# **Original Article**

# Invisalign and Traditional Orthodontic Treatment Postretention Outcomes Compared Using the American Board of Orthodontics Objective Grading System

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## ABSTRACT

**Objective:** To compare the postretention dental changes between patients treated with Invisalign and those treated with conventional fixed appliances.

**Materials and Methods:** This is a comparative cohort study using patient records of one orthodontist in New York City. Two groups of patients were identified that differed only in the method of treatment (Invisalign and Braces group). Dental casts and panoramic radiographs were collected and analyzed using the objective grading system (OGS) of the American Board of Orthodontics (ABO). The cases were evaluated immediately after appliance removal (T1) and at a postretention time (T2), three years after appliance removal. All patients had completed active orthodontic treatment and had undergone at least one year of retention. A Wilcoxon rank sum test was used to evaluate differences in treatment outcomes between the groups for each of the eight categories in the OGS, including four additional subcategories in the alignment category. A Wilcoxon signed rank test was used to determine the significance of changes within each group from T1 to T2.

**Results:** The change in the total alignment score in the Invisalign group was significantly larger than that for the Braces group. There were significant changes in total alignment and mandibular anterior alignment in both groups. There were significant changes in maxillary anterior alignment in the Invisalign group only.

**Conclusions:** In this sample for this period of observation, patients treated with Invisalign relapsed more than those treated with conventional fixed appliances.

KEY WORDS: Invisalign; Cohort study; Objective grading system; Treatment outcome; Relapse

### INTRODUCTION

In 1999, Align Technology Inc addressed the demand for an esthetic alternative to braces by developing an "invisible" method of orthodontic treatment (Invisalign) that uses a series of computer-generated, clear, removable aligners to move the dentition. Since

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Accepted: November 2006. Submitted: October 2006. © 2007 by The EH Angle Education and Research Foundation, Inc. then, Invisalign has been used to treat over 300,000 orthodontic patients with a variety of malocclusions. The primary benefit of the Invisalign system is the superior esthetics during treatment compared to metal braces. Other advantages of the system include the ability to remove aligners to eat, brush and floss, and the superior comfort and ease of use.<sup>1</sup>

Based on case reports, this technique appears effective in treating mild malocclusions and is more visually appealing than conventional braces.<sup>2</sup> Align has claimed that 90% of orthodontic patients are candidates for Invisalign. These include patients with mild to moderate crowding (1–6 mm), mild to moderate spacing (1–6 mm), nonskeletal constricted arches, and those who have experienced relapse after fixed appliance therapy.<sup>3</sup>

To this date, little clinical research has been published to comprehensively study the effectiveness of Invisalign treatment. The lack of such objective information on this product has made it difficult for clini-

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cians to objectively characterize the efficacy of Invisalign as compared to fixed appliances. Previous literature has focused on presenting descriptions of the product and anecdotal information on individual successful cases.<sup>4-6</sup>

A recent systematic review of Invisalign research by Lagravere and Flores-Mir<sup>7</sup> found that no strong conclusions could be made regarding the treatment effects of Invisalign appliances. They concluded that randomized clinical trials are the only way to address the many concerns surrounding the Invisalign system. Despite the thousands of completed cases treated with Invisalign and the many published successful case reports, some orthodontists feel that this treatment can be inferior to conventional braces.<sup>8</sup> Until randomized studies are performed, orthodontists will have to rely on their individual clinical experiences.

Only one case-controlled cohort study comparing the treatment results of Invisalign patients to conventional fixed appliance patients has been published. Using the American Board of Orthodontics objective grading system (OGS), it was reported that the cases treated with Invisalign had a mean OGS score 13 points worse than the Braces group, and the OGS passing rate for Invisalign was 27% lower than for the conventional Braces group. It was implied that, according to this measurement technique, treatment results of braces are superior to those of Invisalign and that Invisalign did not treat patients with large anteroposterior discrepancies as well.9 However, the data for this project were taken immediately post treatment, with no assessment of the long-term stability of these cases.

