# COMPARISON OF FINISHED CASE QUALITY BETWEEN INVISALIGN VS. TRADITIONAL FIXED APPLIANCES – A RANDOMIZED CONTROL TRIAL

A Thesis

by

ERIC LIN

Submitted to the Office of Graduate and Professional Studies of
Texas A&M University
in partial fulfillment of the requirements for the degree of

MASTER OF SCIENCE

| | |
|---|---|
| Chair of Committee, | Peter Buschang |
| Committee Members, | Katie Julien |
| | Matthew Kesterke |
| Head of Department, | Larry Bellinger |

May 2020

Major Subject: Oral Biology

# ABSTRACT

The purpose of this study was to compare treatment outcomes between Invisalign and traditional fixed appliances using the Discrepancy Index and the ABO Objective Grading System, both at debond and 6 month retention.

This randomized controlled trial included 80 patients, recruited from the Texas A&M College of Dentistry orthodontic clinic, who were randomly assigned to either the aligner or the braces group. Three time points were examined: initial (T0), debond (T1), and 6 month retention (T2). At T1, there were 66 total patients, 32 aligner and 34 braces patients. The median age of aligner patients was 26.7 (IQR 9.8) and median age of braces patients was 25.9 (IQR 16.6). At T2 there were a total of 54 patients, 26 aligner and 28 braces patients. Subjects were analyzed at T0 using the ABO Discrepancy Index (DI score) , and at T1 and T2 using the ABO Objective Grading System (ABO-OGS score). All patients were treated by one ABO certified orthodontist and all measurements were completed by one examiner.

The median DI score for the aligner group was 4.5 and for the braces group was 7.0 ($p=0.015$), a statistically significant but clinically insignificant difference. At debond, there were no significant between group differences for total score ($p=0.158$) or any of the individual categories. At 6 month retention, there were also no significant between group differences for total score ($p=0.367$) or any of the individual categories. From debond to 6 month retention, the aligner group showed no significant changes in total score ($p=0.314$), and the braces group also showed no significant difference in total score ($p=0.169$). From T1 to T2, there were also no between group differences in score change between the aligner and brace group ($p=0.677$).

The braces group finished 0.4 years, or 4.8 months faster than the aligner group, a difference that was significant ($p<0.0001$). For simple orthodontic cases, is faster and more cost effective to treat with traditional fixed appliances over clear aligners.

# ACKNOWLEDGEMENTS

I would like to thank my committee chair, Dr. Peter Buschang, and my committee members, Dr. Katie Julien, and Dr. Matthew Kesterke for their guidance and support throughout the course of this research. I would like to thank Dr. Helder Jacob for helping to take and organize the patient records. Finally, I would like to thank all of the orthodontics residents for making our three years in residency an enjoyable and memorable experience.

# CONTRIBUTORS AND FUNDING SOURCES

## Contributors

The work was supervised by a thesis committee consisting of Dr. Peter Buschang and Dr. Katie Julien, of the Department of Orthodontics, and Dr. Matthew Kesterke of the Department of Biomedical Sciences. The statistical analyses were completed with the assistance of Dr. Buschang of the Department of Orthodontics. Patient records were completed with the assistance of Dr. Helder Jacob, formerly of the Department of Orthodontics. All other work conducted for the thesis was completed by the student independently.

## Funding Sources

This work was made possible by the Robert E. Gaylord Endowed Chair in Orthodontics and the Texas A&M College of Dentistry Office of Graduate Studies.

TABLE OF CONTENTS

Page

LIST OF FIGURES

Page

LIST OF TABLES

Page

# 1. INTRODUCTION

Traditionally, orthodontics has been primarily thought of as a treatment for younger, growing patients [8]. However, as time has gone on, both the appliances used and the patient demographics have drastically changed. An increasing number of adult patients have begun to seek treatment, and these patients often present with higher esthetic demands [9]. Thus, in recent years, heavy emphasis has been placed on developing appliances that are acceptable to these patients.

One of the most significant developments in orthodontics over the past 30 years has been the advent of clear aligner therapy [9]. Among the many options of clear aligners available, Invisalign is by far the most widely used [1]. Originally meant to treat mild to moderate cases, Invisalign has since been used to treat much more complex cases. These include open bites, cross bites, underbites, spacing, and even orthognathic surgery cases [11, 24]. In 2010, Invisalign developed Smartforce features and attachments, which they claim allows for both more accurate and a wider range of tooth movements.

With the increasing popularity of clear aligners, many studies have been conducted to assess what their capabilities and limitations are. Clear aligners have been found to be poor at intruding or extruding posterior teeth, poor at intruding incisors, but effective at extruding incisors during overbite corrections [4, 16, 19]. One of the most difficult movements for clear aligners to accomplish is derotation of teeth, especially canines and premolars, which are often cylindrical in shape [8,15,16,25]. These teeth often do not have adequate undercuts for the plastic to grab onto. Overall, studies have found that Clincheck also tends to greatly overestimate the amount of tooth movement that will be clinically expressed [16,25,57].

Adjunctive studies regarding clear aligners and braces have found that clear aligner patients tend to have better periodontal health, better hygiene, and lower oral bacterial counts during treatment than their braces counterparts [27,28,32,33]. Clear aligner patients also were shown to have less severe root resorption and less patient discomfort compared to braces patients [35,36,37]. Some studies have also shown that clear aligners can finish cases faster than braces [2,35].

### 1.1 Problem and Significance

The question that many clinicians face is whether to use clear aligners or traditional fixed appliances to treat their patients. To compare treatment outcomes, two widely accepted objective grading criteria are often used: PAR scores and ABO-OGS scores. Between the two, studies have found that ABO-OGS scoring is superior to PAR in accurately assessing deviations from ideal treatment outcomes [7,40,43,46]. ABO-OGS also asses both dental and radiographic results of orthodontic treatment, while PAR score only assess dental results[13].

However, the current literature that utilizes ABO-OGS scoring to compare treatment outcomes between clear aligners and braces is severely lacking. To date, there are only 2 published studies that look into this topic[1,47], and there is a lack of retention patients included in these studies. These studies were also conducted over 13 years ago, and Invisalign has had numerous advancements since then in both their materials and technologies. In addition, none of these studies was a randomized controlled trial, and both studies use flawed statistical methods to analyze their data.

## 1.2 Objectives

The purpose of this study is to evaluate the differences in treatment outcomes, both at debond and 6 month recall, between patients treated with Invisalign and fixed appliances, utilizing the ABO-OGS scoring criteria as laid out by the American Board of Orthodontics.

## 1.3 Hypotheses

Null Hypotheses:

1. There is no difference in treatment outcomes between Invisalign and braces patients at debond.

2. There is no difference in treatment outcomes between Invisalign and braces patients at 6 month retention.

# 2. LITERATURE REVIEW

As the desire of achieving the perfect "Hollywood" smile has increased over time, so has the desire for orthodontic treatment. Traditional orthodontics uses edgewise appliances. Born from the mind of Dr. Edward angle in 1925, the appliance has undergone numerous changes over the years. However, the 022 standard appliance that Angle described in the 1920's is fundamentally the same as the appliances used by many orthodontic clinicians today [20]. Over time though, patient demographics and expectations have changed.

The last 20-30 years has seen a drastic shift in orthodontics. Traditionally, orthodontics was thought of as a treatment primarily focusing on younger, growing patients. However, as time has gone on, social norms have changed. Keeping a youthful appearance has become increasingly important in the western world, and maintaining teeth and a pleasant smile has become more desirable [8]. Thus, today's orthodontic population is comprised of a greater number of adult patients [9]. These adult patients often present with higher esthetic and comfort demands than their younger counterparts. Many adult patients have esthetic concerns during treatment, and are not willing to accept the traditional metal braces appearance. For example, it has been shown that traditional brackets are acceptable to 55-58% of adults, but alternative appliances such as aligners or lingual braces were acceptable to over 90% of adults surveyed [10]. Adults are also willing to pay, on average, an additional $610 for these alternative appliances [10].

One of the most significant developments in orthodontics over the past 30 years has been the advent of clear aligner therapy. The history of clear aligners can be traced back to 1945, when an orthodontist named Harold Kelsing invented the tooth positioner [58]. The appliance was made of rubber and worn on both arches. Used in conjunction with fixed appliances, it was

meant to help speed up treatment. The 1960's – 70's saw the advent of plastic splints meant for minor tooth correction. By the 1980's plastic was replaced with silicone and for the first time, tooth movements of up to a 3mm could be achieved [58]. However, by far the biggest breakthrough in clear aligner technology came in the 1990's. In 1996, Sassani et al. developed a computer controlled system for partial automation of the fabrication of upper-mouth orthodontic appliances [59]. This allowed an engineer to take digital information of a patient's dentition, and fabricate an accurate acrylic model. With this technology, appliances could be fabricated without having to take alginate impressions on the patient or pour up stone models. In 1997 Align Technology introduced one of the first and most popular clear aligner therapies, Invisalign [1]. Originally designed for minimal to moderate treatment [4], providers have since used Invisalign for more complex cases. According to Align Technology, Invisalign has the ability to treat open bites, deep bites, cross bites, under bites, spacing, and crowding. Some providers have even advocated that Invisalign can effectively treat complex multi jaw orthognathic surgical cases [11, 24]. Since its inception, Invisalign has had numerous improvements to their materials and technologies. One of Invisalign's main innovations were SmartForce features and attachments, which were introduced in 2010. The company claims that these are engineered to deliver customized force systems for more predictable tooth movements and are positioned more precisely to deliver necessary forces while eliminating interferences [26].

It should be noted that due to Invisalign's stature as the first and most popular commercially available clear aligner therapy, and the fact that almost all existing literature on clear aligner therapy utilizes Invisalign, the terms are used interchangeably here. One of the reasons the vast majority of clear aligner research has been conducted using Invisalign is due to the large number of patents protecting their intellectual property [60]. At their height, Invisalign

had over 400 patents. However, on Oct 2017, the first of 40 key patents expired, and from 2018 and beyond an average of 23 patents will expire a year. Many of these patents involve the critical step of the planning phase of clear aligners. Thus, recently more clear aligner companies have appeared on the market. One of the newest and popular choices is 3M Clarity aligners, made by the 3M Company [39]. Another up and coming clear aligner modality are in house aligners made off of 3D printed models [38]. Proponents of in house aligners state that they can help reduce costs and give the doctor full control of all tooth movements and attachments.

