Original Article

Outcome assessment of orthodontic clear aligner vs fixed appliance treatment in a teenage population with mild malocclusions

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ABSTRACT

Objective: To assess the efficacy and efficiency of treatment in adolescents presenting with mild malocclusions, comparing outcomes using clear aligners to fixed appliances.

Materials and Methods: Patients identified retrospectively and consecutively from one private practice had been treated with either clear aligners (Invisalign, Align Technology, Santa Clara, Calif) or fixed appliances (0.022 Damon, Ormco, Orange, Calif; n = 26/group). Assessments of occlusion were made using the American Board of Orthodontics Discrepancy Index (DI) for initial records and Cast-Radiograph Evaluation (CRE) for final records. Number of appointments, number of emergency visits, and overall treatment time were determined from chart reviews. Data were analyzed using Pearson's correlation, Wilcoxon rank tests, unpaired *t*-tests, and Chi-square tests, with significance set to $P \leq .05$.

Results: Pretreatment, the aligner and fixed groups showed no significant difference in overall severity (DI: 11.9 ± 5.3 vs 11.6 ± 4.8) or in any individual DI category. Posttreatment scores showed finishes for the aligner group had fewer discrepancies from ideal relative to the fixed appliance group (CRE: 30.1 ± 8.3 vs 37.0 ± 9.3; $P < .01$). Patients treated with aligners had fewer appointments (13.7 ± 4.4 vs 19.3 ± 3.6; $P < .0001$), fewer emergency visits (0.8 ± 1.0 vs 3.6 ± 2.5; $P < .0001$), and shorter overall treatment time (16.9 ± 5.7 vs 23.4 ± 4.4 months; $P < .0001$).

Conclusions: Outcomes for treatment of mild malocclusions in adolescents showed equivalent effectiveness of clear aligners compared to fixed appliances, with significantly improved results for clear aligner treatment in terms of tooth alignment, occlusal relations, and overjet. Assessment of the number of appointments, number of emergency visits, and overall treatment time showed better outcomes for treatment with clear aligners. (*Angle Orthod.* 2020;90:485–490.)

KEY WORDS: Clear aligner; Teenagers; Outcome assessment; Fixed appliance

INTRODUCTION

Orthodontic treatment involving clear aligners was introduced in 1997 (Invisalign, Align Technology, Santa Clara, Calif). Based on an initial impression of the dental arches, digital technology was used to simulate progressive alignment of teeth, from which a series of semielastic polyurethane aligners was fabricated for

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Accepted: February 2020. Submitted: December 2019.
Published Online: April 28, 2020

delivery to patients.[1–3] Over time, several updates, or generations, of clear aligners have been released involving changes in appliance material, tooth attachment design, and software simulation.[4] Although originally confined to treatment of adults, an aligner approach aimed at teenage patients was introduced in 2008 (Invisalign Teen System).[5]

Studies on the outcome of orthodontic treatment using clear aligners have shown mixed results. When treatment with aligners was compared to that involving fixed orthodontic appliances in adult populations, several studies[3,6–8] showed that the use of aligners resulted in significantly poorer outcomes, whereas others[9,10] demonstrated near equal efficacy of the two treatment approaches. The previous studies were based on treatment of adults with varying ranges of malocclusion severity, using earlier generations of aligner technology.

The focus of the current study was to assess treatment responses to aligner treatment in teenagers with mild malocclusions using more recent approaches for aligner treatment (Invisalign 5th and 6th generation). Standardized indices were applied to compare outcomes among teenage patients treated with clear aligners vs fixed appliances. The null hypothesis was that there was no difference in outcome between the two treatment approaches for treatment of mild malocclusion.

MATERIALS AND METHODS

Sample Collection

The research protocol was reviewed by the institutional review board and was given an exempt determination. Records of teenage patients 11–17 years of age were collected from the private practice of an orthodontist (JSG) with certification by the American Board of Orthodontists (ABO) and over 10 years of experience treating patients with fixed appliances and clear aligners. During treatment presentations with patients and caregivers, the pros and cons of aligners (Invisalign) and fixed appliances (0.022×0.028-inches, Damon, Ormco, Orange, Calif) were discussed. The treatment fee was the same for either option, and all patients were allowed to select the treatment modality that they preferred.