Despite extensive research, the various elements leading to relapse of treated malocclusions are not completely understood, which makes retention one of the most challenging aspects of orthodontic treatment. Although researchers have published retention recommendations, they admit that long-term alignment is variable and unpredictable. In addition, there appear to be no descriptive characteristics of a case or pretreatment variables that can accurately predict relapse.<sup>10</sup> In 2005, Nett and Huang<sup>11</sup> used the American Board of Orthodontics (ABO) objective grading system to measure long-term relapse of conventionally treated cases and found that overall OGS scores actually improved. Alignment was the only criterion that worsened.

The main objective of this study was to assess and compare postretention treatment outcomes of patients treated with the Invisalign system to treatment outcomes of patients treated with traditional fixed appliances.

#### MATERIALS AND METHODS

This is a comparative cohort study using patient records of one ABO board-certified and Invisalign-certified orthodontist in New York City. Dental casts and panoramic radiographs from patients were collected and analyzed. The posttreatment records were taken immediately after appliance removal (T1) and the postretention records were taken three years later (T2).

Two groups of patients were evaluated: the Invisalign group and the Braces group. To establish the Invisalign group, all patients from the 2005 Invisalign treatment outcome study were contacted (48 patients).<sup>9</sup> Eleven returned to the clinic for postretention evaluations. A pool of patients treated to completion with tip-edge fixed appliances and debonded in 2002 or 2003 was then established. Because there were no extraction cases in the Invisalign group, it was decided to eliminate all extraction cases from the Braces group as well. Patients in the Braces group fitting the inclusion criteria were contacted for records in alphabetical order. The final sample size for both groups was 11.

Retention in the Invisalign group consisted of the final aligners. Patients were instructed to wear retainers full time for six months, and then nightly for at least another six months. In the Braces group, Essix retainers were used with the same retention protocol.

Using the OGS, all casts and panoramic radiographs were randomly ordered and identification masked by one examiner before being evaluated. Eight measurements were made for each case and points were deducted for any discrepancy from the ideal. The measurement categories of the OGS are alignment, marginal ridges, buccolingual inclination, occlusal contacts, occlusal relations, overjet, interproximal contacts, and root angulation. The alignment category, as defined by the ABO website, comprises four subcategories: maxillary anterior, maxillary posterior, mandibular anterior, and mandibular posterior.<sup>12</sup> The number of points lost was totaled for each patient to give an OGS score. A perfect score is 0. A case that loses 30 points or fewer would be considered a successfully treated case and will usually receive an acceptable grade on the ABO Phase III exam.13 To ensure examiner reliability, three sets of records from each group were ordered and masked as previously described and evaluated by a second examiner.

Fisher's exact tests were used to determine the significance of differences in distributions between the Invisalign and Braces groups with regard to gender, ethnicity, and if they still wear their retainers. Unpaired *t*tests or Wilcoxon rank sum tests were performed to assess the significance of differences with regard to age, treatment length, and posttreatment length. Unpaired *t*-tests or Wilcoxon rank sum were also used to

Table 1.	Attributes of Patients in Ir	nvisalign and Braces	Groups $(N = 11)$
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Attributes <sup>a</sup>	Invisalign	Braces	P Value
Female patients	10 (90.9%)	10 (90.9%)	.5238
Male patients	1 (9.1%)	1 (9.1%)	
African-American	7 (63.6%)	8 (72.7%)	.1642
White	2 (18.2%)	2 (18.2%)	
Hispanic	2 (18.2%)	1 (9.1%)	
Still wear retainers	5 (45.4%)	3 (27.2%)	.2384
Do not wear retainers	6 (54.6%)	8 (72.8%)	
Mean age at posttreatment (T1)	33.97 (SD 8.98)	26.79 (SD 12.12)	.1337
Mean age postretention (T2)	37.05 (SD 9.20)	29.50 (SD 12.15)	.0942
Treatment length (y)	1.74 (SD 0.83)	2.34 (SD 0.77)	.0941
Postretention length (y)	3.08 (SD 0.78)	2.70 (SD 0.21)	.1400

<sup>a</sup> T1 indicates immediately after appliance removal; T2, postretention time.