### 2.1 Capabilities and Limitations of Clear Aligners

With such an increased public demand for clear aligner therapy, many studies have been conducted to assess the capabilities and limitations of clear aligners [4,8,15,16,19,25,27]. Khosravi et al found that Invisalign was relatively successful in managing overbites, with most of the correction being accomplished with extrusion or intrusion of incisors [4]. For open bite corrections, they found that posterior teeth did not significantly intrude, and that the correction was accomplished mainly through incisor extrusion. For deep bites, improvement was accomplished primarily through proclination of mandibular incisors [4]. This is consistent with other studies showing that intrusion of incisors is a difficult movement with Invisalign [16, 19]. When leveling, much of the movement is accomplished with incisor proclination rather than purely incisor intrusion. A systematic review by Rossini et al found that Clincheck was only 45% accurate in predicting actual intrusion of maxillary incisors, and only 47% accurate at predicting actual intrusion of mandibular incisors [8].

One of the most difficult movements to perform with aligners is the derotation of a cylindric tooth because thermoplastic appliances tend to lose anchorage and slip off due to the

presence of few undercuts and a round tooth shape [8, 15, 16, 25, 57]. The amount of rotation clinically expressed after treatment has been reported to be far less than anticipated by Clincheck [16, 25, 57]. Rossini et al found that predicted maxillary canine rotation accuracy is 32-36%, while for mandibular canines it is only 29% [8]. The same study found rotational accuracy for premolars to range from 23% to 41.8%. Thus, it is a common clinical practice to compensate for this by planning for over rotation of canines and premolars in the Clincheck.

When it comes to bodily movement of teeth with Invisalign, studies have found that Clincheck tends to overestimate the amount of bodily movement and underestimate the amount of tipping. In the transverse dimension, Houle et al found the mean accuracy of expansion planned with Invisalign for the maxilla was 72.8% while the lower arch presented an overall predicted accuracy of 87.7% [18]. The authors thus recommended overexpansion in the posterior maxillary region. For anterior-posterior movement of molars, Simon et al found that Invisalign is effective in controlling upper molar bodily movement when a distalization of at least 1.5 mm has been prescribed, with 87% of predicted movement being achieved [57]. When it comes to extraction cases, Dai et el found that in maxillary first premolar extraction cases treated with Invisalign's G6 extraction protocol, first molars achieved greater mesial tipping, greater mesial translation, and more intrusion than predicted. Central incisors achieved less retraction and greater lingual crown torque and extrusion than predicted [17]. Overall, the authors found that first molar anchorage control and central incisor retraction were not fully achieved as predicted in first premolar extraction treatment with Invisalign [17], even when utilizing the newest Invisalign technologies and protocols.

## 2.2 Adjunctive Studies: Clear Aligners vs Braces

Apart from tooth movement, many studies have examined other aspects regarding treatment with clear aligner therapy. When it comes to periodontal health, a meta-analysis done by Jiang et al found that clear aligners were better for periodontal health than fixed appliances, suggesting that aligners should be recommended for patients with high risk of developing gingivitis [28]. Periodontal health indices (i.e. gingival index, papillary bleeding index, bleeding on probing, probing pocket depth) were 15%% - 46% better with clear aligners compared to fixed appliances [27, 33]. Overall, patients treated with removable appliances display better compliance with oral hygiene, less plaque, and fewer gingival inflammatory reactions than their counterparts with fixed appliances [32]. On a more microscopic level, Sifakakis et al discovered that patients treated with clear aligners had 37% lower salivary levels of S. sanguinis compared to those treated with fixed appliances [34]. This is significant because Streptococcus sanguinis is a pioneering colonizer and a key player in oral biofilm development and may also facilitate the attachment of succeeding pathogens associated with periodontitis[58].

The improved hygiene associated with clear aligner therapy also helps to reduce other complications associated with poor oral hygiene. Patients treated with aligners have less risk of developing white spot lesions than do patients treated with traditional braces. Buschang et al found that approximately 1.2% of the aligner patients develop WSLs, compared to 26% of traditionally treated patients [31].

Another negative iatrogenic consequence often associated with orthodontic treatment is root resorption. Fang et al found that while clear aligners do not prevent external root resorption during treatment, both the incidence and severity of external root resorption appear to be lower compared with results reported by studies for fixed appliance therapy [29]. Clear aligners have an

8% less incidence and 86% less severity of root resorption compared to fixed appliances. This could be due to intermittent force systems associated with clear aligner therapy, as a force is not constantly applied to a tooth at each given moment [23, 29].

Clear aligner therapy has also been shown to have shorter treatment times than fixed appliances [2, 35]. Buschang et al found that compared to clear aligners, fixed appliances required more visits (approximately 4.0), a longer treatment duration (5.5 months), more emergency visits (1.0), greater emergency chair time (7.0 minutes), and greater total chair time (93.4 minutes) [35]. However, they also found that clear aligners showed significantly greater total material costs and required significantly more total doctor time than fixed appliances [35].

Patient discomfort has also been shown to be decreased with clear aligner therapy. White et al found that patients treated with fixed appliances reported 237% more discomfort and consumed 277% more analgesics in the first week after bonding for dental pain than patients treated with clear aligners [36]. Fixed appliance patients also reported significantly more discomfort than aligner patients after the first and second month adjustment appointments[36]. Braces patients reported 372% greater discomfort after the first month adjustment and 221% greater discomfort after the second month adjustment compared to aligner patients. Almasoud et al had similar results, and found that fixed patients reported 513% greater pain in the first week of treatment compared to aligner patients. One thing to note is that pain for both treatment groups peaked at 24 hours and was lowest on day 7, indicating that discomfort does decrease post adjustment regardless of treatment modality [37].

However, not all studies reflect positively on clear aligner therapy. A systematic review and meta- analysis found that, despite claims, concrete evidence about the effectiveness of clear aligners is generally lacking [8,30,62]. Most studies have significant bias, and there is a lack of well-

designed randomized control trials[8,62]. The authors found that shortened treatment duration and reduced chair time in mild- to- moderate cases appear to be the only significant effectiveness of clear aligners over conventional systems that are supported by the current evidence [30]. There were no significant differences in terms of quality of treatment outcomes and stability of treatment. Pogal et al found that wearing Invisalign aligners has a negative impact on the articulation of consonants [22]. Fricative alveolar consonants are the primary phonemes impacted by aligner wear. Due to the fact that the efficacy of Invisalign treatment is based primarily on compliance and that speech impairment may interfere with compliance, difficulties with speech may negatively impact a patient's compliance with Invisalign treatment [22]. Another systematic review and meta-analysis by Papageorgiou et al found that orthodontic treatment with aligners is associated with overall worse treatment outcomes compared to fixed appliances[62].

It should be noted that some of these studies were conducted before Invisalign's newest technology and protocols were implemented, so it is important to have more up to date research regarding these topics.

### 2.3 Objective Scoring Comparisons of Invisalign and Fixed Appliances

The dilemma that providers face is whether to use clear aligners or traditional fixed appliances to better treat their patients. To help answer this question, it is vital that providers have a body of evidence showing which method produces better treatment outcomes. The answer to this question, depends on methods to objectively evaluate a set of records and determine how far the pretreatment and post treatment records deviate from ideal. One of the earliest and widely used evaluation methods is the Peer Assessment Rating index (PAR score) [3, 42]. It is used to quantitatively evaluate treatment outcomes by comparing pretreatment and post-treatment casts

[7]. PAR scores were developed in the UK to assess occlusion at any stage of development. It is a measure of occlusal change that assigns scores to (1) alignment of the dentition (including impactions), (2) buccal segment relationship, (3) overjet, (4) overbite, and (5) midline discrepancy. It is applied to pretreatment and posttreatment dental casts and the change in PAR scores thus reflects the treatment effect on the dental occlusion and alignment[44]. At least a 30 % reduction in PAR score is required for a case to be considered as 'improved', and a decrease of 22 total points is considered 'great improvement' [13, 41]. The PAR score has good reliability and validity, but has difficulty distinguishing minor inadequacies. The main criticisms of PAR scores are for leniency with residual extraction space, unfavorable incisor inclination, and rotations. PAR also excludes many important aspects of malocclusion, such as root angulation or parallelism, spacing or crowding of buccal segments[6, 13]. PAR scores also place a disproportional weight on overjet and AP discrepancy. A Class I malocclusion may be scored as having a 'Great' deviation from normal occlusion by an expert panel, yet its weighted pre-treatment PAR might be only 15 points. Correction of the malocclusion to an ideal occlusion (reduction of PAR score to 0) would still fall short of a 'Greatly improved' result [45].

The deficiencies regarding PAR scores led the American Board of Orthodontics (ABO) to develop an alternative method to assess case treatment quality, the American Board of Orthodontics Cast-Radiograph Evaluation. The pretreatment records are scored using the Discrepancy Index (DI score). The DI score was developed in 1998 at a meeting of 8 ABO directors along with 6 former directors [12]. The DI score is based on 10 criteria: overjet, overbite, anterior open bite, lateral open bite, crowding, occlusion, lingual posterior crossbite, buccal posterior crossbite, cephalometric values, and a "other" criteria [6, 7]. Post treatment case quality was evaluated using the Objective Grading System (ABO-OGS). The ABO-OGS has 8 criteria:

alignment, marginal ridge height, buccolingual inclination, occlusal relationship, occlusal contact, overjet, interproximal contact, and root angulation [13]. Measurements are done using a standardized ABO measuring gauge. A score <27 points is considered a passing score on the American Board of Orthodontics exam.

The ABO-OGS assesses both dental and radiographic results of orthodontic treatment [13]. Many studies have been carried out to evaluate the reliability of ABO-OGS scoring, and most agree that it provides an effective method for objective assessment of orthodontic treatment outcomes [7]. Onyeaso et al found that compared to 3 other scoring indices, including PAR, ABO-OGS is the best at detecting deviations from the ideal in completed cases [40]. Liu et al found that using professional judgment as an outcome variable, multiple regression analysis showed that PAR index and ABO-OGS were capable of predicting 62 per cent and 73 percent , respectively, of the total variance in the clinical judgment of malocclusion severity [43, 46]. Overall, the American Board of Orthodontics Cast-Radiograph Evaluation is considered one of the most professional standards measurements – designed for specialist training and board examination in the USA [3].

With standardized methods of scoring and evaluating cases, it has become possible to conduct studies evaluating differences between patients treated with Invisalign and conventional fixed appliances. Some studies have utilized the PAR score to assess treatment outcomes while others have used the ABO-OGS. Despite the ABO-OGS being the more comprehensive scoring system [6, 7, 12, 13] , there is still merit to reviewing studies that use both.

