Evaluation of Invisalign treatment effectiveness and efficiency compared with conventional fixed appliances using the Peer Assessment Rating (PAR) Index

THESIS

Presented in Partial Fulfillment of the Requirements for the Degree Master of Science in the Graduate School of The Ohio State University

By

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ABSTRACT

Introduction: The purpose of this retrospective case-control study was to compare the treatment effectiveness and efficiency of the Invisalign system and conventional fixed appliances in treating orthodontic patients with mild to moderate malocclusion in a graduate orthodontic clinic. Methods: Using the peer assessment rating (PAR) index, we evaluated pretreatment and posttreatment records of 48 Invisalign patients and 48 fixed appliances patients. Those two groups of patients were controlled for general characteristics and initial severity of malocclusion. We analyzed treatment outcome, duration and improvement between the Invisalign and fixed appliances groups. Results: The average pretreatment PAR score (United Kingdom weighting) was 20.81 for Invisalign and 22.79 for fixed appliances (P = 1.0000). Posttreatment weighted PAR scores between Invisalign and fixed appliances were not statistically different (P = 0.7420). On average, Invisalign finished 5.7 months faster than fixed appliances (P = 0.0040). The weighted PAR score reduction with treatment was not statistically different between the Invisalign and fixed appliances groups (P = 0.4573). All cases in both groups had more than 30% reduction in PAR score. Logistic regression analysis indicates the odds of achieving “great improvement” in Invisalign group was only 0.329 times the odds of achieving “great improvement” in the fixed appliances group after controlling for age (P = 0.0150). Conclusions: Our data show that both Invisalign and fixed appliances
were able to improve the malocclusion. Invisalign finished treatment faster than fixed appliances. However, it appears that Invisalign may not be as effective as fixed appliances in achieving “great improvement” in the malocclusion. This study might help clinicians to determine appropriate cases for Invisalign treatment.
Dedication

This document is dedicated to my wife Lin and my family.
ACKNOWLEDGEMENTS

I would like to thank my thesis committee, Dr. Toru Deguchi, Dr. Michael Beck, Dr. Henry Fields and Dr. Allen Firestone, for their support and guidance.

I would like to thank my co-residents and the faculty and staff of the Division of Orthodontics for supporting me in my education.

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CHAPTER 1

INTRODUCTION

Orthodontics has experienced great advances in technology over the last few decades. Use of vacuformed removable orthodontic appliances to move teeth has been documented since 1940s\(^1\). Kesling first introduced tooth positioner to move teeth\(^1\), which is often used today to refine the occlusion after fixed appliance treatment. In 1964, Nahoum published an article to describe his “vacuum formed dental contour appliance”\(^2\). In his system, he also utilized elastics and attachment apparatus which are still being used today and erroneously considered to be a revolutionary new tooth movement system. In the 1990s, Sheridan popularized the use of “Essix” overlay appliance either as a passive retainer or an active orthodontic appliance\(^3\).

The Invisalign system, introduced by Align Technology (Santa Clara, Calif) in 1999, involves moving teeth in increments with a series of removable clear polyurethane trays (“aligners”). The main feature that distinguishes the Invisalign system from those mentioned above is 3-D computer analysis and fabrication, which dramatically enhances the ability to manipulate teeth via a series of precise, small and directional movements\(^4\).

Over the past few years, Align Technology has been through exponential growth, with more than 3 million cases treated with Invisalign worldwide\(^5\). Patients prefer Invisalign treatment over conventional fixed appliances due to its superior esthetics\(^6\),
comfort\textsuperscript{7} and better oral hygiene\textsuperscript{8}. However, in the era of “evidence based dentistry”, the scientific evidence upon which to base the treatment of more than 3 million cases is limited. The most recent systematic review of clear aligners only identified eleven relevant scientific articles\textsuperscript{9}. Of those, six were published more than five years ago. And, no evidence-based conclusions can be drawn from those studies due to poor quality level\textsuperscript{9}.

Randomized clinical trials (RCT) have been conducted by one research group to evaluate the effects of aligner material stiffness and activation frequency on Invisalign treatment completion and outcome\textsuperscript{10-12}. The authors concluded patients with a 2-week activation protocol, no extractions, and a low initial Peer Assessment Rating (PAR) score were more likely to complete their initial series of aligners\textsuperscript{10}. This study supports Align Technology’s 2-week activation time recommendation and also suggests Invisalign is not suitable for extraction cases and complex treatment plans. Further, study by the authors reported fixed appliances will be needed in premolar extraction patients treated with aligners to correct dental tipping\textsuperscript{12}. The authors also concluded that the aligners were most successful in improving anterior alignment, transverse relationships and overbite, moderately successful in improving midline and overjet, and least successful in improving buccal occlusion\textsuperscript{11}.

Two retrospective comparative cohort studies compared the treatment results of Invisalign patients to those with braces using the American Board of Orthodontics’s (ABO) Objective Grading System (OGS)\textsuperscript{13,14}. The authors reported Invisalign patients lost 13 more OGS points on average than braces patients and achieved an ABO passing rate 27% lower than braces\textsuperscript{13}. The study indicated that Invisalign and braces are similar in
correcting rotations, marginal ridge heights, space closure and root alignment, but braces are superior in correcting occlusal contacts, posterior torque and A-P discrepancies\textsuperscript{13}. In their follow-up study on postretention dental changes of treated Invisalign patients, the authors reported that patients treated with Invisalign relapsed more than those treated with braces, particularly in the maxillary anterior alignment\textsuperscript{14}.

Nevertheless, all those studies were conducted during the early years of Invisalign system development when limitation existed in its material and techniques. With an evolving technology, there is a need for additional clinical studies to evaluate the biomechanics and treatment efficacy of the Invisalign system.