\* *P* < .05.

determine the significance of differences between the two groups from T1 to T2. Paired *t*-tests or Wilcoxon signed rank tests were used to determine the significance of changes within each group between the two time points.

#### RESULTS

The Invisalign group and Braces group had similar distributions of gender, ethnicity, age, retainer wear, treatment, and posttreatment length. All subjects claimed to have worn their retainers for at least one year post treatment, six months full time (Table 1). Table 2 provides means and standard deviations for each OGS category by group, and associated *P* values. No statistically significant differences were found between the Invisalign group and Braces group at T1 or T2 (Table 2).

The difference between the two groups with regard to changes from T1 to T2 was statistically significant for total alignment (P = .034). The total alignment of the Invisalign group decreased from -5.91 at T1 to -8.81 at T2, while the total alignment of the Braces

group decreased from -8.36 to -9.73. No other OGS category was statistically significant, nor was further breakdown of the alignment category (Table 3).

With regard to differences between T1 and T2 within each group, both groups showed significant decreases in total alignment (P = .0020 for the Invisalign group, P = .0156 for the Braces group; Table 4), and mandibular anterior alignment (P = .0039 for the Invisalign group, P = .0313 for the Braces group; Table 4). Only the Invisalign group showed a significant difference in maxillary anterior alignment (P = .0156; Table 4). The maxillary anterior alignment of the Invisalign group decreased from -0.91 at T1 to -2.00 at T2, while the maxillary anterior alignment of the Braces group decreased from -0.82 to -1.18 (Table 2).

There were no significant differences between the measurements performed by the two examiners. The data listed in the tables are from the first examiner only.

#### DISCUSSION

Because Invisalign has been used to treat patients only since 1999, obtaining records on subjects that

 Table 2.
 OGS Scores and P Values for Invisalign and Braces Groups at T1 and T2

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OGS CATEGORY	Invisalign (T1)	Braces (T1)	P Value	Invisalign (T2)	Braces (T2)	P Value
Total alignment	-5.91 (SD 4.09)	-8.36 (SD 3.93)	.1665	-8.81 (SD 4.97)	-9.73 (SD 3.77)	.6344
Maxillary anterior alignment	-0.91 (SD 0.83)	-0.82 (SD 0.87)	.8051	-2.00 (SD 1.26)	-1.18 (SD 0.87)	.0928
Maxillary posterior alignment	-2.09 (SD 1.58)	-3.45 (SD 1.70)	.0650	-2.36 (SD 1.75)	-3.63 (SD 1.75)	.1031
Manidubular anterior alignment	-1.27 (SD 1.01)	-1.64 (SD 0.81)	.3622	-2.82 (SD 1.66)	-2.36 (SD 1.43)	.5001
Mandibular posterior alignment	-0.1.54 (SD 1.37)	-2.45 (SD 1.51)	.1542	-1.64 (SD 1.69)	-2.55 (SD 1.37)	.1808
Marginal ridges	-5.45 (SD 2.50)	-6.72 (SD 2.53)	.2499	-5.00 (SD 2.52)	-5.72 (SD 1.90)	.4549
Buccolingual inclination	-3.45 (SD 2.07)	-2.81 (SD 2.40)	.5129	-3.63 (SD 1.85)	-2.73 (SD 2.90)	.3919
Occlusal contacts	-8.27 (SD 4.24)	-9.72 (SD 5.02)	.4717	-7.90 (SD 5.11)	-7.82 (SD 3.57)	.9619
Occlusal relations	-6.73 (SD 4.64)	-6.90 (SD 4.83)	.9292	-6.36 (SD 3.70)	-6.36 (SD 3.95)	1.0000
Overjet	-7.00 (SD 3.79)	-5.45 (SD 4.29)	.3820	-6.09 (SD 2.63)	-5.36 (SD 3.44)	.5836
Interproximal contacts	-0.55 (SD 1.21)	-0.90 (SD 1.30)	.5055	-0.36 (SD 0.67)	-0.27 (SD 0.65)	.7502
Root angulations	-2.09 (SD 1.44)	-2.09 (SD 1.70)	1.0000	-2.00 (SD 1.48)	-2.45 (SD 1.92)	.5409
Total OGS score	-39.45 (SD 10.26)	-43.00 (SD 12.52)	.4760	-40.18 (SD 10.32)	-40.45 (SD 9.81)	.9500

