The study results associated with previous features may not be suitable for direct application to current patients. For example, the patients included in the overbite study of Khosravi et al. started treatment before the G5 protocol (Invisalign protocol for deep bite) was implemented and the SmartTrack material was released.[29] Hence, the ability for overbite to be controlled using new features remains unclear.

General outcome

Early studies showed low completion rate, poor root control, and even severe dental tipping in extraction cases with Invisalign appliance.[5-7] For non-extraction cases, Kassas et al. showed significant improvements in alignment and buccolingual inclination after treatment. However, the control of overjet, occlusal relations, buccolingual inclination, and occlusal contacts was still less than that achieved by fixed appliances ($p<0.05$).[8]

The studies conducted after SmartForce features were introduced showed similar outcome; less control of overjet, overbite, occlusal relationship, buccolingual inclination, and occlusal contacts compared to fixed appliances.[10, 13] However, in the extraction study of Li et al., they found that with well-designed attachment placement and treatment protocol, root control at the extraction site can be as good as that of fixed appliances.

Efficacy of various types of orthodontic tooth movement (OTM)

Treatment did not follow the tooth movement predicted in ClinCheck.[18] Therefore, many studies evaluated the accuracy of different types of OTM. Certain OTM should be planned with what appears as overcorrecting in ClinCheck as a biomechanical force plan.[30] Otherwise, accessories may be needed to achieve the desired outcome.

Non-extraction cases constituted the majority of the subjects in the collected samples of all types of aligner research. Therefore, the distance of each OTM was limited. Grünheid et al. generally evaluated the accuracy of different types of OTM of each tooth and found that rotation of rounded tooth, intrusion of anterior teeth and the movements of posterior teeth were not fully achieved.[20] Charalampakis et al. found that intrusion of incisors and rotation of canines were the most inaccurate OTM.[22] These findings were, to some extent, inconsistent with the accuracy study of Kraviz et al..[15] The differences in attachments and aligner material used, superimposition methods, and target teeth between these studies may have contributed to the inconsistency.

Rotation

Rotation, a challenging movement with Invisalign,[31, 32] was also the first type of OTM examined. Creating a space with IPR for the rotated tooth may play a critical role.[14] Vertically placed ellipsoid attachments only offer modest improvements in rotational accuracy. Simon et al. found that the accuracy of premolar de-rotation with optimized rotation attachment was even lower (37.5%).[23] These findings should be interpreted carefully. Sampling bias was present in the study conducted by Kravitz et al.; more severe tooth rotation (greater than 5°) was observed in the attachment group (15 out of 17 cases) than in the IPR (12 out of 18 cases) and control groups (2 out of 18 cases).[14] The results of Simon et al. were due to poor patient compliance; if outliers are excluded, the mean accuracy of the attachment group was 47.3%. This finding also reveals that attachment may interact with an unfitted aligner to generate an unwanted force system and worse

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rotation. The crown shape, severity of rotation, and the amount of correction per aligner also affect the treatment accuracy.[15, 20, 23]

Root torque

The accuracy of incisor lingual root torque was approximately 50%.[23] PowerRidge showed no significant advantage over horizontal ellipsoid attachment. Castroflorio et al. claimed that aligners could provide greater root control than fixed appliances.[17] However, all of the cases in this study had planned lingual crown tipping, not lingual root torque, and therefore the conclusions should be considered cautiously. For posterior teeth, torque control in molars can be compromised, which may be due to the smaller force generated by the aligner in this area and the larger roots of the molars.[20]

Distalization/ Arch expansion

The accuracy of these types of OTM was relatively high, and both were useful alternatives to resolve mild crowding with Invisalign appliance.[21, 23] Duncan et al. reviewed their cases, showed significant arch expansion in majority of patients. For more crowded cases (>6 mm), Invisalign treatment was more likely to procline the incisors.[28]

In the study of Simon et al., the linear accuracy of molar distalization was around 87%; the attachments provide mild benefit to the accuracy (NS).[23] Garino et al. further examined two different attachment design and found that when vertical rectangular attachments were applied from the canines to second molars, distalization was achieved almost translationally; if the attachments were only applied from the first premolars to first molars, less distal movement of posterior segments ($p<0.05$) and more crown tipping of the first molar occurred.[24, 26] Therefore, designing overcorrection in molar distalization can be considered to achieve desired results. Meanwhile, applied vertical rectangular attachments from the canines to second molars may be beneficial.