It is clear from Align Technology that individual clinicians are responsible for the treatment outcome of their patients with the Invisalign system. That makes it important to select appropriate patients based on evidence from clinical studies. Therefore, well-designed clinical trials are needed to provide evidence for contemporary Invisalign treatment\textsuperscript{15}.

An assessment of orthodontic treatment outcomes with a quantitative index helps to establish goals, evaluate efficacy, and achieve a measureable finish for completed patients. Several quantitative indexes have been developed to evaluate the malocclusion severity/orthodontic treatment need or treatment outcome\textsuperscript{16-20}. One of these indexes, the Peer Assessment Rating (PAR) index, has been used widely for evaluating the effects of treatment in a variety of circumstances\textsuperscript{21-23}. The PAR index is an occlusal index which not only measures how much a patient deviates from ideal occlusion, but also quantitatively evaluates orthodontic treatment outcomes by comparing pretreatment and posttreatment casts\textsuperscript{19,20}.
The purpose of this retrospective case-control study was to determine the efficacy and efficiency of the Invisalign system compared to conventional fixed appliances in treating orthodontic patients with mild to moderate malocclusion using PAR index. The specific aims were to compare (1) post treatment PAR scores between Invisalign and braces patients; (2) treatment reduction in PAR scores and treatment duration between Invisalign and braces patients; and (3) malocclusion improvement between Invisalign and braces patients after establishing two groups of Invisalign and braces patients with comparable pre-treatment characteristics.
CHAPTER 2

MATERIALS AND METHODS

The study protocol was reviewed and approved by The Ohio State University Institutional Review Board.

The sample for this retrospective case-control study was selected from approximately 1500 conventional orthodontic cases and 250 Invisalign cases in the archives of the Division of Orthodontics at The Ohio State University College of Dentistry. All patients were started and completed by orthodontic faculty and residents and finished between 2009 and 2014. The patients were chosen without regard to patient history or final treatment results. Selection was based on the following criteria: 1) available pre-treatment and posttreatment records included digital models (OrthoCad) and photos; 2) patients were 16 years of age or older when treatment started; 3) no auxiliary appliances other than elastics were used during treatment; 4) no extraction cases were included; 5) no orthognathic surgery or syndromic patients were included and 6) full permanent dentition except third molars. After initial review, 62 fixed appliances cases and 61 Invisalign cases met the above criteria. To match the pre-treatment malocclusion between the two groups and eliminate any early termination cases, 48 cases from each group were selected. With a non-directional alpha risk of 0.05 and an
estimated standard deviation of $4.3^{22}$, our power to detect a difference of $\pm 3$ units of weighted post PAR score was 0.92.

Patients in the fixed appliances group were treated with fixed orthodontic appliances with various prescriptions, but all appliances are straight wire Edgewise appliances.

The PAR index (United Kingdom (UK) weighted PAR which includes the mandibular anterior$^{24}$) was used in this study to assess 8 components: maxillary anterior segment alignment, mandibular anterior segment alignment, anteroposterior discrepancy, transverse discrepancy, vertical discrepancy, overjet, overbite, and midline.

Digital models were used to determine the PAR scores. Previous research has demonstrated that PAR index scores derived from digital models are valid and reliable measures of malocclusion$^{25}$. One investigator (Jack Tang) was trained and calibrated for the PAR index, and performed all the PAR measurements. This investigator (J.T.) was blinded to the group assignment (Invisalign or fixed appliances) to which the models belonged. Intraexaminer reliability was assessed with intraclass correlation coefficients (ICC) which were determined by a duplicate scoring of 12 randomly selected cases from each category (total 24 cases) 2 months after initial data collection.

In their original article to evaluate the PAR index, Richmond et al. determined that “at least a 30 percent reduction in PAR score was required for a case to be considered as improved and a change of 22 PAR points brought about great improvement”$^{19}$. However, not every case starts with PAR scores above 22. In order to be inclusive for all the cases, we redefined “great improvement” as either: (1) weighted PAR
score reduction of 22 points or more, or (2), if the initial PAR score was <22, a weighted PAR score after treatment equal to 0 (Table 4).

**Statistical analysis**

All statistical analyses were performed with SAS software (SAS, Cary, NC). Subject characteristics were compared for the 2 treatment groups using chi-square or Fisher exact tests for categorical variables and randomization test for continuous variables. Multiple comparisons were adjusted using the step-down Bonferroni method of Holm. The Fisher exact test was also used to compare the distribution of percent reduction of weighted PAR scores between the two groups.

Logistic regression was used to evaluate differences in great improvement outcome due to treatment group after controlling for age. The level of statistical significance for all analyses was set at $\alpha = 0.05$. 
CHAPTER 3

MANUSCRIPT

Evaluation of Invisalign treatment effectiveness and efficiency compared with conventional fixed appliances using the Peer Assessment Rating (PAR) Index

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ABSTRACT

Introduction: The purpose of this retrospective case-control study was to compare the treatment effectiveness and efficiency of the Invisalign system and conventional fixed appliances in treating orthodontic patients with mild to moderate malocclusion in a graduate orthodontic clinic. Methods: Using the peer assessment rating (PAR) index, we evaluated pretreatment and posttreatment records of 48 Invisalign patients and 48 fixed appliances patients. Those two groups of patients were controlled for general characteristics and initial severity of malocclusion. We analyzed treatment outcome, duration and improvement between the Invisalign and fixed appliances groups. Results: The average pretreatment PAR score (United Kingdom weighting) was 20.81 for Invisalign and 22.79 for fixed appliances (P = 1.0000). Posttreatment weighted PAR scores between Invisalign and fixed appliances were not statistically different (P =
On average, Invisalign finished 5.7 months faster than fixed appliances (P = 0.0040). The weighted PAR score reduction with treatment was not statistically different between the Invisalign and fixed appliances groups (P = 0.4573). All cases in both groups had more than 30% reduction in PAR score. Logistic regression analysis indicates the odds of achieving “great improvement” in Invisalign group was only 0.329 times the odds of achieving “great improvement” in the fixed appliances group after controlling for age (P = 0.0150). **Conclusions:** Our data show that both Invisalign and fixed appliances were able to improve the malocclusion. Invisalign finished treatment faster than fixed appliances. However, it appears that Invisalign may not be as effective as fixed appliances in achieving “great improvement” in the malocclusion. This study might help clinicians to determine appropriate cases for Invisalign treatment.