Selection of records entailed reviewing consecutively finished cases, working backwards in time until 26 cases were identified for each group. Patients included were required to meet the following inclusion criteria: nonsyndromic diagnosis, nonextraction treatment, no prior orthodontic treatment, no missing teeth, and no impacted teeth needing surgical exposure. A retrospective power analysis indicated that the sample size achieved a power of 0.8, assuming a difference between cohorts for the average ABO Cast-Radiograph Evaluation (CRE) scores of 7.0, with a standard deviation of 8.8 points.

Measurements

Pre- and posttreatment records were assessed by a calibrated reviewer (AFB) blinded to the group assignment. Using the ABO Discrepancy Index (DI), in which digital models and lateral cephalometric images were analyzed, measurements from pretreatment records were made in the 10 categories of the DI using OrthoCAD (Cadent, Fairview, NJ) digital software. Case complexity was assigned based on criteria used in previous investigations: a DI score of 7–15 was considered "mild," 16–24 was "moderate," and 25 or greater was "severe."[6,9] Posttreatment outcomes were assessed using digital models and panoramic radiographic images and scored using the CRE. Eight measurements were made for each subject using the OrthoCAD CRE measuring tool. Points were scored for any discrepancy from ideal, as described by the ABO.[11] The number of points was totaled to give the overall CRE score. To investigate intraexaminer reliability, five cases treated with aligners and five treated with fixed appliances were randomly selected and measured again at least 1 week after the first assessment.

Statistical Analyses

For continuous variables, values were analyzed for the type of distribution using a Shapiro-Wilk test. Scores for the 10 individual categories of the DI and the eight individual categories of the CRE scores were compared between groups using Wilcoxon rank test. Age, overall DI score, overall CRE score, and treatment duration were tested with an unpaired *t*-test. For the categorical variables of age and gender, Chi-square tests of percentages were used to compare cohorts. To assess intrarater reliability, a Pearson correlation coefficient was measured. $P < .05$ was considered statistically significant. All analyses were conducted using SAS version 9.4 (SAS Institute Inc, Cary, NC).

RESULTS

As shown in Table 1, the mean age of patients at the start of treatment was 13.7 ± 1.4 years for the aligner group and 13.0 ± 1.3 years for the fixed group. Males composed 38% of the aligner group and 54% of the fixed group. No significant difference was found between groups for age or sex distribution.

As shown in Table 2, the average DI score was 11.9 ± 5.3 (range: 6–23) for the aligner group and 11.6 ± 4.7 (range: 4–19) for the fixed appliance group, with no

Table 1. Demographics of Clear Aligner and Fixed Appliance Groups

Attribute	Aligner (N = 26)	Fixed (N = 26)	*P* Value*
Age at treatment start, in years (standard deviation)	13.7 (1.4)	13.0 (1.3)	.07
No. of male patients (% of total)	10.0 (38)	14.0 (54)	.27
No. of female patients (% of total)	16.0 (62)	12.0 (46)	.27

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

significant difference between groups overall or when comparing individual DI categories.

Table 3 demonstrates parameters related to treatment efficiency. The fixed appliance group averaged more treatment visits relative to the aligner group (19.3 ± 3.6 vs 13.7 ± 4.4; $P < .0001$). The fixed appliance group averaged more emergency visits relative to the aligner group (3.6 ± 2.5 vs 0.8 ± 1.0; $P < .0001$). Treatment time in the fixed appliance group was longer than in the aligner group (23.4 ± 4.4 vs 16.9 ± 5.7 months; $P < .0001$).