For the expansion, moving the cusp tip was more effective than at the gingival margin (tipping movement). The mean accuracy measured from cusp tip was 82.9% in upper arch, and close to 100% in lower arch with tipping movement[19, 21] Therefore, overcorrection in expansion should be used with caution. Over-expansion may jeopardize the periodontal tissue. It should be noted that both the studies of Solano-Mendoza et al. and Houle et al. used the EX30 material, which has been superseded by the SmartTrack material since 2013. To our knowledge, there is no expansion study using new material has been published.

Several studies compared the efficacy of aligners to the fixed appliances in many different aspects, and the results varied. Grünheid et al. showed that aligners tend to increase intercanine distance in lower arch rather than fixed appliances.[11] Hennessy et al. showed no difference in lower incisors proclination produced by two appliances.[12] An earlier study showed better arch expansion with fixed self-ligating brackets.[9] These inconsistent findings may have been due to 1) insufficient information (e.g., the study of Hennessy et al. only evaluated the root axis on cephalograms without linear measurements), and 2) inadequate description of the treatment modality, including the amount of IPR, the movement planned in ClinCheck, and the intention to change the arch form. If the ClinCheck design did not include arch expansion, comparison with a fixed group using a broad archwire cannot be justified.

Overbite control

Several case reports have shown that deep bite cases can be corrected successfully with Invisalign.[33, 34] However, the efficacy of incisor intrusion and overbite control in our review was unpredictable.[15, 16, 20, 22] Khosravi et al. revealed the treatment effect of overbite control and deepbite correction in their cases; molar extrusion and increasing of SN-MP and AFH play a critical role in reducing overbite. Furthermore, proclination of the lower incisors and intrusion of the upper incisors also contributed to the treatment results. These changes may have been due to the bite ramp feature used in this group.

The findings also reflect the connection between the aligner features and treatment results.

For the open bite group, overbite was improved by extrusion of incisors, whereas SN-MP and AFH were maintained. Conversely, Moshiri et al. found that open bite correction was achieved by molar intrusion and incisor extrusion combined with mandible autorotation,[27] and they postulated that the thickness of the aligner material in the posterior region was insufficient to cause molar intrusion; inclusion of intrusion movement in ClinCheck should be requested.

Invisalign treatment incorporates many features and auxiliaries. Moreover, the wearing strategy, overcorrection, staging, patient compliance, and even the combined use of accelerating devices influence the efficacy of aligner treatment. Unfortunately, the articles in our review rarely described the details of the treatment protocol. Future studies investigating more advanced Invisalign features and materials with well-designed protocols are needed to provide more updated information on the efficacy of Invisalign treatment.

CONCLUSION

Twenty-five articles on the treatment efficacy of Invisalign were reviewed. Because most of the studies were retrospective, the results should be interpreted carefully. The study design must be examined in detail to determine the implications of particular treatment protocols and the associated treatment results.

From the available studies, the following conclusions can be drawn:

- With advancements in material, technology, and knowledge, comparable results can be achieved between Invisalign and fixed appliances except for the control of buccolingual inclination and occlusal contacts.
- Treatment accuracy in each type of OTM varied. Careful Clincheck design and the use of accessories are crucial to accomplish difficult OTM.
- Overcorrection in Clincheck design can be considered for certain types of OTM, but over-expansion should be used with caution.

Conflict of interest

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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