**INTRODUCTION**

The Invisalign system, introduced by Align Technology (Santa Clara, CA) in 1999, involves moving teeth in increments with a series of removable clear polyurethane trays (“aligners”). Over the past few years, Align Technology has seen significant growth, with more than 3 million cases treated with Invisalign worldwide¹. Patients prefer Invisalign treatment over conventional fixed appliances due to its superior esthetics², comfort³ and better oral hygiene⁴.

However, in the era of “evidence based dentistry”, the scientific evidence upon which to choose the treatment of more than 3 million cases is limited. The most recent systematic review of clear aligners only identified eleven relevant scientific articles⁵. Of
those, six were published more than five years ago. And, no evidence-based conclusions can be drawn from those studies due to poor quality level\textsuperscript{5}.

Randomized clinical trials (RCT) have been conducted by one research group to evaluate the effects of aligner material stiffness and activation frequency on Invisalign treatment completion and outcome\textsuperscript{6-8}. The authors concluded that patients with a 2-week activation protocol, no extractions, and a low initial Peer Assessment Rating (PAR) score were more likely to complete their initial series of aligners\textsuperscript{6}. This study supports Align Technology’s 2-week activation time recommendation and also suggests Invisalign is not suitable for extraction cases and complex treatment plans. Further, study by the authors reported fixed appliances will be needed in premolar extraction patients treated with aligners to correct dental tipping\textsuperscript{8}. The authors also concluded that the aligners were most successful in improving anterior alignment, transverse relationships and overbite, moderately successful in improving midline and overjet, and least successful in improving buccal occlusion\textsuperscript{7}.

Two retrospective cohort studies compared the treatment results of Invisalign patients with those with fixed appliances using the American Board of Orthodontics (ABO) Objective Grading System (OGS)\textsuperscript{9,10}. The authors reported Invisalign patients lost 13 more OGS points on average than fixed appliances patients and achieved an ABO passing rate 27\% lower than fixed appliances\textsuperscript{9}. The study indicated that Invisalign and fixed appliances are similar in correcting rotations, marginal ridge heights, space closure and root alignment, but that fixed appliances are superior in correcting occlusal contacts, posterior torque and A-P discrepancies\textsuperscript{9}. In their follow-up study on postretention dental changes of treated Invisalign patients, the authors reported that patients treated with
Invisalign relapsed more than those treated with fixed appliances, particularly in the maxillary anterior alignment\textsuperscript{10}.

Many of those studies were conducted several years ago before Align Technology introduced changes to the tray material, attachments and treatment algorithms. It seems reasonable to re-evaluate the effectiveness and efficiency of this very popular treatment system after the introduction of what the company calls significant advances in materials. Therefore, well-designed clinical trials are needed to provide evidence for contemporary Invisalign treatment\textsuperscript{11}.

An assessment of orthodontic treatment outcomes with a quantitative index helps to establish goals, evaluate effectiveness, and achieve a measureable finish for completed patients. Several quantitative indexes have been developed to evaluate the malocclusion severity/orthodontic treatment need or treatment outcome\textsuperscript{12-16}. One of these indexes, the Peer Assessment Rating (PAR) index, has been used widely for evaluating the effects of treatment in a variety of circumstances\textsuperscript{17-19}. The PAR index is an occlusal index which not only measures how much a patient deviates from ideal occlusion, but also quantitatively evaluates orthodontic treatment outcomes by comparing pretreatment and posttreatment casts\textsuperscript{15,16}.

The purpose of this retrospective case-control study was to determine the effectiveness and efficiency of the Invisalign system compared to conventional fixed appliances in treating orthodontic patients with mild to moderate malocclusion using PAR index. The specific aims were to compare patients treated with Invisalign and fixed appliances for: (1) posttreatment PAR scores; (2) posttreatment reduction in PAR scores; (3) treatment duration and (4) malocclusion improvement between Invisalign and fixed
appliances patients after establishing two groups of Invisalign and fixed appliances patients with comparable pre-treatment characteristics.

**MATERIALS AND METHODS**

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Patients in the fixed appliances group were treated with fixed orthodontic appliances with various prescriptions, but all appliances are straight wire Edgewise appliances.

The PAR index (United Kingdom (UK) weighted PAR which includes the mandibular anterior) was used in this study to assess 8 components: maxillary anterior segment alignment, mandibular anterior segment alignment, anteroposterior discrepancy, transverse discrepancy, vertical discrepancy, overjet, overbite, and midline.

Digital models were used to determine the PAR scores. Previous research has demonstrated that PAR index scores derived from digital models are valid and reliable measures of malocclusion. One investigator (J.T.) was trained and calibrated for the PAR index, and performed all the PAR measurements. This investigator (J.T.) was blinded to the group assignment (Invisalign or fixed appliances) to which the models belonged. Intraexaminer reliability was assessed with intraclass correlation coefficients (ICC) which were determined by a duplicate scoring of 12 randomly selected cases from each category (total 24 cases) 2 months after initial data collection.