<sup>a</sup> OGS indicates objective grading system; T1, immediately after appliance removal; T2, postretention time.

\* *P* < .05.

Table 3.	OGS Score Changes Between	T2 and T1 for Patients	Treated With Invisalign and Braces <sup>a</sup>

OGS Category	Invisalign Change (T2-T1)	Braces Change (T2-T1)	P Value
Total alignment	-2.91 (SD 1.64)	-1.36 (SD 1.21)	.0340*
Maxillary anterior alignment	-1.09 (SD 1.04)	-0.36 (SD 0.51)	.0859
Maxillary posterior alignment	-0.27 (SD 0.64)	-0.18 (SD 0.40)	.9615
Mandibular anterior alignment	-1.55 (SD 1.21)	-0.72 (SD 0.79)	.1133
Mandibular posterior alignment	-0.09 (SD 0.54)	-0.09 (SD 0.30)	1.0000
Marginal ridges	0.45 (SD 2.30)	1.00 (SD 2.00)	.4726
Buccolingual inclination	-0.18 (SD 1.40)	0.09 (SD 2.30)	.8644
Occlusal contacts	0.36 (SD 4.63)	1.91 (SD 3.36)	.6244
Occlusal relations	0.36 (SD 4.18)	0.55 (SD 3.47)	.2083
Overjet	0.91 (SD 3.78)	0.90 (SD 2.43)	.7676
Interproximal contacts	0.18 (SD 0.60)	0.64 (SD 1.21)	.3670
Root angulations	0.09 (SD 0.30)	-0.36 (SD 0.81)	.1169
Total OGS score	-0.73 (SD 5.58)	2.55 (SD 7.30)	.1208

<sup>a</sup> OGS indicates objective grading system; T1, immediately after appliance removal; T2, postretention time.

\* *P* < .05.

met the criteria of "post retention" was challenging. Obviously, the authors would have preferred a much larger sample size, but these data should provide some preliminary insight to the long-term post treatment changes in the dentition using the Invisalign system.

To ensure that both groups followed a similar retention protocol, each patient was asked if they followed the posttreatment retention instructions and if they continued to wear their retainers. Obviously, there will be some self-reporting errors, but all subjects claimed at least one year of retention (six months full time), and there was no statistically significant difference between the groups as to how many still wore retainers for maintenance (Table 1).

The OGS was chosen to measure records in this study because it is a standardized method of grading orthodontic treatment results. It provides an objective protocol to thoroughly evaluate changes in the dentition.<sup>12,13</sup>

Since relapse is a function of time, it was essential to equate the two groups with regard to posttreatment length. Although the Invisalign group had a slightly longer posttreatment length (3.08 vs 2.70 years), this result was not statistically significant nor considered clinically important. There was also no significant discrepancy between the treatment times. As a whole, patient characteristics for the Invisalign and Braces groups were similar (Table 1). An analysis of the disparity between the groups revealed no significant differences immediately post treatment or post retention (Table 2).

