ORIGINAL ARTICLE

Outcome assessment of Invisalign and traditional orthodontic treatment compared with the American Board of Orthodontics objective grading system

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Introduction: This treatment-outcome assessment objectively compares Invisalign (Align Technology, Santa Clara, Calif) treatment with braces. **Methods:** This study, a retrospective cohort analysis, was conducted in New York, NY, in 2004. Records from 2 groups of 48 patients (Invisalign and braces groups) were evaluated by using methods from the American Board of Orthodontics Phase III examination. The discrepancy index was used to analyze pretreatment records to control for initial severity of malocclusion. The objective grading system (OGS) was used to systematically grade posttreatment records. Statistical analyses evaluated treatment outcome, duration, and strengths and weaknesses of Invisalign compared with braces. **Results:** The Invisalign group lost 13 OGS points more than the braces group on average, and the OGS passing rate for Invisalign was 27% lower than that for braces. Invisalign scores were consistently lower than braces scores for buccolingual inclination, occlusal contacts, occlusal relationships, and overjet. Invisalign's OGS scores were negatively correlated to initial overjet, occlusion, and buccal posterior crossbite. Invisalign patients finished 4 months sooner than those with fixed appliances on average. $P < .05$ was used to determine statistically significant differences. **Conclusions:** According to the OGS, Invisalign did not treat malocclusions as well as braces in this sample. Invisalign was especially deficient in its ability to correct large anteroposterior discrepancies and occlusal contacts. The strengths of Invisalign were its ability to close spaces and correct anterior rotations and marginal ridge heights. This study might help clinicians to determine which patients are best suited for Invisalign treatment. (Am J Orthod Dentofacial Orthop 2005;128: 292-8)

Since 1999, the Invisalign system (Align Technology, Santa Clara, Calif) has become a popular treatment choice for clinicians because of the esthetics and comfort of the removable clear aligners compared with traditional appliances. With the advent of 3-dimensional graphic imaging and computer-aided design/computer-aided modeling techniques, Align can accurately fabricate numerous aligners to move many teeth with relative precision to provide comprehensive orthodontic treatment. However, few studies have been published that assess the efficacy or the outcome of the treatment.

Align Technology provides guidelines for the types of malocclusion that can be successfully treated with Invisalign. Cases for which Invisalign is indicated include mild to moderate crowding (1-6 mm), mild to moderate spacing (1-6 mm), nonskeletal constricted arches, and relapse after fixed appliance therapy.[1] The manufacturer claims that Invisalign can effectively perform the following orthodontic movements: space closure, alignment after interproximal reduction, dental expansion, flaring, and distalization.[1] Closure of a mandibular incisor extraction site can also be executed successfully. Currently, Invisalign is not generally recommended in treating more complicated malocclusions such as severe deep bite, anteroposterior corrections greater than 2 mm, uprighting severely tipped teeth, or premolar extraction cases.[1] Nevertheless, the case selection criteria of Align Technology are merely guidelines and are not restrictive. Align Technology defers to the clinician's professional judgment in determining how Invisalign can be incorporated into a patient's treatment and rejects only a small percentage of all submitted cases. This underlines the importance of the

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clinician's ability to make a proper diagnosis and offer an appropriate treatment plan.

Insufficient clinical research has been published to adequately assess the effectiveness of Invisalign treatment, leaving some doubt among clinicians about the suitability of the appliances. McNamara and others have stressed the importance of continuing studies to expand the understanding of the appropriateness of Invisalign.[1-3] In particular, there has been a paucity of treatment outcome assessments of Invisalign in case-controlled settings. This lack of research has made it difficult for clinicians to objectively characterize the efficacy of Invisalign relative to standard fixed appliances. The few articles in the literature have mainly been case reports and descriptions of the use of the system.[4-8]

The primary goal of this study was to assess treatment outcomes of the Invisalign system by comparing the results of Invisalign treatment with that of braces. Past studies have not included a control group or used objective methods to characterize pretreatment malocclusions or evaluate posttreatment results. A thorough case-controlled study was desired to shed more light on which patients are best treated with Invisalign and to measure how the severity of the malocclusion affects treatment success.