Gu et al (2017) used PAR scores to compare pre and posttreatment outcomes in patients treated with Invisalign vs fixed appliances [2]. The study was a retrospective cohort study that included 48 aligner and 48 braces patients. All patients were treated nonextraction. The mean age

was 26.0 ± 9.7 for aligner patients and 22.1 ± 7.9 for braces patients. The mean weighted pretreatment PAR scores between the Invisalign and fixed appliances groups were not statistically different and there were no statistically significant differences between the 2 groups for the 8 individual components of pretreatment PAR scores. Immediately after treatment, weighted PAR scores for both groups were less than 5 and did not differ significantly. None of the 8 individual components of posttreatment PAR scores differed significantly between the groups. The authors also found that Invisalign patients finished on average 5.7 months faster. However, despite Invisalign being faster, logistic regression analysis found that odds of achieving "great improvement" in the Invisalign group were only 0.33 times the odds of achieving "great improvement" in the fixed appliances group after controlling for age. "Great improvement" was defined as either a reduction in PAR score of 22 points or a final PAR score of 0. It should be noted that both groups had more than 30% reduction in PAR score[2].

There are currently 2 studies comparing patients using the ABO-OGS scoring system. Djeu et al (2005) conducted a retrospective cohort study consisting of 48 aligner and 48 braces patients. All patients were treated nonextraction and has similar DI scores before treatment, with Invisalign patients having a mean DI score of 18.67 (SD 8.62) and braces patients having a mean score of 19.85 (SD 10.87), a difference which was not statistically significant (p=0.9066). The average age of the aligner group was 33.6 ± 11.8 and the average age of the braces group was 23.7 ± 11.0. Djeu et al found that Invisalign lost on average 13 ABO-OGS points more than braces patients [1]. The overall passing rate for the Invisalign group (20.8%) was 27.1% lower than the passing rate for the braces group (47.9%), and the difference was statistically significant (p=.0052). Invisalign patients had an average OGS score of 45.35 (SD 15.56) and braces patients had an average score of 32.21 (SD 11.73), which was statistically significant (p=0.0001).

Braces patients scored significantly better than Invisalign patients for 4 categories: buccolingual inclination, occlusal contacts, occlusal relationships, and overjet. Invisalign patients did finish 4 months earlier. The study concluded that Invisalign is not as good at correcting large AP discrepancies and occlusal contacts. The authors suggested that Invisalign was good for space closure, correcting anterior rotations, and leveling marginal ridge heights.

One of the problems with this study was that in 2004, when the patients were treated, Invisalign was not recommended for cases with severe deep bite, AP corrections greater than 2 mm, derotating severely rotated teeth, or premolar extraction cases. Since 2004, Invisalign has made numerous modifications to their materials, software and protocols. New options such as virtual bite ramps and specially designed optimized attachments have increased number of movements possible [4]. Another flaw with the study is the lack of retention visits. To fully compare treatment outcomes and extrapolate if one is better than the other, it is vital to also compare treatment stability. The only way to accomplish this is to take records at follow-up visits.

To date, only one study has examined treatment outcomes between Invisalign and fixed appliances patients with ABO-OGS scoring, while also including retention visits [47]. Kuncio et al (2007) conducted a retrospective cohort study with 11 aligner and 11 braces patients. All patients were treated nonextraction. No DI score was given for T0. Rather patients were standardized using gender, ethnicity, retainer wear, mean ages at T1 and T2, treatment length, and postretention length. No significant differences were found between the Invisalign and braces groups for these variables. The average age of aligner patients was 33.97 $\pm$ 8.98 and 26.79 $\pm$ 12.12 for braces patients. The authors had records at 3 time points: T0 (initial), T1 (appliance removal), and T2 (3 years post appliance removal). No statistically significant differences were

found between the Invisalign group and braces group at T1. Both groups showed that total alignment and mandibular anterior alignment worsened postretention (T2); maxillary anterior teeth alignment worsened only in the Invisalign group. Overall, the changes in total alignment, as measured by the ABO OGS, were significantly worse postretention in patients treated with Invisalign than in patients treated with conventional fixed appliances. For all other categories, there were no statistically significant differences at T2. However, despite having a 3-year retention time point, two main flaws exist with this paper. As with the previous study, Invsialign has made significant advancements since publication of this paper (2007). Also, at T2 there were only 11 patients who returned for their retention visit. A larger sample size of retention patients would help us feel more confident in drawing conclusions about the stability of Invisalign vs. fixed appliances.

It is important to examine cases post retention because many clinicians believe that some aspects of the occlusion "settle" after treatment, even if ideal relationships have been established[56]. This suggests that evaluation systems might be overly critical of some posttreatment results. Nett et al conducted a study of 100 randomly chosen post retention patients. Pretreatment peer assessment rating (PAR) scores and posttreatment and postretention OGS scores were measured on study casts [56]. All post retention records were taken at least 10 years post treatment. The authors found that mean scores for all ABO categories improved except alignment, which got worse. After 10+ years post treatment, overall ABO-OGS scores improved by an average of 4 points . This study indicates that settling does occur after treatment [56], further reinforcing the importance of including retention patients in objective comparison studies.

The next question that needs to be addressed is how long after debond to take post retention records to assure that adequate settling has occurred. Varga et al found that settling of the occlusion reaches its peak 10 weeks after the removal of orthodontic appliances [51]. Thus, future studies that want to examine retention should have postretention records taken at least 10 weeks posttreatment to assure enough time has elapsed for settling. Bauer et al found that the most significant changes for settling occur in the first 2 months, but that settling continues up to 6 months [61.] They also found that at 8 months there is no longer significant settling [61]. Thus, is it reasonable to use a 6 month retention checkup to account for the changes in OGS scoring after settling has occurred.

There is currently only 1 randomized control trial that compares treatment outcomes of Invisalign and fixed appliances using the ABO-OGS scoring system [55]. The study was conducted in 2015 by Li et al and involved extraction patients who all had a DI score of at least 25. The study had 76 Invisalign and 76 braces patients. However, the study was retracted by the publishing journal due to plagiarism and problems with unsubstantiated data and scientific misconduct. Thus, the results from this study were excluded from this literature review.

Despite there being previous research comparing treatment outcomes of Invisalign and fixed appliances, further research is needed [8,57]. A systematic review of the literature on this topic, published in November 2014, found that most of the current studies had methodological problems, such as a small sample size, bias and confounding variables, lack of method error analysis, blinding in measurements, and deficient or missing statistical methods [8]. The review concluded that quality level of the studies was not sufficient to draw any evidence-based conclusions about whether Invisalign or fixed appliances provided better treatment outcomes [8].

To date there is not a randomized control trial examining the treatment outcomes of

Invisalign vs fixed appliances using the ABO-OGS grading system. Furthermore, none of the existing studies are recent enough to incorporate Invisalign's newest technology. Another problem is that the one study which includes retention patients does not have a substantial number of patients. This study looks to address these gaps in the literature. More specifically, this RCT will include patients treated with Invisalign's newest technology, a 6 month retention check, and a greater number of retention patients than any previous study that utilizes DI and ABO-OGS scores to assess quality of case outcomes.

# 3. MATERIALS AND METHODS

## 3.1 Data collection

The present study was designed as a randomized controlled trial. Eighty patients were recruited from screenings at the Graduate Orthodontic Clinic of Texas A&M College of Dentistry and advertisements on the school website. To be selected for the study, patients had to meet the following criteria:

Inclusion Criteria: class 1 molar and canine relationships, non-extraction treatments, mandibular crowding of 4 mm or less, no missing teeth (from second molar to second molar)

Exclusion criteria: anterior or posterior crossbites, anterior or lateral open bites, maxillary overjet exceeding 4 mm, impacted teeth

Of the 80 patients, 14 patients had to be excluded from the study for the following reasons: 2 had no final models, 4 had no final panoramic radiographs, 5 dropped out prior to completion of treatment, and 3 had no initial cephs (Figure 1). Among the patients that completed the study, 24 were male and 42 were female. There were 32 Invisalign and 34 braces patients. Median age of Invisalign patients was 26.7 years (IQR 9.8) and median age of braces patients was 25.9 years (IQR 16.6) (Figure 2A). Of the patients that completed treatment, 54 returned for their 6-month retention visit, including 26 Invisalign and 28 braces.

### 3.1.1 Sample Allocation

Power analyses were performed using descriptive statistics reported by Djeu et al (2) and Kuncio et al (16), who evaluated Invisalign treatment outcomes. The analysis assumed a clinically meaningful group difference of 10 OGS points, which is the range reported by the

American Board of Orthodontics for distinguishing between acceptably and not acceptably treated cases. Using an Alpha error of 0.05, it was estimated that 31 subjects per group were needed to achieve a power of 90%, with an effect size of 0.76.

Prior to the treatment portion, patient randomization and statistical analyses was performed. An excel spreadsheet was used to generate the random assignment of patients to treatment groups (Invisalign or fixed appliances). Group assignments were sealed in an envelope and placed in a binder that examiners do not have access to. The study was approved by the institutional IRB #2012-21-BCD-FB and informed consent was obtained from all patients and parents.

### 3.2 Treatment Protocols

All patients were treated at the faculty practice in the Orthodontics Department at Texas A&M College of Dentistry by an ABO certified orthodontist.

#### 3.2.1 Invisalign

A series of custom made clear aligners are fabricated specifically for each patient. The patients in this study were instructed to wear each tray 22 hours per day, and to change trays every 2 weeks. To monitor progress, patients were evaluated at 4 week intervals. After informed consent was obtained, a full set of diagnostic records (intra and extraoral photos, panoramic radiograph, lateral ceph radiograph, and plaster models) were taken at the first appointment. At the second appointment, an intraoral scan was taken using an iTero scanner and sent to Align Technology . The Clincheck digital model was then used to fabricate a treatment plan**.** After the aligners arrived, two pairs of aligners were delivered and patients were instructed to wear each

aligner for 2 weeks. Checkup appointments were scheduled every 4 weeks. If correction of malocclusion was not deemed to be satisfactory, patients were brought in for a refinement scan to fabricate additional aligners. Each aligner patient had at least one refinement scan, but no more than two refinement scans. At the debond appointment, final records (same as initial records) were taken. One month after the completion of treatment, patients were seen for a retainer check and new photographs were taken**.** At the 6 month retention check visit, another set of full records was taken.

### 3.2.2 Traditional Fixed Appliances

Traditional fixed appliances used in this study consisted of 0.018" x 0.028" Radiance MBT prescription brackets in the maxillary arch and 0.018" x 0.028" Alexander LTS brackets with Alexander prescription in the mandibular arch. A sequence of niti (.014", .016" and .016" x .022") and stainless steel (.016" x .022" and .017" x .025") wires was used according to the progress of malocclusion correction. A combination of elastic O-rings and stainless steel ligatures were used to tie archwires into the brackets. To monitor progress of treatment, patient was seen every 4 weeks.