In their original article to evaluate the PAR index, Richmond et al. determined that “at least a 30 percent reduction in PAR score was required for a case to be considered as improved and a change of 22 PAR points brought about great improvement”. However, not every case starts with PAR scores above 22. In order to be inclusive for all the cases, we redefined “great improvement” as either: (1) weighted PAR score reduction of 22 points or more, or (2), if the initial PAR score was <22, a weighted PAR score after treatment equal to 0 (Table 4).
Statistical analysis

All statistical analyses were performed with SAS software (SAS, Cary, NC). Subject characteristics were compared for the 2 treatment groups using chi-square or Fisher exact tests for categorical variables and randomization test for continuous variables. Multiple comparisons were adjusted using the step-down Bonferroni method of Holm. The Fisher exact test was also used to compare the distribution of percent reduction of weighted PAR scores between the two groups.

Logistic regression was used to evaluate differences in great improvement outcome due to treatment group after controlling for age. The level of statistical significance for all analyses was set at α = 0.05.

RESULTS

The calibrated examiner demonstrated good intra-examiner reliability (The ICC scores ranged from 0.66 for posttreatment overbite to ≥ 0.98 for the remaining variables).

The basic sample description and characteristics are presented in Table 1. The Invisalign group had a mean pretreatment age of 26.0 ± 9.7 years (average ± SD), while the fixed appliances group had a pretreatment age of 22.1 ± 7.9 years. This difference was statistically significant (P = 0.0374). The differences between the two groups for the following variables were not statistically different: sex, race/ethnicity, percentage of class I molar cases, percentage of retreatment cases (cases had previous orthodontic treatment) (P > 0.05, Table 1).

The mean weighted pretreatment PAR scores (PREWPAR) between the Invisalign and fixed appliances groups were not statistically different (P = 1.0000, Table
There were no statistically significant differences between the two groups for all the 8 individual components of pretreatment PAR scores (Table 2).

After treatment, weighted PAR scores (POSTWPAR) for both groups were less than 5 and did not differ significantly (P = 0.7420, Table 3). None of the 8 individual components of posttreatment PAR scores differed significantly between the two groups (Table 3).

Neither of the weighted PAR reduction (ΔWPAR) after treatment or the reduction scores of the 8 individual PAR components was statistically different between the two groups (Table 4). The treatment time for the Invisalign group (13.35 months) was significantly shorter than that for the fixed appliances group (19.08 months) (P = 0.0040, Table 4). To compare the treatment efficiency of the two groups, we evaluated ΔWPAR/month. The Invisalign group was not significantly different compared to fixed appliances group in reducing weighted PAR score per month of treatment (P = 0.2318, Table 4).

In our study, all cases in both groups were “improved”, i.e., at least a 30% reduction in PAR score. However, logistic regression analysis indicates that, using our definition of “great improvement” as either a reduction in PAR score of 22 points or a final PAR score of “0”, the odds of achieving “great improvement” in Invisalign group was 0.329 times as likely to achieve “great improvement” in the fixed appliances group after controlling age (95% confidence interval = 0.133/0.815, P = 0.0150, Table 5). We further analyzed the distribution of percent reduction in weighted PAR scores between the two groups. Our data indicated fixed appliances are significantly more effective to reduce weighted PAR scores than invisalign (P = 0.0322, Figure 1).
DISCUSSION

In our study, the patients in the Invisalign group were significantly older than those in the fixed appliances group, 26.0 years and 22.1 years, respectively. This might indicate that older people tend to prefer the cosmetic benefit of the Invisalign system and also that older people might feel more confident that they could wear their trays as directed. Walton et al.\textsuperscript{2} reported that older subjects tend to rate clear orthodontic appliances higher than did younger subjects. In our study, both the Invisalign and fixed appliances patients were older than 16 years, and had generally finished growth, so that it is unlikely that growth played a significant role in the treatment outcome. Djeu et al.\textsuperscript{9} also found that Invisalign patients are relatively older than fixed appliances patients. Otherwise, our treatment groups were balanced for all the other demographic components (sex, race/ethnicity, Class I molar relationship and retreatment percentage). Previous research\textsuperscript{22} indicates that more females choose Invisalign treatment, however in our study there was no statistical difference in sex between Invisalign and fixed appliances patients (P = 0.6695).

Our two treatment groups were comparable in malocclusion severity with regard to pretreatment weighted PAR scores and all its eight individual components (Table 2). The average weighted pretreatment PAR scores of our Invisalign and fixed appliances patients were similar to the study by Miller et al.\textsuperscript{23}, although only part of their patients were from a university clinic. Our fixed appliances patient weighted pretreatment PAR score was also comparable to previously reported dental school orthodontic patients\textsuperscript{24}. Thus, our sample seemed consistent with other reported groups of orthodontically treated patients. The Invisalign and fixed appliances patients in this study were treated by various
orthodontic residents under supervision of different orthodontic faculty. In contrast, the study by Djeu et al\textsuperscript{9} analyzed only the first 50 Invisalign patients treated by a single orthodontist. Therefore, our study provides greater generalizability.

The average weighted posttreatment PAR score of the Invisalign group was higher than that of the fixed appliances group by less than 2 points, which is not statistically different. None of the individual components of posttreatment PAR scores demonstrated a significant difference between the Invisalign group and the fixed appliances group. However, regarding deep overbite correction with either posterior extrusion or anterior intrusion, previous reports only recommend Invisalign to treat simple malocclusions with small overbite discrepancies\textsuperscript{5} and indicate significant correction of a deep overbite with Invisalign appears unlikely\textsuperscript{7,25}. Recently, Align Technology introduced Invisalign G5 with optimized attachments and precision bite ramps to improve deep overbite correction. However, this innovation was introduced after the time period covered in this sample, so its effect on the results of deep bite treatment is unknown. The PAR index does not differentiate between deep overbite and openbite. Boyd et al.\textsuperscript{26,27} reported that Invisalign may have advantages in correcting mild anterior openbite due to the intrusive effect on the posterior teeth from the double thickness of the aligner trays.