When analyzing the changes between the groups during the time interval from T1 to T2, a significant difference was found in the alignment category (Table 3). This indicates that the patients treated with Invisalign showed more deterioration in the alignment of the dentition than the patients treated with traditional fixed appliances. This is clinically important because tooth alignment is probably the most visually noticeable characteristic measured by the OGS and is the main reason people seek orthodontic treatment.<sup>14</sup>

In order to investigate this finding further, the alignment category of the OGS was further broken down into maxillary anterior, maxillary posterior, mandibular anterior, and mandibular posterior subcategories (Table 3). These subcategories are not independent OGS criteria, but have been identified by the ABO as subsets of the alignment category.<sup>12</sup> When changes between the groups were compared for these subcategories, no statistically significant differences were found.

Even though the Invisalign group did show a larger decrease in the alignment score, the mean alignment of the Invisalign group was superior to the Braces group before and after the retention phase, but these differences were not statistically significant (Table 2). Therefore, even though the Invisalign cases relapsed more, they appear to have the same, if not better, overall alignment scores.

With regard to changes within each of the two groups, changes in total alignment in both groups were significant (Table 4). More specifically, there was deterioration in the maxillary and mandibular anterior alignment of the Invisalign group, but only in the mandibular anterior alignment of the Braces group. Therefore, while the mandibular anterior teeth were relapsing significantly in both groups, the maxillary anterior teeth were relapsing significantly only in the Invisalign group. This finding is clinically significant, because the maxillary anterior teeth are the most visible in the mouth. These data are in agreement with the results of Nett et al,11 who found that of the eight OGS categories, only alignment worsened postretention. Also in agreement with this study, it was found that almost all of the changes in the alignment occurred in the anterior teeth.11

OGS Category	Invisalign (T1)	Invisalign (T2)	Invisalign ( <i>P</i> Value)		Braces (T2)	Braces (P Value)
Total alignment	-5.91 (SD 4.09)	-8.81 (SD 4.97)	.0020**	-8.36 (SD 3.93)	-9.73 (SD 3.77)	.0156*
Maxillary anterior alignment	-0.91 (SD 0.83)	-2.00 (SD 1.26)	.0156*	-0.82 (SD 0.87)	-1.18 (SD 0.87)	.1250
Maxillary posterior alignment	-0.2.09 (SD 1.58)	-2.36 (SD 1.75)	.5000	-3.45 (SD 1.70)	-3.63 (SD 1.75)	.5000
Mandibular anterior alignment	-0.1.27 (SD 1.01)	-2.82 (SD 1.66)	.0039**	-1.64 (SD 0.81)	-2.36 (SD 1.43)	.0313*
Mandibular posterior alignment	-0.1.54 (SD 1.37)	-1.64 (SD 1.69)	1.0000	-2.45 (SD 1.51)	-2.55 (SD 1.37)	1.0000
Marginal ridges	-5.45 (SD 2.50)	-5.00 (SD 2.52)	.6250	-6.72 (SD 2.53)	-5.72 (SD 1.90)	.1182
Buccolingual inclination	-3.45 (SD 2.07)	-3.63 (SD 1.85)	.8125	-2.81 (SD 2.40)	-2.73 (SD 2.90)	1.0000
Occlusal contacts	-8.27 (SD 4.24)	-7.90 (SD 5.11)	.7734	-9.72 (SD 5.02)	-7.82 (SD 3.57)	.0977
Occlusal relations	-6.73 (SD 4.64)	-6.36 (SD 3.70)	.6875	-6.90 (SD 4.83)	-6.36 (SD 3.95)	.2949
Overjet	-7.00 (SD 3.79)	-6.09 (SD 2.63)	.5547	-5.45 (SD 4.29)	-5.36 (SD 3.44)	.8594
Interproximal contacts	-0.55 (SD 1.21)	-0.36 (SD 0.67)	1.0000	-0.90 (SD 1.30)	-0.27 (SD 0.65)	.1875
Root angulations	-2.09 (SD 1.44)	-2.00 (SD 1.48)	1.0000	-2.09 (SD 1.70)	-2.45 (SD 1.92)	.3125
Total OGS score	-39.45 (SD 10.26)	-40.18 (SD 10.32)	.7578	-43.00 (SD 12.52)	-40.45 (SD 9.81)	.2275

Table 4. Comparison of OGS Scores Within Each Group at T1 and T2ª

<sup>a</sup> OGS indicates objective grading system; T1, immediately after appliance removal; T2, postretention time.