Intrarater reliability for the CRE assessment showed high reliability, with a Pearson correlation value of .96 (Figure 1). Table 4 shows that the fixed appliance group finished treatment with somewhat higher CRE scores (less ideal results) compared to the aligner group (37.0 ± 9.3 vs 30.1 ± 8.3; $P < .01$). Comparisons of CRE categories showed the fixed appliance group finished with significantly greater number of points for alignment, occlusal relations. and overjet (all $P < .05$), with no significant differences for marginal ridges, buccolingual inclination, occlusal contacts, interproximal contacts, or root angulation.

Table 2. American Board of Orthodontics (ABO) Discrepancy Index (DI) Scores Reflecting Mean Number of Points and Standard Deviation (SD) Recorded for Severity of Malocclusion in Clear Aligner and Fixed Appliance Groups

Attribute	Aligner Mean (SD)	Fixed Mean (SD)	*P* Value*
Overjet**	1.3 (1.1)	1.2 (1.3)	.68
Overbite**	1.9 (1.3)	2.2 (1.6)	.42
Anterior open bite**	0.2 (0.8)	0.1 (0.4)	.98
Lateral open bite**	0.2 (0.9)	0.2 (0.8)	.57
Crowding**	2.8 (2.4)	3.4 (2.8)	.40
Occlusion**	1.4 (1.7)	1.7 (2.1)	.70
Lingual posterior crossbite**	0.2 (0.5)	0.2 (0.6)	.71
Buccal posterior crossbite**	0.2 (0.5)	0.0 (0.0)	.15
Cephalometrics ANB*	0.0	0.0	NA
Cephalometrics IMPA**	2.2 (3.2)	1.2 (2.2)	.34
Cephalometrics SN-MP**	0.5 (1.3)	1.1 (2.8)	.94
Other**	1.0 (2.0)	0.4 (0.1)	.37
DI score***	11.9 (5.3)	11.6 (4.7)	.85

* Statistically significant difference, $P < .05$; ** Individual categories (nonparametric) tested using Wilcoxon rank test; *** Overall DI score (parametric) tested using unpaired *t*-test.

Table 3. Treatment Efficiency Parameters Showing Mean and Standard Deviation (SD) Values for Clear Aligner and Fixed Appliance Groups

Attribute	Aligner Mean (SD)	Fixed Mean (SD)	*P* Value*
No. of Scheduled Visits	13.7 (4.4)	19.3 (3.6)	.0001*
No. of Emergency Visits	0.8 (1.0)	3.62 (2.5)	.0001*
Treatment duration, mo	16.9 (5.7)	23.4 (4.4)	.0001*

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

DISCUSSION

This retrospective study assessed the outcomes of orthodontic treatment in adolescents with mild malocclusions, comparing results achieved with clear aligners to those achieved with fixed appliances in the practice of an orthodontist with 10 years of private practice experience with both treatment approaches. Based on ABO DI scores, there was no pretreatment difference between treatment groups in any of the characteristics of malocclusion. At the end of treatment, using the CRE scoring, a statistically significant 7 point–lower (better) overall mean score was found in the group treated with clear aligners relative to those treated with fixed appliances. Parameters assessed regarding treatment efficiency found that the aligner treatment group had shorter overall treatment times and fewer emergency visits. Thus, based on statistical comparisons, the null hypothesis of no difference between the two treatment groups was rejected for several of the assessments. Nevertheless, the 7-point overall difference in the CRE assessment is of debatable clinical significance, and a conservative interpretation would be that the two treatment approaches achieved comparable outcomes.