Another point to note is posttreatment overjet, although there were no statistical differences between the two groups, fixed appliances corrected the overjet in all the patients, but Invisalign still left some patients with significant overjet (maximum score: 12.00, Table 3). This result agrees with previous observations on overjet and A-P
correction by Invisalign. To overcome Invisalign’s deficiency in overjet and AP correction, auxiliary appliances might be utilized.

We further evaluated the appliance efficiency between Invisalign and fixed appliances by considering treatment duration. In our study, there was a statistically significant difference between the treatment duration of the two groups: Invisalign treatment was on average 5.7 months faster than the fixed appliances group (Table 4). This result is comparable to previous reports between Invisalign and fixed appliances on nonextraction treatment with mild to moderate malocclusion. However, the average reduction in weighted PAR score (ΔWPAR) is not significantly different between the two groups; neither was treatment efficiency (ΔWPAR/MOS).

Richmond et al. reported that at least a 30 percent reduction in PAR score is required for a case to be considered as “improved”. All the cases in our Invisalign and fixed appliances groups improved by at least 30 percent (Table 4 and Figure 1). The mean PAR score percentage reduction in our Invisalign group and fixed appliances group were 80.3% and 87.0% respectively. However, “a change of 22 PAR points” is needed to be considered as “great improvement”. Since not every case has more than 22 PAR points at pretreatment, in order to be inclusive of more of the cases, we redefined the “great improvement” to include those cases with pretreatment PAR score less than 22 points if their posttreatment PAR score was 0. Using this definition of “great improvement”, there were significantly more cases that were classified as “greatly improved” in the fixed appliances group (P = 0.0150, Table 4). Even if we consider only the cases with the original definition of “great improvement”, i.e., “a change of 22 PAR points”, there were 9 of 48 cases in the Invisalign group and 19 of 48 cases in the fixed
appliances group that met this definition. However, this difference did not reach statistical significance (P = 0.0628). The distribution of percent reduction in weighted PAR scores between the two groups further indicates fixed appliances is significantly more effective at reducing weighted PAR scores than Invisalign (P = 0.0322, Figure 1).

Previously, the mean accuracy of tooth movement with Invisalign was reported to be about 41%\(^2\), and they also reported 70% to 80% of clinicians need either midcourse correction, refinement, or conversion to fixed appliances to finish treatment\(^2\). Very recently, Simon et al.\(^2\) reported overall mean efficacy of tooth movement was 59%. They also demonstrated that incisor torque, premolar derotation and molar distalization can be performed using Invisalign\(^2\). In our study, the refinement rate for Invisalign is 37.5%, which is much lower than that reported previously\(^2\). This significant difference may reflect the improvement of the aligner material and attachment features, or may also indicate the increased clinician experience with the system.

Refinement features with the Invisalign system may partially account for the disparity in treatment effectiveness between Invisalign and fixed appliances. Treatment with fixed appliances is continuous. In contrast, treatment with Invisalign may be interrupted by requesting midcourse correction or refinement. Patients who choose Invisalign due to esthetic reasons may well also prefer shorter treatment time, thus more likely to prefer to avoid refinement or any fixed appliance treatment to complete difficult tooth movement. The higher PAR score and shorter treatment times may indicate greater patient autonomy with Invisalign treatment. The PAR index was developed based on the judgment of dental professionals and may not be fully concurrent with patient values.
There are several shortcomings with this study. Most significantly it is a retrospective study. This introduces selection bias. Only cases with complete records are included, so early termination cases due to poor co-operation or hygiene are excluded. Further, because Invisalign was introduced into the clinic only a few years before the period of this study, there were only a few clinicians familiar with the system and they had limited experience with it. Additionally, the residents who delivered care had much more experience with fixed appliances. Further, while developments in materials and protocols with fixed appliance systems have been very modest during and after the time period encompassed in this investigation, there have been major changes in materials and protocols to the Invisalign system after 2009 and the results of this study do not reflect them.

Like fixed appliances, Invisalign is capable of achieving outstanding outcomes with appropriate cases. However, the clinician’s orthodontic knowledge and clinical experience, and patient compliance and motivation all play significant role in the process. Practitioners with limited experience with Invisalign should be conservative in case selection with this system. Further research with randomized clinical trials is warranted to compare the treatment outcomes between Invisalign and fixed appliances.

**CONCLUSIONS**

This study examined the treatment effectiveness and treatment efficiency between Invisalign and fixed appliances with the weighted UK PAR index. Final occlusal scores did not differ between the two systems. Fixed appliances improved malocclusion more effectively than Invisalign. Treatment with Invisalign was finished on average 30% (5.7
months) faster than with fixed appliances. However, achieving “great improvement” in a malocclusion appears to be better with fixed appliances.

REFERENCES

CHAPTER 4

RESULTS

The calibrated examiner demonstrated good intra-examiner reliability (The ICC scores ranged from 0.66 for posttreatment overbite to $\geq 0.98$ for the remaining variables).

The basic sample description and characteristics are presented in Table 1. The Invisalign group had a mean pretreatment age of $26.0 \pm 9.7$ years (average $\pm$ SD), while the fixed appliances group had a pretreatment age of $22.1 \pm 7.9$ years. This difference was statistically significant ($P = 0.0374$). The differences between the two groups for the following variables were not statistically different: sex, race/ethnicity, percentage of class I molar cases, percentage of retreatment cases (cases had previous orthodontic treatment) ($P > 0.05$, Table 1).

The mean weighted pretreatment PAR scores (PREWPAR) between the Invisalign and fixed appliances groups were not statistically different ($P = 1.0000$, Table 2). There were no statistically significant differences between the two groups for all the 8 individual components of pretreatment PAR scores (Table 2).