After informed consent was obtained, initial diagnostic records were taken at the first appointment. At the second appointment, fixed appliances were bonded to the maxillary and mandibular teeth for leveling and alignment. Adjustment appointments were scheduled every 4 weeks until the malocclusions were corrected. Once good occlusion had been achieved, brackets were debonded, and at debond appointment final records were taken. One month after the completion of treatment, patients were seen for a retainer check and photographs**.** At the 6 month retention check visit, another set of alginate impressions and photographs was taken.

### 3.2.3 Retention

At the completion of treatment, patients were retained with upper wrap around Hawley and lower extended Gemini retainers. If severe lower incisor irregularity was present at pretreatment, patients were also retained with a bonded lower 3-3 fixed retainer. If a diastema was present at start of treatment, patients were retained with an additional bonded upper 2-2 fixed retainer**.** Thirteen patients received both a bonded lower 3-3 and an upper 2-2 fixed retainer, 12 braces patients and 1 Invisalign patient Thirty seven patients received just a bonded lower 3-3 retainer, 17 braces patients and 20 Invisalign patients. One braces patient received only an upper 2-2 fixed retainer. In total, 29 braces patients and 22 Invisalign patients received fixed retention. Two other patients received bonded retainers at the 6 month retention visit, but this would not influence the final or 6 month records.

## 3.3 Records Protocol

The data was derived from the following records. Plaster models were made from deep alginate impressions

- Intraoral and extraoral photos according to ABO standards
- Panoramic radiograph
- Lateral cephalometric radiograph in maximum intercuspation, traced in dolphin imaging using ABO 2012 ceph analysis
- Complete health/medical history
- Three time points were included in study: T0 (initial), T1 (final), T2 (6 months retention).

### 3.3.1 Measurements

Each patient's initial Discrepancy Index score, was determined based on initial ceph and T1 models. DI calculations were completed as defined by the American Board of Orthodontics with the individual categories as follows: : overjet, overbite, anterior open bite, lateral open bite, crowding, occlusion, lingual posterior crossbite, buccal posterior crossbite, cephalometric values, and a "other" criteria [6,7].

The primary outcome variable examined was the difference in quality of case finishes between Invisalign vs. fixed appliance patients, assessed using ABO OGS scores. Each of the ABO-OGS components was examined along with the overall score, both at T1 and at T2. Scoring was conducted as outlined by the American Board of Orthodontics[12]. A standardized ABO measuring gauge was utilized for all cast measurements to allow for greatest accuracy possible. The independent variable was the patient treatment method, being either Invisalign or fixed appliances. Secondary outcome variables examined included between-group differences in treatment time (T0-T1) and differences within each treatment modality group from T1-T2.

There was one examiner. Intra-examiner reliability was demonstrated by having the examiner score 8 randomly selected casts, then rescoring those casts 2 weeks later. The examiner was blinded to whether each set of casts was an Invisalign case, or a fixed appliance case. The examiner was calibrated in this manner for both DI scores and for ABO-OGS scores. This process was repeated a second time with another 8 randomly selected casts to further ensure intra-examiner reliability. A reliability of over 90% was achieved.

All cephalograms for DI calculations were digitally traced by one investigator using Dolphin Imaging software and traditional cephalometric landmarks as defined by the American

Board of Orthodontics. Cephalometric analysis was completed using the ABO 2012 Analysis within Dolphin.

### 3.3.2 Statistical Methods

Based on the skewness and kurtosis statistics, many of the variables were not normally distributed. The variable's central tendencies and dispersion were described using medians and interquartile ranges. The Mann Whitney U test was used to evaluate differences in both total scores along with scores for each individual category. The same test was used to evaluate group differences in treatment times.

# 4. RESULTS

## 4.1 Intragroup Comparison

The median alignment score of the Invisalign group increased from 2.0 (IQR 3.75) at T1 to 3.5 (IQR 3.5) at T2. The buccolingual inclination score decreased from a median of 2.0 at T1 (IQR 2.0) to 1.0 (IQR 2.25) at T2. The overjet score for this group increased from a median of 1.0 (IQR 3.0) at T1 to 2.0 (IQR 4.25) at T2. The occlusal relationship score decreased from a median of 2.0 (IQR 4.0) at T1 to 1.5 (IQR 4.0) at T2. The changes for these 4 categories were statistically significant ($p < 0.05$). The Invisalign group showed no statistically significant changes from T1 to T2 for marginal ridges, occlusal contacts, interproximal contacts, root angulation, and overall OGS score for the Invisalign group (Table 5).

The median alignment scores of the braces group increased from 3.0 (1.0; 4.0) at T1 to 3.0 (2.0; 5.75) at T2. Buccolingual inclination decreased from a median of 2.0 (2.0; 4.0) at T1 to 2.0 (IQR 0.0; 2.0) at T2. Both of these changes were statistically significant ($p < 0.05$). There were no statistically significant between-group differences in the changes from T1 to T2 for marginal ridges, occlusal contacts, overjet, interproximal contacts, root angulation, occlusal relationships, and total OGS score for the braces group (Table 5).

Average treatment time from initial records to debond for the Invisalign group was 1.7 years (IQR 0.7) and 1.3 years (IQR 0.7) for the braces group (Figure 3), which was a statistically significant difference ($p< 0.05$). Patient ages at T1, at T2, and total retention time (T1-T2), showed no statistically significant between-group differences. (Table 1).

### 4.2 Group Comparison

The median DI scores for the Invisalign and braces group were 4.5 (IQR 6.0) and 7.0 (IQR 5.0), respectively (Figure 4). This difference was statistically significant ($p<0.05$). At the end of treatment (T1), Invisalign scored better for alignment, occlusal contacts, overjet, and root angulation while braces scored better for marginal ridges . However, none of these differences were statistically significant. There were almost no differences between the two groups for buccolingual inclination, interproximal contacts, and occlusal relationships. Overall, there were no statistically significant between-group differences at debond (T1) for alignment, marginal ridges, buccolingual inclination, occlusal contacts, overjet, interproximal contacts, root angulation, occlusal relationships, or overall OGS score (Table 2). The overall OGS scores at the end of treatment were 12.0 (IQR 18.0) and 17.0 (IQR 12.0), for the Invisalign and braces groups, respectively, a difference that was not statistically significant ($p=0.158$) (Figure 5).

At the 6 month retention visit, Invisalign scored better for buccolingual inclination, occlusal contacts, overjet, root angulation, and occlusal relationships, while braces scored better for alignment and marginal ridges. There were almost no differences between the two groups for interproximal contacts. However, none of these differences were statistically significant. Overall, there were no statistically significant between-group differences at T2 (Table 3) for alignment, marginal ridges, buccolingual inclination, occlusal contacts, overjet, interproximal contacts, root angulation, or occlusal relationships, as well as the overall OGS score (Figure 6). The overall OGS scores at the 6 month recall were 12.5 (IQR 9.25) and 14.5 (IQR 12.5), for the Invisalign and braces groups, respectively, a difference that was not statistically significant ($p=0.367$) (Figure 6).

Between T1 and T2, braces patients had improvements in buccolingual inclination, occlusal contacts, occlusal relationships, and overall OGS score. Braces patients saw minimal changes for marginal ridges, overjet, interproximal contacts, and root angulation. Invisalign patients got worse for alignment but improved for occlusal relationships. Also, Invisalign patients had minimal changes for marginal ridges, buccolingual inclination, occlusal contacts, overjet, interproximal contacts, root angulation, and total OGS scores. However, there were no statistically significant between-group differences in the changes that occurred between the end of treatment (T1) and the 6 -month recall visit (T2) (Table 4) for alignment, marginal ridges, buccolingual inclination, occlusal contacts, overjet, interproximal contacts, root angulation, occlusal relationships, and total OGS score (Figure 7). The overall OGS score changes from T1 to T2 were 0.0 (IQR 6.5) and -1.5 (IQR 8.5), for the Invisalign and braces groups, respectively, a difference that was not statistically significant (p=0.677) (Figure 7).

# 5. DISCUSSION

In the present study, the patients who were treated with braces finished 0.4 years (4.8 months) faster than the aligner patients. In contrast, Gu et al (2017) found that Invisalign patients finished on average 5.7 months faster than braces patients [2], and Buschang et al found aligner patients finished on average 5.5 months faster than braces patients [35]. There are several possible reasons why Invisalign patients in the present study took longer to complete treatment than braces patients. In the present study, compliance throughout treatment was much more important for the aligner than braces patients. All of the patients started treatment with Class 1 molars and canines, minimal crowding, no major overjet, and no open bites, which negated much of the need for anteroposterior and vertical corrections. These corrections typically require patient compliance, as elastics wear is often necessary. In contrast, compliance could very well have been a problem for many of the aligner patients in the present study, resulting in an extended treatment duration. Moreover, previous studies did not specify whether there were refinements. The Invisalign patients in the present study had 1-2 refinements, which could easily add weeks to months onto treatment duration.

Initial case difficulty cannot explain this difference in treatment time. Parris et al found that each point increase of the DI resulted in an average increased treatment duration of 11 days[63]. However, the braces patients in the present study actually started out with a higher average DI score (7.0) than the aligner patients (4.5) and yet they finished 4.8 months faster. While the difference in DI was statistically significant, it was minimal. Based on ABO discrepancy index guidelines, a DI score of 7-15 is considered mild, 16-24 is moderate, and 25 or

greater is considered to be severe[1]. While the difference in DI was statistically significant, a DI difference of 2.5 is not clinically significant.

There were also no significant between-group differences for total OGS score, or for any of the OGS component scores at debond. Kuncio et. al also found no significant differences between braces and aligners for overall OGS scores or OGS component scores [47]. They reported that aligner patients finished with an average OGS score of 39.5 while the braces patients finished with an average OGS score of 43.0, a difference that was not statistically significant. Their findings were similar to the present study, in finding no significant differences between aligner and braces patients, but their patients finished treatment with poorer occlusions. Given the discrepancy in final scores, it is likely that their patients started treatment with more severe malocclusions. Another reason for the difference in scores between the two studies can be attributed to each study having a different clinician treating the cases. Two different clinicians can have drastically treatment standards, but the standards would likely be the same for their own patients, whether they were treated with aligners or braces.

In contrast, Djeu et al found that braces patients had significantly better post treatment buccolingual inclination, occlusal contacts, occlusal relationships, overjet, and total OGS scores than aligner patients [1]. Their aligner patients finished with an average OGS score of 45.4 and their braces patients finished with an average score of 32.2. These differences could be that due to the fact that cases in present study were less complex at the start, and discrepancies in each category were much lower to begin with. The patients in Djeu's study had starting DI scores that were 14.1 and 12.9 points higher than the aligner and braces patients in the present study, respectively. The fact that their braces patients finished with lower OGS scores than their aligner

patients could be due to the study not utilizing the newest materials and technologies that are now available for Invisalign.