This study was a retrospective records analysis to determine the treatment results of Invisalign appliances compared with braces. Pretreatment records (diagnostic casts and lateral cephalograms) were analyzed by using the discrepancy index (DI) of the American Board of Orthodontics (ABO) Phase III clinical examination to classify patients by severity of malocclusion. This scoring system allowed comparison of Invisalign treatment and treatment with braces while controlling for case complexity. Posttreatment records (diagnostic casts and panoramic radiographs) were quantitatively scored by using the objective grading system (OGS) of the ABO Phase III clinical examination. Each of the 8 categories of the OGS was measured to analyze the specific strengths and weaknesses of Invisalign treatment relative to traditional fixed appliances. Length of treatment was also compared to characterize the relative efficiencies of the 2 types of appliances.

Designed to enhance the reliability of ABO examiners and give candidates a means to determine the adequacy of finished cases, the OGS is a tool to numerically grade final casts and panoramic radiographs submitted for the Phase III examination.[9] Both the DI and the OGS are reliable and valid tools to measure pretreatment and posttreatment records. Because ABO certification is the highest achievement in orthodontic credentials, using these indexes as prescribed by the ABO was the best method to assess the treatment outcome of Invisalign relative to conventional braces. The data compiled from this study will help orthodontists answer several important questions that have thus far been unresolved.

MATERIAL AND METHODS

The sample for this retrospective cohort study comprised records of patients treated by an ABO-certified orthodontist in New York City. Pretreatment records consisted of initial dental casts and lateral cephalograms. Posttreatment records included final dental casts and panoramic radiographs taken immediately after treatment, so that no time was allowed for settling.

Two groups of nonextraction patients were evaluated: Invisalign and braces. Before data collection, a power index calculation determined that 48 patients would be needed in each group to achieve 80% power. The Invisalign group comprised all completed patients that the orthodontist had treated solely with removable Invisalign appliances. The braces group consisted of an equal number of randomly selected patients who were fully treated with tip-edge fixed appliances (298-804F, TP Orthodontics, LaPorte, Ind).

Pretreatment records were assessed with the DI. As described by the ABO (www.americanboardortho.org), pretreatment study casts and lateral cephalograms were analyzed by measurements in 10 categories to objectively score severity of malocclusion. The DI measurements are overjet, overbite, anterior open bite, lateral open bite, crowding, occlusion, lingual posterior crossbite, buccal posterior crossbite, cephalometrics, and other. Points were awarded for deviations from ideal in each category, and the sum of the points gave the DI score. A DI score of 7-15 is considered mild, 16-24 is moderate, and 25 or greater is severe, in accordance with the ABO discrepancy index guidelines.

Posttreatment study casts and panoramic radiographs were scored by using the OGS. Eight measurements were made for each patient with the ABO gauge, and points were deducted for any discrepancy from ideal as described by the ABO.[9] The measurements of the OGS are alignment, marginal ridges, buccolingual inclination, occlusal contacts, occlusal relations, overjet, interproximal contacts, and root angulation. The number of points lost was totaled to give the OGS score. A case that loses 30 or fewer points generally receives a passing grade for the ABO Phase III examination.

To ensure examiner reliability, 5 Invisalign cases and 5 braces cases were randomly selected and remeasured 2 weeks after data collection. This second set of

measurements was compared with the first data to see whether there was a statistically significant difference between them.

All statistical analyses were performed with SAS software (SAS, Cary, NC). Chi-square tests were used to determine whether there were any differences in distributions between the Invisalign and braces groups with regard to severity of malocclusion and number of OGS passing scores. Wilcoxon 2-sample tests ascertained whether there was a significant difference between the groups with regard to treatment duration, DI categories, DI score, OGS categories, and OGS score. Spearman correlation tests were used to test for relationships between OGS score and severity of malocclusion, and between treatment duration and severity of malocclusion, as determined by the 10 DI categories. Spearman correlation tests were also used to check examiner reliability to determine whether there was a correlation between first and second measurements. An alpha error of 0.05 was used as the level of statistical significance for all analyses.