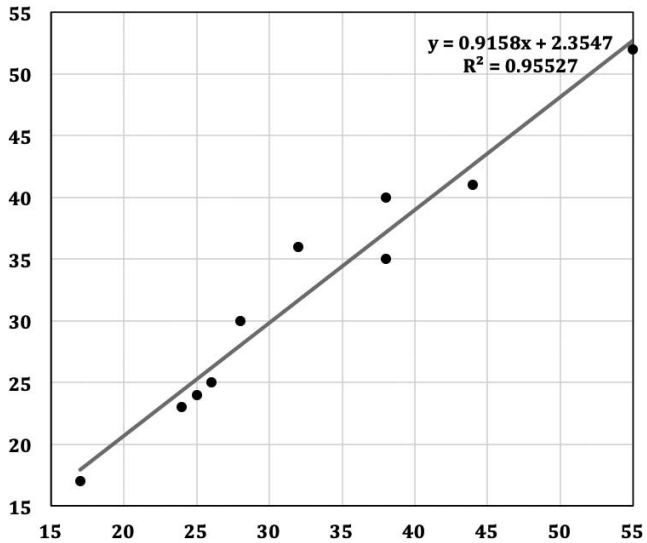

Figure 1. Intrarater reliability. Pearson correlation coefficient between initial and repeat measurements using the ABO CRE method.

Table 4. Objective Grading System (OGS) Scores Reflecting Mean Points and Standard Deviations (SDs) Recorded for Variations from Ideal in Clear Aligner and Fixed Appliance Groups

Attribute	Aligner Mean (SD)	Fixed Mean (SD)	*P* Value*
Alignment**	2.2 (2.1)	3.8 (2.6)	.03*
Marginal ridges**	3.6 (2.3)	3.9 (2.0)	.40
Buccolingual inclination**	5.9 (2.4)	7.2 (3.1)	.10
Occlusal contacts**	7.7 (5.3)	6.3 (3.8)	.39
Occlusal relations**	3.2 (2.7)	5.2 (3.6)	.04*
Overjet**	6.6 (4.1)	9.4 (3.4)	.01*
Interproximal contacts**	0.6 (1.1)	0.7 (1.1)	.77
Root angulations**	0.3 (0.6)	0.4 (0.6)	.52
OGS score***	30.1 (8.3)	37.0 (9.3)	.01*

* Statistically significant difference, $P < .05$; ** Individual categories (nonparametric) tested using Wilcoxon rank test; *** Overall OGS score (parametric) tested using unpaired *t*-test.

To assess validity of the treatment comparisons, characteristics of the two cohorts were evaluated to determine equivalency of the groups prior to the start of treatment. Comparisons of mean DI scores (overall and by category), age, and gender showed no differences. Within the limits of the ABO DI assessment method,[11] both groups exhibited similar severity of malocclusion, with most being mild and ranging up to moderate.

Regarding treatment efficiency, the clear aligner group finished treatment approximately 6 months sooner than the fixed appliance group (16.9 $\pm$ 5.7 vs 23.4 $\pm$ 4.4 months, respectively), and with fewer appointments (14 vs 19). The differences in treatment duration between treatment groups were consistent with the findings of Djeu et al.[6] and Gu et al.,[8] in which patients treated with clear aligners finished treatment in a significantly shorter time compared to those treated with fixed appliances (aligners: 16 and 13 months, respectively, vs fixed: 19 months for both studies).[6,8] On the other hand, the results differed from those of Li et al.[9] and Kuncio et al.,[7] who found no difference in treatment duration between aligner and fixed treatment groups. Findings of shorter treatment time using clear aligners in the current and previous studies may be related to the severity of the malocclusions in the various treatment samples.

Other factors may be related to the sequencing of mechanics commonly used with fixed appliances, during which the correction of particular aspects of malocclusions are not rigorously addressed until later in the treatment course, when stiffer archwires are engaged, for example, in correction of deep bites or antero-posterior discrepancies. With aligner treatment, such corrections can begin from initial aligner placement. Another factor that impacted treatment efficiency may be related to the number of emergency appointments; in the current study, this was on average one appointment with aligner treatment compared to 3.5 appointments with fixed appliances.