The present study found that 6 months post retention, there were no between-group differences for aligners and braces patients for component scores or total OGS scores. Kuncio et al also found no significant between-group differences at retention for the component and total OGS scores. Both their study and the present study showed decreases in total OGS and component scores, while the P values in both studies increased [47]. This shows that both groups had better occlusal results after retention, and that the between-group differences gradually decreased post debond.

In the present study, alignment and overjet worsened in the aligner groups from T1-T2, while buccolingual inclination and occlusal relationships improved. Total OGS score slightly worsened, but this change was not statistically significant. Nett et al also found that alignment got worse during retention, while all of the other components, including overall score, slightly improved [56]. A possible explanation for the present study having more statistically significant component changes could be the low initial DI score for aligner patients. These cases were relatively simple, so at the end of treatment the component scores might be expected to be very low. A slight change in a given category might register as statistically significant, but not necessarily clinically significant. However, the cases treated by Kuncio and coworkers were likely much more difficult, requiring greater changes to register as statistically significant.

Braces patients in the present study showed a significant worsening of alignment, but a significant improvement in buccolingual inclination. Kuncio also reported a worsening of alignment among braces patients during retention. For all other components, they showed improvements, but none of the changes were statistically significant, including changes in total

OGS score [47]. Given that the two studies likely had cases with very different complexities, it is interesting to note that changes during retention between the two were quite similar, and consistent with what is reported for settling by Nett's study.

Based on ABO discrepancy index guidelines, a DI score of 7-15 is considered mild, 16-24 is moderate, and 25 or greater is considered to be severe [1]. On that basis, the patients in the present study would be classified as mild complexity while the patients in Djeu et al's study would be classified as moderate. Djeu's patients finished on average in 1.4 years and 1.7 years for aligner and braces, respectively, a difference that was statistically significant. The patients in the present study finished in 1.7 years for aligners and 1.3 years for braces, which was also a significant difference. However, while Djeu's aligner patients finished quicker, they also finished to a significantly poorer result than their braces patients. The present study found that aligner and braces patients finished to the same quality of result.

The cases in the present study were treated to an excellent result, with overall and component OGS scores much lower than those previously reported at debond (T1). Djeu et al had average total OGS scores of 45.4 and 32.2 for aligners and braces patients, respectively (Figure 7). Kuncio et al had average total OGS scores of 39.5 and 43.0 for aligner and braces patients, respectively. The present study had median total OGS scores of 12.0 and 17.0 for aligner and braces patients, respectively. The present study also found much lower component scores compared to what is reported in the literature, likely reflecting that the cases were simpler to begin with.

# 6. CONCLUSIONS

1. There are differences in the duration of treatment between aligners and braces.

2. Aligners can produce the same occlusal results as traditional brace at debond (T1).

3. Following 6 month recall (T2), there are no differences in occlusal results between aligners and braces.

4. There are significant intragroup differences for OGS components during retention, but not for total OGS scores.

5. Simple cases can be finished over a shorter time period with braces

6. Excellent treatment results are possible for simple cases treated either with aligners or braces.

7. Clinical Implication: For simple orthodontic cases, it is faster and more cost effective to treat with traditional fixed appliances over clear aligners.

# REFERENCES


1. Djeu G, Shelton C, Maganzini A. Outcome assessment of Invisalign and traditional orthodontic treatment compared with the American Board of Orthodontics objective grading system. American Journal of Orthodontics and Dentofacial Orthopedics. 2005;128(3):292-298.
2. Gu J, Tang JS, Skulski B, et al. Evaluation of Invisalign treatment effectiveness and efficiency compared with conventional fixed appliances using the Peer Assessment Rating index. American Journal of Orthodontics and Dentofacial Orthopedics. 2017;151(2):259-266.
3. Hong M, Kook Y-A, Kim M-K, Lee J-I, Kim H-G, Baek S-H. The Improvement and Completion of Outcome index: A new assessment system for quality of orthodontic treatment. The Korean Journal of Orthodontics. 2016;46(4):199.
4. Khosravi R, Cohanim B, Hujoel P, et al. Management of overbite with the Invisalign appliance. American Journal of Orthodontics and Dentofacial Orthopedics. 2017;151(4).
5. Vincent S. Evaluation of Invisalign treatment utilizing the American Board of Orthodontics Objective Grading System for dental casts. American Journal of Orthodontics and Dentofacial Orthopedics. 2005;127(2):268-269.
6. Cansunar HA, Uysal T. Relationship between pretreatment case complexity and orthodontic clinical outcomes determined by the American Board of Orthodontics criteria. The Angle Orthodontist. 2014;84(6):974-979.

7. Vu CQ, Roberts WE, Hartsfield JK, Ofner S. Treatment complexity index for assessing the relationship of treatment duration and outcomes in a graduate orthodontics clinic. American Journal of Orthodontics and Dentofacial Orthopedics. 2008;133(1).
8. Rossini G, Parrini S, Castroflorio T, Deregibus A, Debernardi CL. Efficacy of clear aligners in controlling orthodontic tooth movement: A systematic review. The Angle Orthodontist. 2015;85(5):881-889.
9. Melsen B. Northcroft Lecture: How has the spectrum of orthodontics changed over the past decades? Journal of Orthodontics. 2011;38(2):134-143.
10. Rosvall MD, Fields HW, Ziuchkovski J, Rosenstiel SF, Johnston WM. Attractiveness, acceptability, and value of orthodontic appliances. American Journal of Orthodontics and Dentofacial Orthopedics. 2009;135(3).
11. Taub DI, Palermo V. Orthognathic surgery for the Invisalign patient. Seminars in Orthodontics. 2017;23(1):99-102.
12. Cangialosi TJ, Riolo ML, Owens S, et al. The ABO discrepancy index: a measure of case complexity. American Journal of Orthodontics and Dentofacial Orthopedics. 2004;125(3):270-278.
13. Casko JS, Vaden JL, Kokich VG, et al. Objective grading system for dental casts and panoramic radiographs. American Journal of Orthodontics and Dentofacial Orthopedics. 1998;114(5):589-599.
14. Owens S, Buschang PH, Throckmorton GS, Palmer L, English J. Masticatory performance and areas of occlusal contact and near contact in subjects with normal occlusion and malocclusion. American Journal of Orthodontics and Dentofacial Orthopedics. 2002;121(6):602-609.

15. How accurate is Invisalign in non-extraction cases? Are predicted tooth positions achieved? British Dental Journal. 2018;224(3):156-156.

16. Charalampakis O, Iliadi A, Ueno H, Oliver DR, Kim KB. Accuracy of clear aligners: A retrospective study of patients who needed refinement. American Journal of Orthodontics and Dentofacial Orthopedics. 2018;154(1):47-54.

17. Dai F-F, Xu T-M, Shu G. Comparison of achieved and predicted tooth movement of maxillary first molars and central incisors: First premolar extraction treatment with Invisalign. The Angle Orthodontist. 2019;89(5):679-687.

18. Houle J-P, Piedade L, Todescan R, Pinheiro FHSL. The predictability of transverse changes with Invisalign. The Angle Orthodontist. 2017;87(1):19-24.

19. Duncan LO, Piedade L, Lekic M, Cunha RS, Wiltshire WA. Changes in mandibular incisor position and arch form resulting from Invisalign correction of the crowded dentition treated nonextraction. The Angle Orthodontist. 2016;86(4):577-583.

20. Vaden JL. A century of the edgewise appliance. APOS Trends in Orthodontics. 2015;5:239-249.

21. Costa AA, Ferreira MC, Serra-Negra JM, Pordeus IA, Paiva SM. Impact of wearing fixed orthodontic appliances on oral health-related quality of life among Brazilian children. Journal of Orthodontics. 2011;38(4):275-281.

22. Pogal-Sussman-Gandia CB, Tabbaa S, Al-Jewair T. Effects of Invisalign® treatment on speech articulation. International Orthodontics. 2019;17(3):513-518.

23. Papadopoulou AK, Cantele A, Polychronis G, Zinelis S, Eliades T. Changes in Roughness and Mechanical Properties of Invisalign® Appliances after One- and Two-Weeks Use. Materials. 2019;12(15):2406.

24. Kankam H, Madari S, Sawh-Martinez R, Bruckman KC, Steinbacher DM. Comparing Outcomes in Orthognathic Surgery Using Clear Aligners Versus Conventional Fixed Appliances. Journal of Craniofacial Surgery. 2019;30(5):1488-1491.

25. Papadimitriou A, Mousoulea S, Gkantidis N, Kloukos D. Clinical effectiveness of Invisalign® orthodontic treatment: a systematic review. Progress in Orthodontics. 2018;19(1).

26. SmartForce features - Amazon S3. https://s3.amazonaws.com/learn-invisalign/docs/SmartForce Features and Attachments_en-gb-en.pdf.

27. Rossini G, Parrini S, Castroflorio T, Deregibus A, Debernardi CL. Periodontal health during clear aligners treatment: a systematic review. The European Journal of Orthodontics. 2014;37(5):539-543.

28. Jiang Q, Li J, Mei L, et al. Periodontal health during orthodontic treatment with clear aligners and fixed appliances. The Journal of the American Dental Association. 2018;149(8).

29. Fang X, Qi R, Liu C. Root resorption in orthodontic treatment with clear aligners: A systematic review and meta-analysis. Orthodontics & Craniofacial Research. 2019;22(4):259-269.

30. Zheng M, Liu R, Ni Z, Yu Z. Efficiency, effectiveness and treatment stability of clear aligners: A systematic review and meta-analysis. Orthodontics & Craniofacial Research. 2017;20(3):127-133.

31. Buschang PH, Chastain D, Keylor CL, Crosby D, Julien KC. Incidence of white spot lesions among patients treated with clear aligners and traditional braces. The Angle Orthodontist. 2019;89(3):359-364.

32. Abbate G, Caria M, Montanari P, et al. Periodontal health in teenagers treated with removable aligners and fixed orthodontic appliances. Journal of Orofacial Orthopedics. 2015;76(3):240-250.

33. Karkhanechi M, Chow D, Sipkin J, et al. Periodontal status of adult patients treated with fixed buccal appliances and removable aligners over one year of active orthodontic therapy. The Angle Orthodontist. 2013;83(1):146-151.

34. Sifakakis I, Papaioannou W, Papadimitriou A, Kloukos D, Papageorgiou SN, Eliades T. Salivary levels of cariogenic bacterial species during orthodontic treatment with thermoplastic aligners or fixed appliances: a prospective cohort study. Progress in Orthodontics. 2018;19(1).

35. Buschang PH, Shaw SG, Ross M, Crosby D, Campbell PM. Comparative time efficiency of aligner therapy and conventional edgewise braces. The Angle Orthodontist. 2014;84(3):391-396.