After treatment, weighted PAR scores (POSTWPAR) for both groups were less than 5 and did not differ significantly ($P = 0.7420$, Table 3). None of the 8 individual components of posttreatment PAR scores differed significantly between the two groups (Table 3).
Neither of the weighted PAR reduction (ΔWPAR) after treatment or the reduction scores of the 8 individual PAR components was statistically different between the two groups (Table 4). The treatment time for the Invisalign group (13.35 months) was significantly shorter than that for the fixed appliances group (19.08 months) (P = 0.0040, Table 4). To compare the treatment efficiency of the two groups, we evaluated ΔWPAR/month. The Invisalign group was not significantly different compared to fixed appliances group in reducing weighted PAR score per month of treatment (P = 0.2318, Table 4).

In our study, all cases in both groups were “improved”, i.e., at least a 30% reduction in PAR score. However, logistic regression analysis indicates that, using our definition of “great improvement” as either a reduction in PAR score of 22 points or a final PAR score of “0”, the odds of achieving “great improvement” in Invisalign group was 0.329 times as likely to achieve “great improvement” in the fixed appliances group after controlling age (95% confidence interval = 0.133/0.815, P = 0.0150, Table 5). We further analyzed the distribution of percent reduction in weighted PAR scores between the two groups. Our data indicated fixed appliances are significantly more effective to reduce weighted PAR scores than invisalign (P = 0.0322, Figure 1).
In our study, the patients in the Invisalign group were significantly older than those in the fixed appliances group, 26.0 years and 22.1 years, respectively. This might indicate that older people tend to prefer the cosmetic benefit of the Invisalign system and also that older people might feel more confident that they could wear their trays as directed. Walton et al.\textsuperscript{6} reported that older subjects tend to rate clear orthodontic appliances higher than did younger subjects. In our study, both the Invisalign and fixed appliances patients were older than 16 years, and had generally finished growth, so that it is unlikely that growth played a significant role in the treatment outcome. Djeu et al.\textsuperscript{13} also found that Invisalign patients are relatively older than fixed appliances patients. Otherwise, our treatment groups were balanced for all the other demographic components (sex, race/ethnicity, Class I molar relationship and retreatment percentage). Previous research\textsuperscript{26} indicates that more females choose Invisalign treatment, however in our study there was no statistical difference in sex between Invisalign and fixed appliances patients ($P = 0.6695$).

Our two treatment groups were comparable in malocclusion severity with regard to pretreatment weighted PAR scores and all its eight individual components (Table 2). The average weighted pretreatment PAR scores of our Invisalign and fixed appliances
patients were similar to the study by Miller et al.\textsuperscript{27}, although only part of their patients were from a university clinic. Our fixed appliances patient weighted pretreatment PAR score was also comparable to previously reported dental school orthodontic patients\textsuperscript{38}. Thus, our sample seemed consistent with other reported groups of orthodontically treated patients. The Invisalign and fixed appliances patients in this study were treated by various orthodontic residents under supervision of different orthodontic faculty. In contrast, the study by Djeu et al\textsuperscript{13} analyzed only the first 50 Invisalign patients treated by a single orthodontist. Therefore, our study provides greater generalizability.

The average weighted posttreatment PAR score of the Invisalign group was higher than that of the fixed appliances group by less than 2 points, which is not statistically different. None of the individual components of posttreatment PAR scores demonstrated a significant difference between the Invisalign group and the fixed appliances group. However, regarding deep overbite correction with either posterior extrusion or anterior intrusion, previous reports only recommend Invisalign to treat simple malocclusions with small overbite discrepancies\textsuperscript{9} and indicate significant correction of a deep overbite with Invisalign appears unlikely\textsuperscript{11,29}. Recently, Align Technology introduced Invisalign G5 with optimized attachments and precision bite ramps to improve deep overbite correction. However, this innovation was introduced after the time period covered in this sample, so its effect on the results of deep bite treatment is unknown. The PAR index does not differentiate between deep overbite and openbite. Boyd et al.\textsuperscript{30,31} reported that Invisalign may have advantages in correcting mild anterior openbite due to the intrusive effect on the posterior teeth from the double thickness of the aligner trays.
Another point to note is posttreatment overjet, although there were no statistical
differences between the two groups, fixed appliances corrected the overjet in all the
patients, but Invisalign still left some patients with significant overjet (maximum score:
12.00, Table 3). This result agrees with previous observations on overjet and A-P
correction by Invisalign\textsuperscript{11,13}. To overcome Invisalign’s deficiency in overjet and AP
correction, auxiliary appliances might be utilized.

We further evaluated the appliance efficiency between Invisalign and fixed
appliances by considering treatment duration. In our study, there was a statistically
significant difference between the treatment duration of the two groups: Invisalign
treatment was on average 5.7 months faster than the fixed appliances group (Table 4).
This result is comparable to previous reports between Invisalign and fixed appliances on
nonextraction treatment with mild to moderate malocclusion\textsuperscript{13,26}. However, the average
reduction in weighted PAR score (\(\Delta WPAR\)) is not significantly different between the two
groups; neither was treatment efficiency (\(\Delta WPAR/MOS\)).