\* *P* < .05; \*\* *P* < .01.

There was a statistically insignificant overall improvement in many of the categories within each group, which is also in agreement with the results of Nett el al.<sup>11</sup> Specifically, marginal ridges, occlusal contacts, occlusal relations, overjet and interproximal contacts all improved from T1 to T2 for both groups. Overall, the total OGS score for the Invisalign group got worse from T1 to T2, while the total OGS score for the Braces group improved (Table 2). This is a function of the significantly worse total alignment in the Invisalign group. The mean total OGS score of the Invisalign group was superior to the mean total OGS score of the Braces group before and after the retention phase, although these differences were not statistically significant.

An important question to come out of these findings is: why does the alignment of the patients treated with Invisalign worsen more postretention than patients treated with fixed appliances? Both groups underwent a similar retention protocol, which means that all gingival and periodontal fibers were equally as reorganized. The difference could be in the characteristics of the new bone formed.<sup>15</sup> The current concept of an optimal force in orthodontics is based on the theory that a force of a certain magnitude and duration would be capable of producing a maximum rate of tooth movement without tissue damage.<sup>16</sup> Tooth movement with the Invisalign system is distance-based, as opposed to forced-based with the fixed appliance systems. Due to static constraints, it is impossible to know exactly what forces are being created by continuous arch mechanics with fixed appliances, but material properties and stress/strain relationships of orthodontic wires and springs are known.<sup>17</sup> Even though both fixed appliances and Invisalign can move teeth to clinically acceptable positions, there is no literature as to how much force is being created by the clear removable appliances. Although no evidence about an optimal force level in orthodontics is available in the literature at this time, the finding in this study illustrates the need for further investigation.

One difference in the treatment protocol of the two groups was that the patients treated with Invisalign inserted new aligners, and therefore new forces, every two weeks. There is no research supporting the 2-week interval recommendation, other than Bollen et al18 who concluded "changing aligners every other week was more likely to lead to completion of the initial series of aligners than changing weekly." The Braces group, on the other hand, was adjusted usually every 4-6 weeks. Even under ideal orthodontic forces, some undermining resorption of the alveolar bone will occur. Undermining resorption requires 7-14 days, with equal time needed for periodontal ligament (PDL) regeneration and repair. This is why orthodontic appliances should not be reactivated more frequently than at 3-week intervals. Activating an appliance too frequently can produce damage to the teeth or bone by cutting short the repair process.<sup>17</sup> It could be postulated that the 2-week interval of aligners in the Invisalign system is too small and is leading to poor bone formation and more relapse.

This study is subject to several limitations. The Invisalign group was created from a pool of patients who successfully completed treatment with Invisalign aligners only. Not included were patients whose treatment needed to be supplemented with fixed appliances. Future studies should take a more random sample of Invisalign patients, as was done with the Braces group. All of the subjects in the Invisalign group were among the first 50 patients treated with Invisalign (Dr Shelton). Any technique requires a learning curve, and future results may be different as the clinician gains experience. In addition, a larger sample size from several orthodontists would be useful in future studies. Because of these limitations, the generalizability of this study is limited.

#### CONCLUSIONS

- Changes in total alignment, as measured by the ABO OGS, were worse postretention in patients treated with Invisalign than in patients treated with conventional fixed appliances.
- Within both groups, total alignment and mandibular anterior alignment worsened postretention.
- Maxillary anterior alignment worsened postretention in the Invisalign group only.
- In this sample for this period of observation, patients treated with Invisalign relapsed more than those treated with conventional fixed appliances, and further investigation is warranted.

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