36. White DW, Julien KC, Jacob H, Campbell PM, Buschang PH. Discomfort associated with Invisalign and traditional brackets:A randomized, prospective trial. The Angle Orthodontist. 2017;87(6):801-808.

37. Almasoud NN. Pain perception among patients treated with passive self-ligating fixed appliances and Invisalign® aligners during the first week of orthodontic treatment. The Korean Journal of Orthodontics. 2018;48(5):326.

38. Werner A. 3D Printing and In-house Aligners. Orthodontic Products. https://www.orthodonticproductsonline.com/treatment-products/aligners/3d-printing-house-aligners/. Published September 12, 2019.

39. Types of Braces and Treatment. 3M. https://www.3m.com/3M/en_US/types-of-braces-and-treatment-us/.

40. Onyeaso CO, Begole EA. Relationship between index of complexity, outcome and need, dental aesthetic index, peer assessment rating index, and American Board of Orthodontics objective grading system. American Journal of Orthodontics and Dentofacial Orthopedics. 2007;131(2):248-252.

41. Richmond S, Shaw WC, Roberts CT, Andrews M. The PAR Index (Peer Assessment Rating): methods to determine outcome of orthodontic treatment in terms of improvement and standards. The European Journal of Orthodontics. 1992;14(3):180-187.

42. Kerr WJS, Buchanan IB, Mccoll JH. Use of the PAR Index in Assessing the Effectiveness of Removable Orthodontic Appliances. British Journal of Orthodontics. 1993;20(4):351-357.

43. Liu S, Oh H, Chambers DW, Xu T, Baumrind S. Interpreting weightings of the peer assessment rating index and the discrepancy index across contexts on Chinese patients. European Journal of Orthodontics. 2017;40(2):157-163.

44. Deguzman L, Bahiraei D, Vig K, Vig P, Weyant R, Obrien K. The validation of the Peer Assessment Rating index for malocclusion severity and treatment difficulty. American Journal of Orthodontics and Dentofacial Orthopedics. 1995;107(2):172-176.

45. Hamdan A. An appraisal of the peer assessment rating (PAR) index and a suggested new weighting system. The European Journal of Orthodontics. 1999;21(2):181-192.

46. Liu S, Oh H, Chambers DW, Baumrind S, Xu T. Validity of the American Board of Orthodontics Discrepancy Index and the Peer Assessment Rating Index for

comprehensive evaluation of malocclusion severity. Orthodontics & Craniofacial Research. 2017;20(3):140-145.

47. Kuncio D, Maganzini A, Shelton C, Freeman K. Invisalign and Traditional Orthodontic Treatment Postretention Outcomes Compared Using the American Board of Orthodontics Objective Grading System. The Angle Orthodontist. 2007;77(5):864-869.

48. Buschang PH, Ross M, Shaw SG, Crosby D, Campbell PM. Predicted and actual end-of-treatment occlusion produced with aligner therapy. The Angle Orthodontist. 2015;85(5):723-727.

49. Hoybjerg AJ, Currier GF, Kadioglu O. Evaluation of 3 retention protocols using the American Board of Orthodontics cast and radiograph evaluation. American Journal of Orthodontics and Dentofacial Orthopedics. 2013;144(1):16-22.

50. Morton S, Pancherz H. Changes in functional occlusion during the postorthodontic retention period: A prospective longitudinal clinical study. American Journal of Orthodontics and Dentofacial Orthopedics. 2009;135(3):310-315.

51. Varga S, Spalj S, Milosevic SA, et al. Changes of bite force and occlusal contacts in the retention phase of orthodontic treatment: A controlled clinical trial. American Journal of Orthodontics and Dentofacial Orthopedics. 2017;152(6):767-777.

52. Chiqueto K, Janson G, Almeida CTD, Storniolo JM, Barros SE, Henriques JFC. Influence of root parallelism on the stability of extraction-site closures. American Journal of Orthodontics and Dentofacial Orthopedics. 2011;139(6).

53. Morais JFD, Freitas MRD, Freitas KMSD, Janson G, Branco NC. Postretention stability after orthodontic closure of maxillary interincisor diastemas. Journal of Applied Oral Science. 2014;22(5):409-415.

54. Lanteri V, Farronato G, Lanteri C, Caravita R, and Cossellu G. The Efficacy of Orthodontic Treatments for Anterior Crowding with Invisalign Compared with Fixed Appliances Using the Peer Assessment Rating Index. Quintessence International 2018;49(7):581-587.

55. Li W, Shimei W, and Yanzhen Z. The Effectiveness of the Invisalign Appliance in Extraction Cases Using the ABO Model Grading System: A Multicenter Randomized Controlled Trial. International Journal of Clinical and Experimental Medicine 2015;8(5): 8276-8282.

56. Nett BC, Huang GJ. Long-term posttreatment changes measured by the American Board of Orthodontics objective grading system. American Journal of Orthodontics and Dentofacial Orthopedics. 2005;127(4):444-450.

57. Ke Y, Zhu Y, Zhu M. A comparison of treatment effectiveness between clear aligner and fixed appliance therapies. BMC Oral Health. 2019;19(1).

58. History of Clear aligner Treatment | Uniform Teeth. https://new.uniformteeth.com/the-fascinating-history-of-clear-aligner-treatment/.

59. Sassania F, Roberts S. Computer-assisted fabrication of orthodontic appliances. Computers in Industry. 1996;29(3):179-195.

60. McOmie. Invisalign Patents Are Running Out What Does This Mean For Clear Aligners? Invisalign Patents Are Running Out What Does This Mean For Clear Aligners? https://mcomiedentistry.com/invisalign-patents-running-out-people-wanting-invisalign-braces/. Published June 7, 2017.

61. Horton JK, Buschang PH, Oliver DR, Behrents RG. Comparison of the effects of Hawley and perfector/spring aligner retainers on postorthodontic occlusion. American Journal of Orthodontics and Dentofacial Orthopedics. 2009;135(6):729-736.

62. Papageorgiou SN, Koletsi D, Iliadi A, Peltomaki T, Eliades T. Treatment outcome with orthodontic aligners and fixed appliances: a systematic review with meta-analyses. European Journal of Orthodontics. 2019.

63. Parrish LD, Roberts WE, Maupome G, Stewart KT, Bandy RW, Kula KS. The relationship between the ABO discrepancy index and treatment duration in a graduate orthodontic clinic. The Angle Orthodontist. 2011;81(2):192-197.

APPENDIX A

FIGURES

Figure 1. Patient Flow Chart Diagram

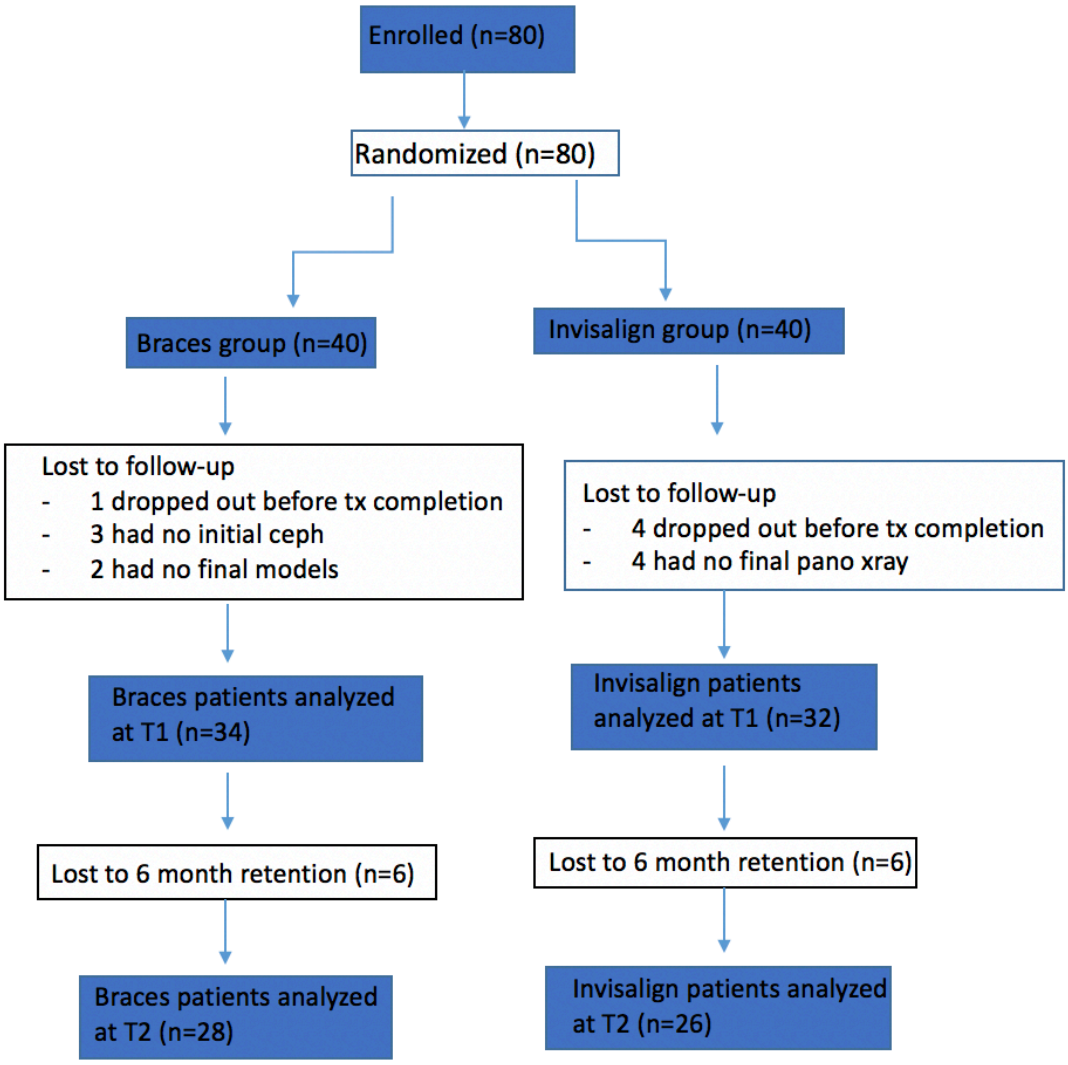


Figure 2. Initial Patient Ages (T0)