Richmond et al. reported that at least a 30 percent reduction in PAR score is
required for a case to be considered as “improved”\textsuperscript{19}. All the cases in our Invisalign and
fixed appliances groups improved by at least 30 percent (Table 4 and Figure 1). The
mean PAR score percentage reduction in our Invisalign group and fixed appliances group
were 80.3\% and 87.0\% respectively. However, “a change of 22 PAR points” is needed to
be considered as “great improvement”\textsuperscript{19}. Since not every case has more than 22 PAR
points at pretreatment, in order to be inclusive of more of the cases, we redefined the
“great improvement” to include those cases with pretreatment PAR score less than 22
points if their posttreatment PAR score was 0. Using this definition of “great
improvement”, there were significantly more cases that were classified as “greatly improved” in the fixed appliances group (P = 0.0150, Table 4). Even if we consider only the cases with the original definition of “great improvement”, i.e., “a change of 22 PAR points”, there were 9 of 48 cases in the Invisalign group and 19 of 48 cases in the fixed appliances group that met this definition. However, this difference did not reach statistical significance (P = 0.0628). The distribution of percent reduction in weighted PAR scores between the two groups further indicates fixed appliances is significantly more effective at reducing weighted PAR scores than Invisalign (P = 0.0322, Figure 1).

Previously, the mean accuracy of tooth movement with Invisalign was reported to be about 41%29, and they also reported 70% to 80% of clinicians need either midcourse correction, refinement, or conversion to fixed appliances to finish treatment29. Very recently, Simon et al.32 reported overall mean efficacy of tooth movement was 59%. They also demonstrated that incisor torque, premolar derotation and molar distalization can be performed using Invisalign32. In our study, the refinement rate for Invisalign is 37.5%, which is much lower than that reported previously29. This significant difference may reflect the improvement of the aligner material and attachment features, or may also indicate the increased clinician experience with the system.

Refinement features with the Invisalign system may partially account for the disparity in treatment effectiveness between Invisalign and fixed appliances. Treatment with fixed appliances is continuous. In contrast, treatment with Invisalign may be interrupted by requesting midcourse correction or refinement. Patients who choose Invisalign due to esthetic reasons may well also prefer shorter treatment time, thus more likely to prefer to avoid refinement or any fixed appliance treatment to complete difficult
tooth movement. The higher PAR score and shorter treatment times may indicate greater patient autonomy with Invisalign treatment. The PAR index was developed based on the judgment of dental professionals and may not be fully concurrent with patient values.

There are several shortcomings with this study. Most significantly it is a retrospective study. This introduces selection bias. Only cases with complete records are included, so early termination cases due to poor co-operation or hygiene are excluded. Further, because Invisalign was introduced into the clinic only a few years before the period of this study, there were only a few clinicians familiar with the system and they had limited experience with it. Additionally, the residents who delivered care had much more experience with fixed appliances. Further, while developments in materials and protocols with fixed appliance systems have been very modest during and after the time period encompassed in this investigation, there have been major changes in materials and protocols to the Invisalign system after 2009 and the results of this study do not reflect them.

Like fixed appliances, Invisalign is capable of achieving outstanding outcomes with appropriate cases. However, the clinician’s orthodontic knowledge and clinical experience, and patient compliance and motivation all play significant role in the process. Practitioners with limited experience with Invisalign should be conservative in case selection with this system. Further research with randomized clinical trials is warranted to compare the treatment outcomes between Invisalign and fixed appliances.

In conclusion, this study examined the treatment effectiveness and treatment efficiency between Invisalign and fixed appliances with the weighted UK PAR index. Final occlusal scores did not differ between the two systems. Fixed appliances improved
malocclusion more effectively than Invisalign. Treatment with Invisalign was finished on average 30% (5.7 months) faster than with fixed appliances. However, achieving “great improvement” in a malocclusion appears to be better with fixed appliances.
Table 1. Comparison of baseline characteristics between Invisalign and fixed appliances groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Treatment groups</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All (N=96)</td>
<td>Invisalign (N=48)</td>
</tr>
<tr>
<td>Age (y)</td>
<td>24.0 (9.0)</td>
<td>26.0 (9.7)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>62 (65%)</td>
<td>32 (67%)</td>
</tr>
<tr>
<td>Male</td>
<td>34 (35%)</td>
<td>16 (33%)</td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>African Ame.</td>
<td>16 (17%)</td>
<td>7 (15%)</td>
</tr>
<tr>
<td>Asian</td>
<td>4 (4%)</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Caucasian</td>
<td>73 (76%)</td>
<td>38 (79%)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>3 (3%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Class I molars</td>
<td>65 (68%)</td>
<td>35 (73%)</td>
</tr>
<tr>
<td>Retreatment</td>
<td>7 (7%)</td>
<td>4 (8%)</td>
</tr>
</tbody>
</table>
Table 2. Pretreatment PAR scores between Invisalign and fixed appliances groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Invisalign (N=48)</th>
<th>Fixed appliances (N=48)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mini.</td>
</tr>
<tr>
<td>UANT</td>
<td>5.25</td>
<td>2.07</td>
<td>1.00</td>
</tr>
<tr>
<td>LANT</td>
<td>4.65</td>
<td>2.41</td>
<td>0.00</td>
</tr>
<tr>
<td>AP</td>
<td>2.48</td>
<td>1.34</td>
<td>0.00</td>
</tr>
<tr>
<td>TRANS</td>
<td>0.17</td>
<td>0.66</td>
<td>0.00</td>
</tr>
<tr>
<td>VERT</td>
<td>0.02</td>
<td>0.14</td>
<td>0.00</td>
</tr>
<tr>
<td>OJ</td>
<td>5.75</td>
<td>5.25</td>
<td>0.00</td>
</tr>
<tr>
<td>OB</td>
<td>1.92</td>
<td>1.65</td>
<td>0.00</td>
</tr>
<tr>
<td>MID</td>
<td>0.58</td>
<td>1.65</td>
<td>0.00</td>
</tr>
<tr>
<td>PREWPAR</td>
<td>20.81</td>
<td>6.79</td>
<td>9.00</td>
</tr>
</tbody>
</table>