RESULTS

The discrepancy between the ages of the patients was statistically significant ($P < .0001$). The Invisalign group had an average pretreatment age of 33.6 years (SD 11.8); the mean age for the braces group was 23.7 years (SD 11.0).

The mean DI scores for the groups were similar, and there was no statistically significant difference between them ($P = .9066$). The average DI scores were 18.67 for Invisalign patients and 19.85 for braces patients (Table I). There were no statistically significant differences between the 2 groups for any of the 10 DI categories.

The OGS score and half of the 8 OGS categories had statistically significant differences between the groups. The mean OGS scores were −45.35 for the Invisalign patients and −32.21 for the braces patients ($P < .0001$) (Table II). The 4 OGS categories that had scores with a statistically significant difference between the groups were buccolingual inclination, occlusal contacts, occlusal relationships, and overjet. In these categories, the Invisalign group lost more points than the braces group on average.

For the Invisalign group, there were statistically significant negative correlations between OGS score and 3 DI categories: overjet, occlusion, and buccal posterior crossbite. For the braces group, there were statistically significant negative correlations between OGS scores and overjet, occlusion, and other (Table III).

According to the ABO, a case can lose only 30 or fewer points to receive a passing grade. In the Invisalign group, 10 cases received passing grades, and 38 received failing grades. In the braces group, 23 received passing grades, and 25 received failing grades. There was a statistically significant difference between the passing rate of the Invisalign group (20.8%) and the passing rate of the braces group (47.9%) ($P = .0052$) (Table IV).

When analyzing the average treatment duration for the 2 groups, the treatment time for the braces group (1.7 years) was significantly longer than that for the Invisalign group (1.4 years) ($P = .0138$). There were no statistically significant correlations between treatment duration and any of the DI categories for either group.

Examiner reliability was analyzed by remeasuring 5 Invisalign cases and 5 braces cases after data collection. No statistically significant difference ($P < .05$) was found between any original measurements and second measurements of the DI and OGS categories.

DISCUSSION

There was a statistically significant difference between the ages of the Invisalign and braces groups. The mean age in the Invisalign group was greater than that in the braces group by almost 10 years. This discrepancy was expected because adults are more likely to be interested in treatment with greater esthetics and comfort. Furthermore, Invisalign is limited to patients whose permanent teeth are erupted; the braces group's average was lower because it included preadolescent children. However, tooth movement should be similar regardless of age with all other things being equal, such as periodontal condition and patient compliance. Although there was an age difference between the 2 groups, both the Invisalign and braces patients were mostly adults who had finished growth. Therefore, it is unlikely that the age discrepancy had a clinically significant effect on treatment outcome.

The DI was used to objectively measure pretreatment records to determine the severity of the malocclusions, to control for the differences between the groups. The mean DI scores for both groups were similar, with no statistically significant differences. These results imply that the overall difficulty of the cases in both groups was nearly identical, providing a homogenous sampling of patients to accurately assess the treatment effectiveness of Invisalign and braces. Furthermore, there were no statistically significant differences between the groups in the 10 categories of the DI score, reinforcing the conclusion that the groups had similar pretreatment occlusions.

Table I. DI Scores reflecting mean points awarded for severity of malocclusion (Wilcoxon 2-sample tests for differences in DI categories between groups)

	Invisalign	*Braces*	P *value*
Overjet	1.42 (SD 1.30)	1.42 (SD 1.44)	.9010
Overbite	0.79 (SD 1.17)	0.88 (SD 1.30)	.8353
Anterior open bite	0.54 (SD 1.80)	1.96 (SD 4.85)	.1475
Lateral open bite	0.63 (SD 1.61)	0.42 (SD 1.75)	.2134
Crowding	2.81 (SD 2.56)	2.69 (SD 2.34)	.9194
Occlusion	1.33 (SD 1.81)	0.75 (SD 1.45)	.0816
Lingual posterior crossbite	0.29 (SD 0.82)	0.40 (SD 0.96)	.5761
Buccal posterior crossbite	0.21 (SD 0.74)	0.08 (SD 0.04)	.3968
Cephalometrics	9.90 (SD 8.49)	10.81 (SD 8.61)	.6099
Other	0.75 (SD 1.14)	0.46 (SD 0.85)	.2212
DI score	18.67 (SD 8.42)	19.85 (SD 10.87)	0.9066