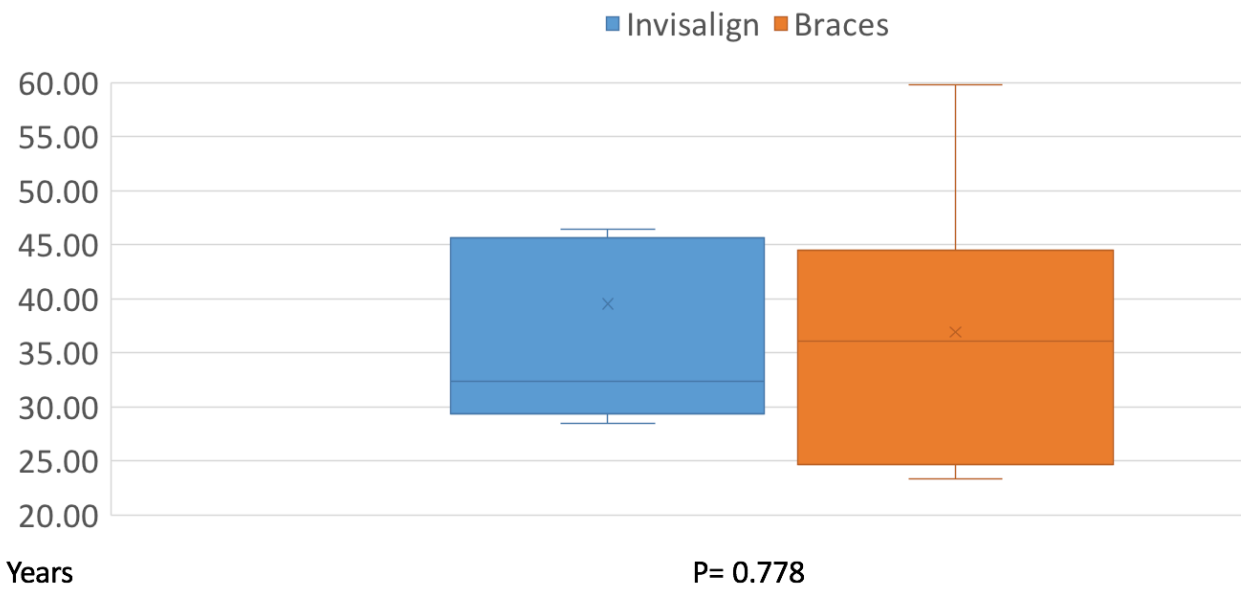


Figure 3. Treatment Time from Initial to Debond

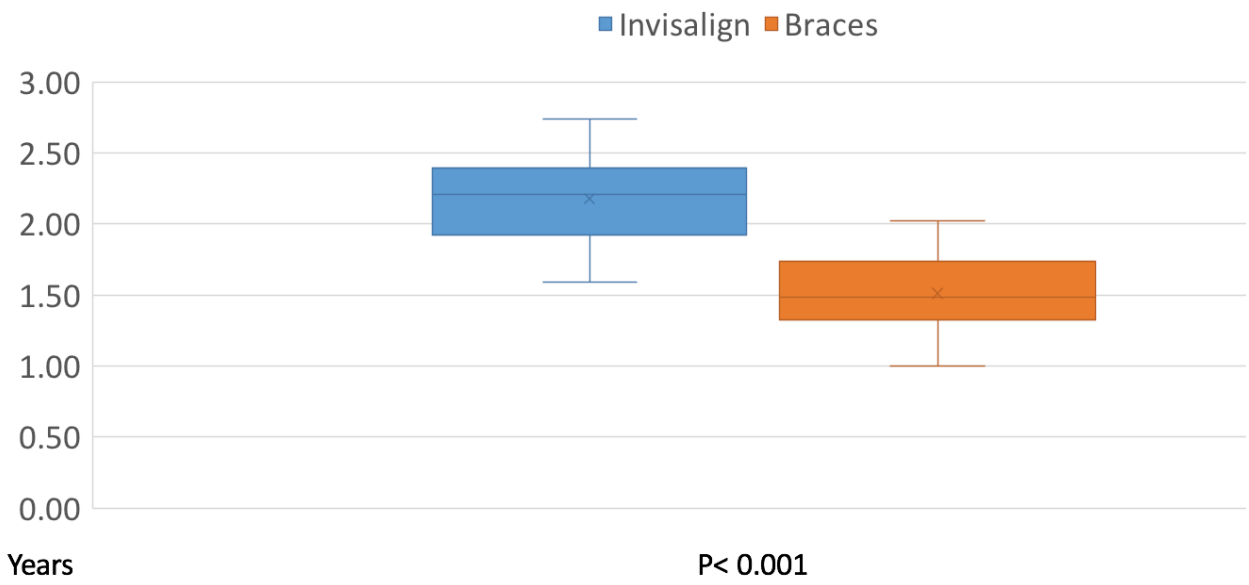


Figure 4. DI Score Comparison between Invisalign and Braces

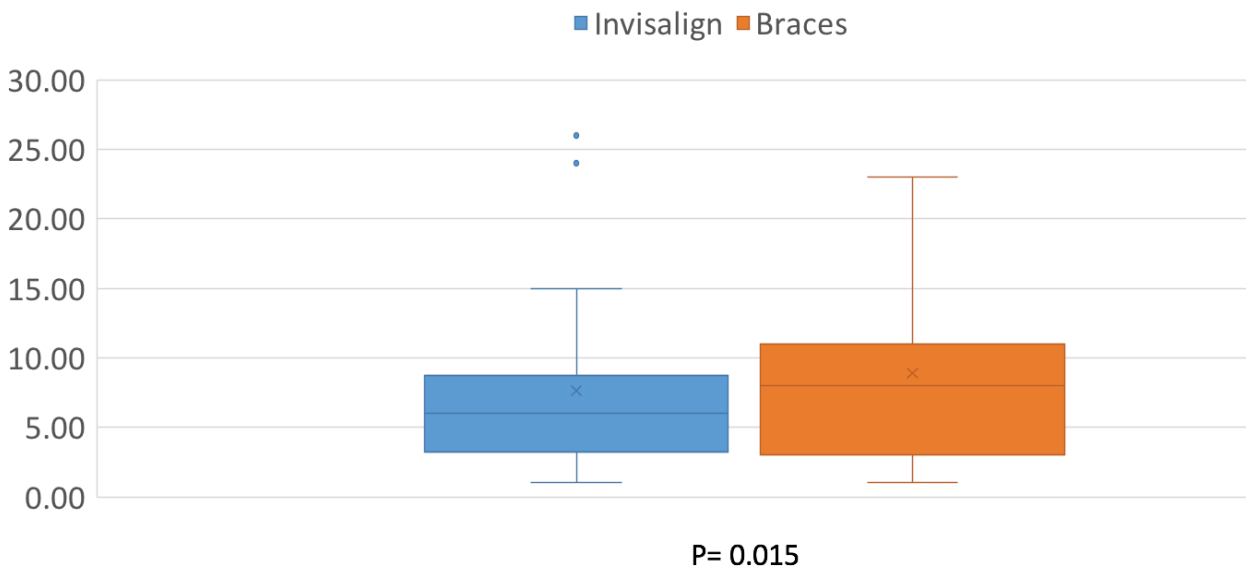


Figure 5. OGS Score Comparisons between Invisalign and Braces at T1

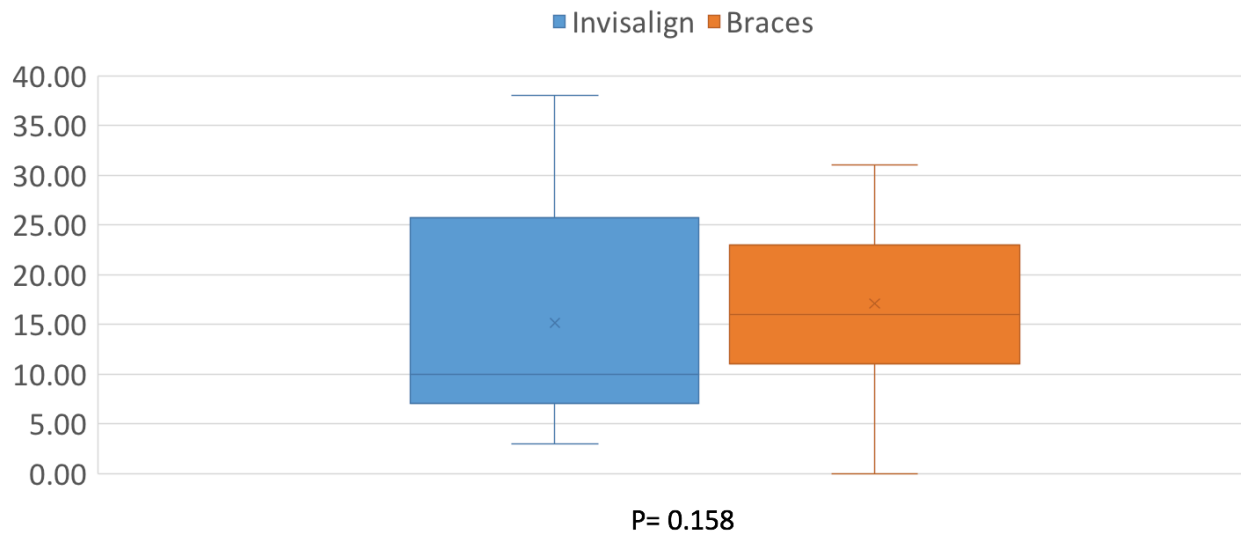


Figure 6. OGS Score Comparison between Invisalign and Braces at T2

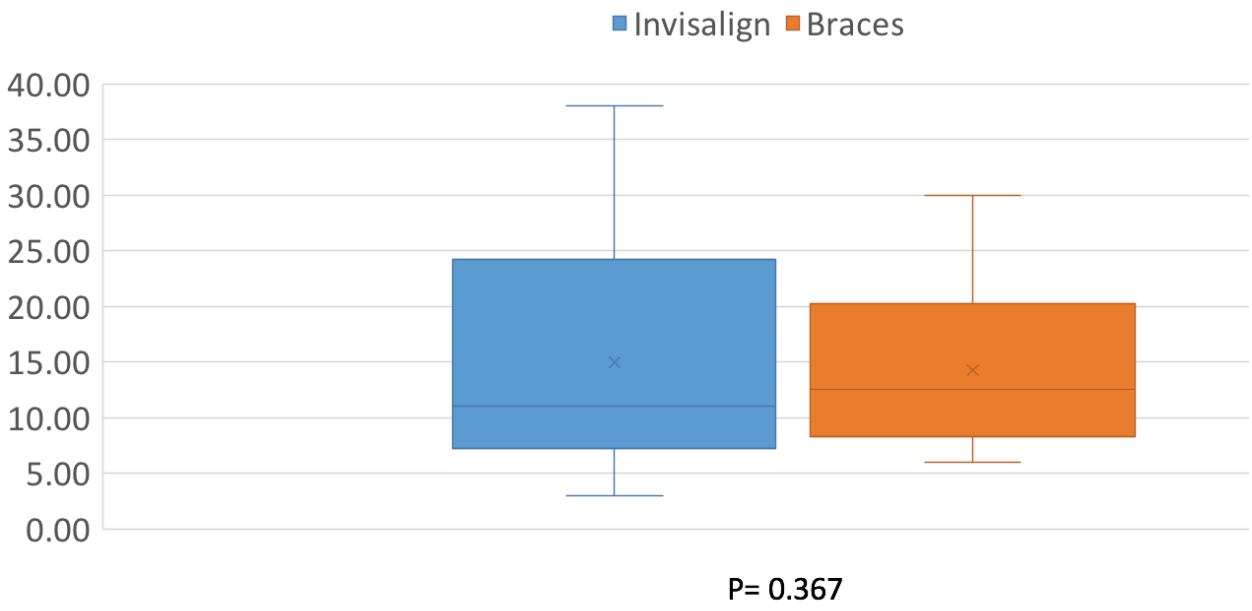
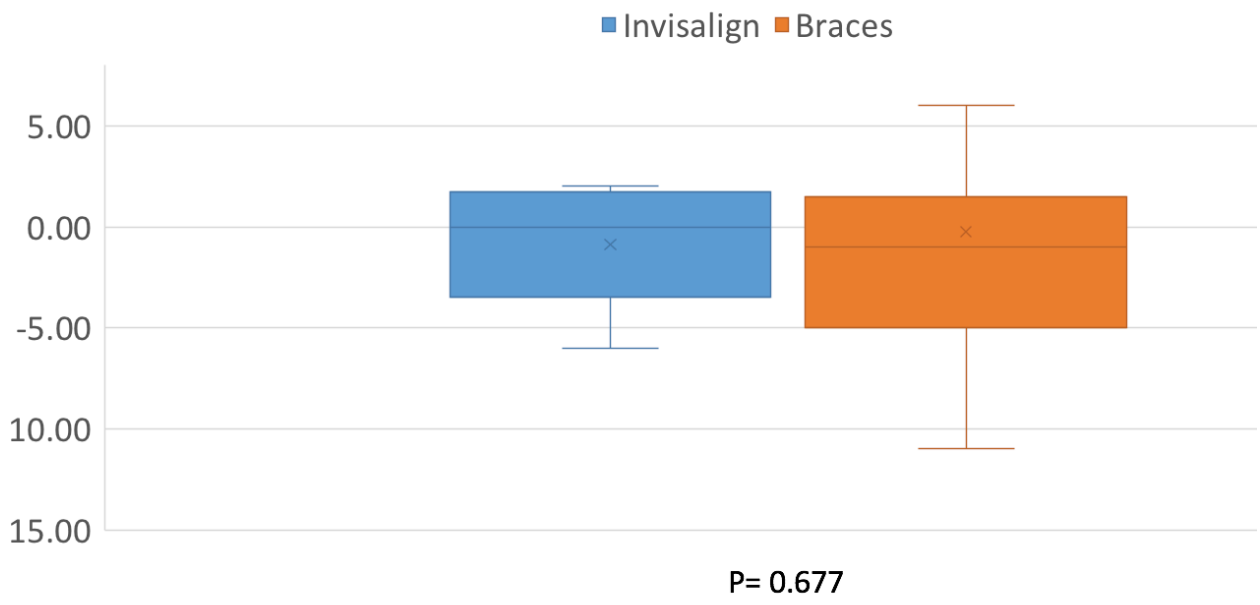


Figure 7. OGS Score Changes from T1 to T2



APPENDIX B

TABLES

Table 1. Patient ages at initial (T0), end of tx (T1), 6 month recall (T2), and time differences at each

| Ages at time points (years) | Invis (50%) median | Invis (25%;75%) IQR | Braces (50%) median | Braces (25%;75%) IQR | P value |
|---|---|---|---|---|---|
| T0 Age | 26.7 | 23.1; 32.9 | 25.9 | 23.4; 39.1 | 0.778 |
| T1 age | 28.6 | 24.7; 35.4 | 27.1 | 24.8; 40.5 | 0.672 |
| T2 age | 28.1 | 24.8; 37.7 | 27.6 | 24.8; 37.7 | 0.849 |
| Tx time (T0-T1) | 1.7 | 1.5; 2.2 | 1.3 | 1.1; 1.8 | <0.001 * |
| Retention (T1-T2) | 0.5 | 0.4; 0.5 | 0.5 | 0.4; 0.5 | 0.646 |

Table 2. OGS scores and P values for Invisalign and Braces group at the end of tx (T1)

| OGS Category | Invis (50%) median | Invis (25%;75%) IQR | Braces (50%) median | Braces (25%;75%) IQR | P value |
|---|---|---|---|---|---|
| DI score | 4.5 | 2.0 ; 8.0 | 7.0 | 5.0 ; 10.0 | 0.015 * |
| Alignment | 2.0 | 1.0 ; 4.75 | 3.0 | 1.0 ; 4.0 | 0.77 |
| Marginal ridges | 2.0 | 1.0 ; 2.0 | 1.0 | 0.0 ; 2.25 | 0.472 |
| BL incl | 2.0 | 1.0 ; 3.0 | 2.0 | 2.0 ; 4.0 | 0.158 |
| Occlusal cont | 1.0 | 0.0 ; 4.75 | 2.0 | 0.0 ; 3.25 | 0.532 |
| Overjet | 1.0 | 0.0 ; 3.0 | 2.5 | 0.0 ; 6.0 | 0.286 |
| Inter Cont | 0.0 | 0.0 ; 0.0 | 0.0 | 0.0 ; 0.0 | 0.719 |
| Root Angulation | 0.0 | 0.0 ; 1.0 | 1.0 | 0.0 ; 2.0 | 0.127 |
| Occlusal Rel | 2.0 | 0.0 ; 4.0 | 2.0 | 1.0 ; 5.25 | 0.219 |
| OGS | 12.0 | 7.0 ; 25.0 | 17.0 | 11.75 ; 23.75 | 0.158 |

Table 3. OGS scores and P values for Invisalign and Braces group at six month recall (T2)

| T2 (6 month retention) | Invis (50%) median | Invis (25%;75%) IQR | Braces (50%) median | Braces (25%;75%) IQR | P value |
|---|---|---|---|---|---|
| Alignment | 3.5 | 2.0 ; 5.5 | 3.0 | 2.0 ; 5.75 | 0.993 |
| Marginal ridges | 1.5 | 0.0 ; 2.0 | 1.0 | 0.0 ; 2.0 | 0.474 |