UANT, maxillary anterior segment alignment. LANT, mandibular anterior segment alignment. AP, anteroposterior discrepancy. TRANS, transverse discrepancy. VERT, vertical discrepancy. OJ, overjet. OB, overbite. MID, midline. PREWPAR, pretreatment weighted PAR.
Table 3. Posttreatment PAR scores between Invisalign and fixed appliances groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Invisalign (N=48)</th>
<th>Fixed appliances (N=48)</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mini.</td>
<td>Maxi.</td>
<td>Mean</td>
<td>SD</td>
<td>Mini.</td>
<td>Maxi.</td>
</tr>
<tr>
<td>PUANT</td>
<td>0.44</td>
<td>0.94</td>
<td>0.00</td>
<td>5.00</td>
<td>0.42</td>
<td>0.79</td>
<td>0.00</td>
<td>3.00</td>
</tr>
<tr>
<td>PLANT</td>
<td>0.04</td>
<td>0.20</td>
<td>0.00</td>
<td>1.00</td>
<td>0.08</td>
<td>0.35</td>
<td>0.00</td>
<td>2.00</td>
</tr>
<tr>
<td>PAP</td>
<td>2.06</td>
<td>1.29</td>
<td>0.00</td>
<td>4.00</td>
<td>1.69</td>
<td>1.27</td>
<td>0.00</td>
<td>4.00</td>
</tr>
<tr>
<td>PTRANS</td>
<td>0.06</td>
<td>0.43</td>
<td>0.00</td>
<td>3.00</td>
<td>0.06</td>
<td>0.43</td>
<td>0.00</td>
<td>3.00</td>
</tr>
<tr>
<td>PVERT</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.02</td>
<td>0.14</td>
<td>0.00</td>
<td>1.00</td>
</tr>
<tr>
<td>POJ</td>
<td>0.75</td>
<td>2.94</td>
<td>0.00</td>
<td>12.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>POB</td>
<td>0.56</td>
<td>0.90</td>
<td>0.00</td>
<td>2.00</td>
<td>0.17</td>
<td>0.56</td>
<td>0.00</td>
<td>2.00</td>
</tr>
<tr>
<td>PMID</td>
<td>0.17</td>
<td>0.81</td>
<td>0.00</td>
<td>4.00</td>
<td>0.25</td>
<td>0.98</td>
<td>0.00</td>
<td>4.00</td>
</tr>
<tr>
<td>POSTWPAR</td>
<td>4.08</td>
<td>4.35</td>
<td>0.00</td>
<td>19.00</td>
<td>2.69</td>
<td>2.23</td>
<td>0.00</td>
<td>9.00</td>
</tr>
</tbody>
</table>

PUANT, posttreatment maxillary anterior segment alignment. PLANT, posttreatment mandibular anterior segment alignment. PAP, posttreatment anteroposterior discrepancy. PTRANS, posttreatment transverse discrepancy. PVERT, posttreatment vertical discrepancy. POJ, posttreatment overjet. POB, posttreatment overbite. PMID, posttreatment midline. POSTWPAR, posttreatment weighted PAR.
Table 4. PAR score reduction after treatment and case improvement between Invisalign and fixed appliances groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Invisalign (N=48)</th>
<th>Fixed appliances (N=48)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mini.</td>
</tr>
<tr>
<td>∆WPAR</td>
<td>16.73</td>
<td>6.78</td>
<td>5.00</td>
</tr>
<tr>
<td>MOS</td>
<td>13.35</td>
<td>8.63</td>
<td>4.00</td>
</tr>
<tr>
<td>∆WPAR/MOS</td>
<td>1.55</td>
<td>0.80</td>
<td>0.25</td>
</tr>
<tr>
<td>∆UANT</td>
<td>4.81</td>
<td>2.09</td>
<td>1.00</td>
</tr>
<tr>
<td>∆LANT</td>
<td>4.60</td>
<td>2.44</td>
<td>0.00</td>
</tr>
<tr>
<td>∆AP</td>
<td>0.42</td>
<td>1.18</td>
<td>-2.00</td>
</tr>
<tr>
<td>∆TRANS</td>
<td>0.10</td>
<td>0.52</td>
<td>0.00</td>
</tr>
<tr>
<td>∆VERT</td>
<td>0.02</td>
<td>0.14</td>
<td>0.00</td>
</tr>
<tr>
<td>∆OJ</td>
<td>5.00</td>
<td>4.85</td>
<td>0.00</td>
</tr>
<tr>
<td>∆OB</td>
<td>1.35</td>
<td>1.76</td>
<td>-2.00</td>
</tr>
<tr>
<td>∆MID</td>
<td>0.42</td>
<td>1.70</td>
<td>-4.00</td>
</tr>
</tbody>
</table>

**Improved**: cases with at least a 30 percent reduction in PAR score. **Great Improvement**: either weighted PAR score reduction of 22 points or more, or weighted PAR score after treatment equal to 0.
Table 5. Logistic regression analysis for “great improvement” (either PAR reduction of 22 or to 0 if initial PAR < 22) with patient age as a random variable

<table>
<thead>
<tr>
<th>Type III Tests of Fixed Effects</th>
<th>Effect</th>
<th>Num DF</th>
<th>Den DF</th>
<th>Chi-Square</th>
<th>Pr &gt; ChiSq</th>
</tr>
</thead>
<tbody>
<tr>
<td>GROUP</td>
<td>1</td>
<td>93</td>
<td>5.92</td>
<td>0.015</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Odds Ratio Estimates</th>
<th>Comparison</th>
<th>Estimate</th>
<th>DF</th>
<th>95% Confidence Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>GROUP INVSLN vs. FIXED</td>
<td>0.329</td>
<td>93</td>
<td>0.133</td>
<td>0.815</td>
</tr>
</tbody>
</table>
Figure 1. Distribution of percent reduction in weighted PAR scores (WPAR) between Invisalign and fixed appliances groups