Table II. OGS scores reflecting mean points lost for deviation from ideal (Wilcoxon 2-sample tests for differences in OGS categories between groups)

	Invisalign	*Braces*	P *value*
Alignment	−7.56 (SD 3.36)	−6.75 (SD 3.31)	.1489
Marginal ridges	−4.90 (SD 2.55)	−4.44 (SD 2.56)	.3874
Buccolingual inclination	−4.19 (SD 2.73)	−2.81 (SD 2.63)	.0061*
Occlusal contacts	−10.46 (SD 7.06)	−5.65 (SD 4.66)	.0004*
Occlusal relations	−7.71 (SD 4.76)	−5.50 (SD 4.71)	.0149*
Overjet	−6.21 (SD 4.64)	−3.56 (SD 2.54)	.0036*
Interproximal contacts	−0.77 (SD 1.39)	−0.65 (SD 1.62)	.2262
Root angulation	−3.56 (SD 2.35)	−2.85 (SD 1.87)	.1437
OGS score	−45.35 (SD 15.56)	−32.21 (SD 11.73)	<.0001*

*Statistically significant difference, $P < .05$.

Treatment outcome assessment of Invisalign and braces groups

The OGS was used to measure posttreatment patient records to accurately assess treatment outcome of both therapies. A large, statistically significant difference between OGS scores was found for the groups in their entirety. The mean OGS score for the Invisalign group (−45.35) was more than 13 points lower than the average OGS score for the braces group (−32.21). This difference in OGS scores was just as significant clinically and clearly indicated that the braces group had better treatment outcomes than the Invisalign group overall.

Half of the OGS categories produced statistically significant differences between the groups. Although Invisalign and fixed appliances had similar scores on alignment, marginal ridges, interproximal contacts, and root angulation, braces therapy had significantly superior scores for correcting buccolingual inclination, occlusal contacts, occlusal relationships, and overjet.

The similar OGS scores between Invisalign and braces for alignment and interproximal contacts were expected. The removable aligners are known to consistently produce adequate space closure of up to 6 mm by progressively tipping teeth into spaces in small increments. In terms of alignment, Invisalign has also had success with straightening arches by derotating teeth, especially when composite attachments are bonded to premolars. In previous reports, these results were largely anecdotal; they have now been confirmed in this study.

However, the similar OGS scores for marginal ridges and root angulation were not expected. The alignment of marginal ridges requires vertical control during tooth movement; braces would presumably do this better than removable aligners. Fixed appliances should have an advantage because of the ability to make precise wire adjustments within 0.5 mm to intrude or extrude teeth as necessary; it has been thought that removable aligners cannot be this accurate. In our study, it was shown that the Invisalign and braces groups received comparable scores for the marginal ridge category, indicating that Invisalign indeed can level arches as well as fixed appliances.

Table III. Correlation between OGS score and DI categories (Spearman correlation test)

	Invisalign		*Braces*	
	Correlation coefficient	P *value*	*Correlation coefficient*	P *value*
Overjet	−0.3034	0.0360*	−0.2975	.0400*
Overbite	0.1204	0.4149	−0.1547	.2939
Anterior open bite	0.1310	0.3747	0.0777	.5999
Lateral open bite	−0.0287	0.8463	−0.1044	.4799
Crowding	0.1073	0.4681	0.0873	.5550
Occlusion	−0.5288	0.0001*	−0.4497	.0013*
Lingual posterior crossbite	−0.3090	0.0326	−0.1896	.1967
Buccal posterior crossbite	−0.2849	0.0497*	−0.1092	.4601
Cephalometrics	−0.0977	0.5089	−0.1106	.4544
Other	−0.2446	0.0939	−0.2954	.0415*
Total DI score	−0.2688	0.0647	−0.1799	.2211
Pretreatment age	−0.0656	0.6580	−0.0167	.9103
Treatment duration	−0.1376	0.3510	−0.2494	.0874

*Statistically significant difference, $P < .05$.