| BL incl | 1.0 | 0.0 ; 2.25 | 2.0 | 0.0 ; 2.0 | 0.586 |
| Occlusal cont | 0.0 | 0.0 ; 2.25 | 1.0 | 0.0 ; 2.0 | 0.373 |
| Overjet | 2.0 | 1.0 ; 5.25 | 3.0 | 1.0 ; 4.75 | 0.740 |
| Inter Cont | 0.0 | 0.0 ; 0.0 | 0.0 | 0.0 ; 0.0 | 0.209 |
| Root Angulation | 0.0 | 0.0 ; 1.0 | 0.50 | 0.0 ; 2.0 | 0.051 |
| Occlusal Rel | 1.5 | 0.0 ; 4.0 | 2.5 | 0.25 ; 5.0 | 0.289 |
| OGS | 12.5 | 8.0 ; 17.25 | 14.5 | 9.25 ; 21.75 | 0.367 |

Table 4. OGS score changes between end of tx (T1) and 6 month recall (T2)

| OGS category | Invis (50%) median | Invis (25%;75%) IQR | Braces (50%) median | Braces (25%;75%) IQR | P value |
|---|---|---|---|---|---|
| Alignment | 1.0 | 0.0 ; 2.0 | 0.0 | 0.0 ; 1.0 | 0.307 |
| Marginal ridges | 0.0 | -1.0; 0.0 | 0.0 | -1.0; 0.0 | 0.897 |
| BL incl | 0.0 | -1.25; 0.0 | -1.0 | -2.75; 0.0 | 0.274 |
| Occlusal cont | 0.0 | -2.0; 0.0 | -1.0 | -2.0; 0.0 | 0.823 |
| Overjet | 0.0 | 0.0; 1.0 | 0.0 | 0.0; 1.0 | 0.551 |
| Inter Cont | 0.0 | 0.0 ; 0.0 | 0.0 | 0.0 ; 0.0 | 0.113 |
| Root Angulation | 0.0 | 0.0 ; 0.0 | 0.0 | 0.0 ; 0.0 | 1.0 |
| Occlusal Rel | -1.0 | -2.0 ; 0.25 | -0.50 | -1.75 ; 0.0 | 0.578 |
| OGS | 0 | -4.5; 2.0 | -1.5 | -5.75; 2.75 | 0.677 |

Table 5. Comparison of OGS scores within each group at end of tx (T1) and 6 month retention (T2)

| OGS category | Invis T1 50% (25%;75%) | Invis T2 50% (25%;75%) | Invis P value | Braces T1 50% (25%;75%) | Braces T2 50% (25%;75%) | Braces P value |
|---|---|---|---|---|---|---|
| Alignment | 2.0 (1.0; 4.75) | 3.5 (2.0; 5.5) | .006 * | 3.0 (1.0; 4.0) | 3.0 (2.0; 5.75) | .023 * |
| Marginal ridges | 2.0 (1.0 ; 2.0) | 1.5 (0.0; 2.0) | .301 | 1.0 (0.0; 2.25) | 1.0 (0.0; 2.0) | .535 |
| BL incl | 2.0 (1.0; 3.0) | 1.0 (0.0; 2.25) | .014 * | 2.0 (2.0; 4.0) | 2.0 (0.0; 2.0) | .004 * |
| Occlusal cont | 1.0 (0.0; 4.75) | 0.0 (0.0; 2.25) | .057 | 2.0 (0.0; 3.25) | 1.0 (0.0; 2.0) | .056 |
| Overjet | 1.0 (0.0; 3.0) | 2.0 (1.0; 5.25) | .012 * | 2.5 (0.0; 6.0) | 3.0 (1.0; 4.75) | .291 |
| Inter Cont | 0.0 (0.0; 0.0) | 0.0 (0.0; 0.0) | .713 | 0.0 (0.0; 0.0) | 0.0 (0.0; 0.0) | .157 |
| Root Angulation | 0.0 (0.0; 1.0) | 0.0 (0.0 ; 1.0) | 1.00 | 1.0 (0.0; 2.0) | 0.50 (0.0; 2.0) | 1.00 |
| Occl Rel | 2.0 (0.0; 4.0) | 1.5 (0.0 ; 4.0) | .041 * | 2.0 (1.0; 5.25) | 2.5 (0.25; 5.0) | .109 |
| OGS | 12.0 (7.0; 25.0) | 12.5 (8.0; 17.25) | .314 | 17.0 (11.75; 23.75) | 14.5 (9.25; 21.75) | .169 |