Analysis of posttreatment outcomes using the ABO CRE, in which points were added for less-than-ideal treatment results, showed significantly better (lower) scores for the clear aligner group (30.1 $\pm$ 8.3) compared to the fixed appliance group (37.0 $\pm$ 9.3). This differed from previous investigations,[6–8] in which outcomes with aligners were the same or less ideal than with fixed appliances. Treatment involving more severe malocclusions in previous studies[6,9] may have been a factor, as cohorts averaged higher DI scores that ranged from 18 to 26 points, compared to 12 points in the current study, and were therefore more likely pushing the limits of effective tooth movement using aligners. Previous investigations[6,9] found that clear aligner treatment had reduced efficiency with more challenging malocclusions and tooth movements. Improved results for clear aligner treatment in the current study may also have been due to the younger age of the patients. A common observation to orthodontists using fixed appliances is that tooth movement in adolescent patients progresses at a faster rate than is observed in adults, a difference that may be attributed to increases in bone density and decreases in osteoclastic activity with increasing age.[12–15] The more rapid bone modeling in adolescents may have disproportionately enhanced the efficiency of tooth movement using aligners relative to the progression obtained with fixed appliances. A third potential factor was that the orthodontist who provided treatment in the current study had relatively extensive experience treating with aligners. According to Boyd,[16] increased experience using computer-aided technology is imperative to the success of clear aligner therapy, such as in determining proper sequencing of tooth movements, tooth attachment design and placement, and prescribing overcorrection when needed for difficult tooth movements. Lastly, relative to earlier generations of aligners that were available at the time the previous studies were conducted, the current investigation used Invisalign's 5th and 6th generation of aligners that incorporated more current aligner materials, attachment designs, shape modifications aimed at deep bite correction, and advances in digital technology for programming tooth movement.[4]

In the current study, three of the 10 individual CRE categories showed significant differences between cohorts where the aligner group had reduced scores (improved outcomes), including alignment, occlusion, and overjet. An explanation for the improved results with aligners compared to fixed appliances may be attributed to the process involved in delivering case refinements used in the majority of patients treated with aligners. Imaging from the intraoral scans made in the

late stage of treatment would have allowed the orthodontist to clearly visualize and assess dental arch alignment and occlusion. Conversely, as is typical in orthodontic practices using fixed appliances, each patient did have tooth positions assessed and brackets repositioned based on a panoramic radiographic and clinical observations earlier in treatment. However, for those patients, no progress intraoral scans or models were obtained during finishing stages. It is likely that relying on direct clinical observation to determine all finishing refinements is more challenging in comparison to making such assessments with the aid of progress intraoral scans.

Five categories of the CRE that did not show significant differences between cohorts included buccolingual inclination, interproximal contacts, marginal ridges, occlusal contacts, and root angulation. The results were similar to those of Djeu et al.[6] and Kuncio et al.,[7] who showed that aligners and fixed appliances were equally effective at leveling arches, maintaining root angulation, and closing spaces.

A limitation of the current and previous studies[6,7] assessing treatment outcomes with aligners was that severe malocclusions for which tooth extractions were needed to manage the malocclusions were excluded. In addition, similar to several studies[6–8] discussed above comparing outcomes of aligners to fixed appliances, this was a retrospective study, with the possibility of biases influencing the outcomes. Although the DI scores showed that the cohorts were similar at pretreatment, the scoring process was not an all-encompassing measure of case difficulty. For example, there was only minimal consideration of the facial growth patterns.[17–19] Lastly, treatment results assessed in the current study were from the practice of one orthodontist with ABO certification who had a depth of experience treating with fixed appliances and clear aligners. In the future, conducting a larger, prospective randomized clinical trial involving multiple orthodontic practices would be of value in broadening the comparisons.

CONCLUSIONS

- When teenage orthodontic patients with mild malocclusions (mean DI: 11.9) were treated with either aligners or fixed appliances, ABO CRE objective measures of treatment results showed comparable outcomes for marginal ridge positioning, buccolingual inclination, interproximal contacts, and occlusal contacts.
- Treatment with clear aligners for mild malocclusions resulted in significantly better results in terms of the assessments of tooth alignment, occlusal relations, overjet, and overall CRE scoring.
- Regarding treatment efficiency, treatment with aligners showed more favorable outcomes for treatment duration, number of emergency visits, and number of overall appointments.

ACKNOWLEDGMENT

The authors wish to thank Dr Thikriat Al-Jewair, State University of New York at Buffalo, for her suggestions following proofreading of this manuscript.

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