Table IV. Number of cases receiving passing scores (≤ 30 points lost on OGS) (chi-square test for differences in passing rates between groups)

	Invisalign	*Braces*	P *value*
Pass	10 (20.8%)	23 (47.9%)	.0052*
Fail	38 (79.2%)	25 (52.1%)	
Total	48 (100%)	48 (100%)	

*Statistically significant difference, $P < .05$.

The shared success in achieving good root angulation was also surprising. Generally, removable aligners can easily tip crowns but cannot tip roots because of the lack of control of tooth movement, especially translating roots through bone. The results of this study, however, indicated no statistically significant difference between the 2 groups. This finding might be due to the exclusion of extraction patients in the sample. Most malocclusions start with relatively well-aligned roots, and root angulation is usually a concern only when closing large spaces, such as in extraction cases. If premolar extraction patients had been included, the Invisalign cases would probably have lost more points than the braces cases for root angulation.

In the other 4 OGS categories, the braces cases had statistically better scores than the Invisalign cases: buccolingual inclination, occlusal contacts, occlusal relationships, and overjet. All of these discrepancies point to the relatively poor control of removable aligners. For instance, the results indicated that Invisalign might not sufficiently produce root torque, especially in the posterior region where buccolingual inclination is measured. This problem has been addressed by using the combination technique in conjunction with fixed appliances. In addition, newer techniques to manipulate the aligners to improve torque are now being used by some practitioners.

Furthermore, it was shown that Invisalign might not be able to produce adequate occlusal contacts as well as braces, probably because it is difficult for the aligner to extrude a tooth unless there is a significant undercut and also because the aligners cover the occlusal surfaces of the teeth, preventing settling of the occlusion.

Finally, Invisalign did not score as well as braces for large anteroposterior (A-P) corrections as shown by the poor scoring in the occlusal relationships and overjet categories relative to the braces group. Invisalign's inability to adequately correct large A-P discrepancies as well as braces was corroborated by the Spearman correlation tests between OGS scores and DI categories. Both groups had a statistically significant negative correlation between OGS score and initial overjet and occlusion (the DI category that measures A-P discrepancy). However, the Invisalign OGS scores had slightly more significant P values and slightly stronger negative correlations to overjet and occlusion than the braces OGS Scores, indicating that the greater the original pretreatment overjet and A-P discrepancy, the more OGS points Invisalign lost relative to braces. These results support the findings that fixed appliances can correct large overjet and A-P discrepancies with greater success than Invisalign.

The only other statistically significant correlation was between Invisalign OGS score and initial buccal posterior crossbite; there was no correlation between this DI category and the braces OGS Score. However, only 4 of the 48 pretreatment Invisalign cases were awarded points for buccal posterior crossbite, so, even though the correlation to OGS score was statistically significant, there were too few cases to make a generalization about Invisalign's ability to coordinate arch widths.

The ultimate purpose for grading cases with the OGS on the Phase III examination is to determine whether a case will receive a passing score for board certification. Generally, a case that loses 30 points or fewer by OGS scoring is given a passing grade. The next step was to determine the passing rates of Invisalign and braces cases in this sample.

The overall passing rate for the Invisalign group (20.8%) was 27.1% lower than the passing rate for the braces group (47.9%), and this difference was statistically significant. These data again confirm that fixed

appliances produced better treatment outcomes than Invisalign in this orthodontist's hands, given his level of expertise. Particularly important to the outcome of Invisalign is proficiency in using Align Technology's Clincheck program that allows the practitioner to accept or modify the treatment plan of tooth movements before the aligners are actually fabricated. In this study, all Invisalign patients were treated as ideally as possible, except one who had a mutilated dentition and requested only anterior alignment.

Furthermore, aligners were simply delivered to these Invisalign patients. Interproximal reduction was performed as prescribed, but no other modifications were made to augment tooth movement. Therefore, the pass rate for Invisalign cases might be higher if more sophisticated techniques, such as auxiliaries, interarch elastics, or combination treatment with braces had been used. On the other hand, the braces patients were treated with tip-edge fixed appliances, which can make fine adjustments with uprighting springs, rotation springs, interarch elastics, and other auxiliaries in addition to the tooth movements made possible by the bracket prescription.

As a side note, even the fixed appliance cases had a surprisingly low OGS pass rate. This finding underlies the strictness of the ABO standards and confirms the OGS as a rigorous measurement of treatment outcome.

Interestingly, there was a statistically significant difference between the treatment durations of the groups: 1.4 years for the Invisalign patients and 1.7 years for the braces patients. These data suggest that Invisalign treatment can be somewhat faster than fixed appliances. Although Invisalign can produce quicker results, the final occlusion might not be as ideal. However, Invisalign might obtain better results if staging is prolonged or a combination technique is used.

Advantages and disadvantages of Invisalign

The advantages of Invisalign have been explained by Align Technology and in many case reports and descriptive publications. The Invisalign system gives the orthodontist a highly esthetic, removable treatment modality to correct adult malocclusions. Patients find the aligners relatively comfortable and have consistently endorsed them. In the original feasibility study, Vlaskalic and Boyd[3] reported that 100% of the patients would select Invisalign over braces.

However, there are several reasons that Invisalign might not be as effective as fixed appliances. Primary among them is compliance. Because the aligners are removable, the orthodontist must rely on the patient's motivation and dependability to achieve the desired results. The removability of Invisalign is an advantage to the patient but not to the clinician.

Another reason that Invisalign fails to compare with braces is that Invisalign minimally addresses the occlusion.[10] Vlaskalic and Boyd[11] admitted that, when evaluating the occlusal outcome of an Invisalign case, it was evident that the same or an even better result could have been achieved with conventional braces in arguably less time. Therefore, the major advantages of Invisalign over braces are that the aligners are esthetic, removable, and comfortable, but there are no biomechanical advantages.

Limitations of the study

The patients in the Invisalign group were the orthodontist's first 48 patients to successfully complete treatment with Invisalign appliances only. This design might underestimate the superiority of braces over Invisalign, because patients were excluded in whom Invisalign did not fare well or whose treatment was not completed. Future studies could eliminate this selection bias by measuring consecutively treated patients regardless of outcome. Additional research should focus on prospective clinical trials and include extraction cases and long-term follow-ups to monitor relapse.

Because Invisalign is a relatively new technique, the patients in that group were the first ones treated by the orthodontist. There have been refinements in the technique since then, and practitioners have had 5 years of additional experience. On the other hand, the braces group included patients treated by the orthodontist after decades of experience. Any technique requires a learning curve, and treatment outcome is only as good as the operator's proficiency, no matter what appliance is used. Therefore, the patients in the braces group might have had an inherent advantage over those in the Invisalign group because of differences in the orthodontist's experience between the types of treatment.

CONCLUSIONS

Invisalign cases did not score as well as braces cases on the OGS, averaging 13 more points lost, implying that treatment results of braces are superior to those of Invisalign, given this practitioner's proficiency.

OGS scores were similar in both groups for rotations, marginal ridge heights, space closure, and root alignment, but Invisalign OGS scores for occlusal contacts, posterior torque, and A-P discrepancies were not as good as those for braces.

Invisalign OGS scores were most significantly correlated to initial overjet and occlusion, implying that

Invisalign did not treat patients with large A-P discrepancies well in this sample.

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COMMENTARY

My main concern about this article is that its purpose was to determine the quality of treatment results that an ABO-certified orthodontist could achieve using Invisalign compared with fixed appliances. The method assumes that there is equivalency between his skills with the 2 techniques. However, the outcomes of the first 48 patients that an orthodontist has finished using a new, emerging technique compared with outcomes of patients treated with another method that he has used for more than 30 years and is considered an expert in is certainly not a valid comparison for the stated purpose of the study. The outcome can only be as good as the orthodontist's skill in each method. It takes time for a practitioner to develop expertise with any appliance, especially if it is new. Although it is technically impossible, the study would have been more valid from a scientific point of view if the authors had used the practitioner's first 48 fixed cases and compared them with his first 48 Invisalign cases.

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