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Analyzing Patient Retention Compliance: Invisalign vs. Fixed Appliances, a Questionnaire-Based Study

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the degree of Master of Science in Dentistry

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Dedication

To my family and friends for their unconditional love, unwavering support and staying by my side through all challenges.
To my co-residents for making residency a fun and enjoyable experience.

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Abstract

The main objective of this study was to analyze and compare post-treatment retention compliance for patients treated with Invisalign compared to patients treated with traditional fixed appliances.

Respondents participated in a web-based survey consisting of 10 questions; 3 demographic identifiers, and 7 pertaining to treatment and retention compliance. The survey was pilot tested using 6 current patients at the graduate orthodontic clinic located in the Midwest of the United States and revised accordingly. The final survey was distributed via email and text to a private practice on the east side of Cleveland using practice management software to 3,094 eligible participants. 143 participants completed the survey (response rate=4.6%).

Independent t-test revealed Invisalign patients wore removable retainers more days per week (4.88, $p = .039$), more hours per 24-hr day (7.34, $p = .004$), and more nighttime hours per day (7.0 , $p = .008$), compared to Fixed Appliances patients. An association between Treatment Modality and retainer compliance was significant, $X2$ (2, $N = 143$) = 9.8, $p = .008$. Invisalign patients were more likely to desire fixed retainers than patients treated with Fixed Appliances. Female respondents were statistically more likely to desire fixed retainers than male respondents, $X2$ (2, $N = 143$) = 6.7, $p = .035$. Following a One-way ANOVA comparing time since active treatment completion and retainer compliance, a Tukey post hoc test revealed the following: the average reported days the removable retainers were worn in a recent 7-day period was significantly lower for patients who completed their active treatment 4 to 6 years ago (3.16, $p = .014$) than for patients who completed active treatment 1 to 3 years ago (4.93).

Keywords: Retention Compliance, Orthodontics, Invisalign, Fixed Appliances

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TABLE OF CONTENTS

DEDICATION……..ii

ABSTRACT……..…iii

LIST OF TABLES AND FIGURES ….……..……..…v

REVIEW OF THE LITERATURE……...1

LITERATURE REFERENCES……...…15

THESIS OBJECTIVE……..…19

MANUSCRIPT FOR PUBLICATION……21

ABSTRACT…….22

INTRODUCTION……...……23

MATERIAL AND METHODS……..…….……26

RESULTS……..…….. 30

DISCUSSION…….. 33

CONCLUSION…… 38

REFERENCES……..…... 39

IRB APPROVAL……...…….. 45

DocuSign Envelope ID: 4818C49B-441B-474B-BC97-07B664C7BE40

List of Tables and Figures

Table I: Independent Sample T-test comparing Treatment Modalities for Retainer Compliance
Table II: One-way ANOVA comparing Ethnicity groups for Retainer Compliance
Table III: Post hoc comparing between Ethnic groups for Retainer Compliance
Table IV: One-way ANOVA comparing Age groups for Retainer Compliance
Table V: Post hoc comparing between Age groups for Retainer Compliance
Table VI: One-way ANOVA comparing Time Since Active Treatment Completion for Retainer Compliance
Table VII: Post hoc comparing between Time Since Treatment Completion groups for Retainer Compliance
Table VIII: Pearson Chi-Square of Ethnicity group responses to Ideal Length of Retention
Table IX: Pearson Chi-Square of Ethnicity group responses to Importance of Stability
Table X: Pearson Chi-Square of Ethnicity group responses to Importance of Stability
Table XI: Pearson Chi-Square of Treatment Modality group responses to Desire for Fixed Retainer
Table XII: Pearson Chi-Square of Treatment Modality group responses to Desire for Fixed Retainer
Table XIII: Pearson Chi-Square of Gender group responses to Desire for Fixed Retainer
Table XIV: Pearson Chi-Square of Gender group responses to Desire for Fixed Retainer

Figure I: Gender distribution graph
Figure II: Ethnic Identification distribution graph
Figure III: Age group distribution graph
Figure IV: Treatment Modality distribution graph
Figure V: Time Since Active Treatment Completion distribution graph
Figure VI: Recent 7-day Period Removable Retainer Wear graph
Figure VII: Patient Perception of Ideal Length of Retention graph
Figure VIII: Patient Perception on Importance of a Stable Result
Figure IX: Patient Perception of Desire for Fixed Retainer Instead of Removable
Figure X: Patient Perception of Who is Responsible for Stability

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Review of Literature

Ever since its recognition as a specialty in 1929, the three main goals of orthodontic treatment have been to create proper function, to achieve excellent esthetics, and then to stabilize these results. The general focus of orthodontic treatment is to assess and diagnosis a patient's initial malocclusion, then move teeth around to correct the malocclusion and a more functional, esthetically pleasing, and stable occlusion. While many studies over the years have looked into stability and retention of orthodontic treatment, many questions still remain in this aspect of the specialty. The Retention Problem is referenced in multiple textbooks, including Graber's Orthodontics Principles and Practice. In Graber's textbook, we learn that malocclusions are stable because the teeth are in balanced harmony between opposing muscular forces.[1,2] No matter how long we attempt to hold teeth in place with a retainer, if the position the teeth following treatment is not in balance with the surrounding musculature, teeth will always have a tendency to shift to a more stable position.

Long Term Stability

While not often the main focus of orthodontic treatment, long term stability is a very important factor to consider with treatment. In his textbook, Handbook of Orthodontics for the Student and General Practitioner, Moyers defines retention following treatment as, "The holding of teeth following orthodontic treatment in the treated position for the period of time necessary for the maintenance of the result".[3] In 1959, Dr. Kaare Reitan published an article explaining the histological findings of

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his experiments that he conducted involving teeth of dogs.[4] In these experiments, Reitan focused on the reorganization of gingival fibers during retention following orthodontic treatment of rotated teeth, particularly upper incisors. Once he had derotated the incisors, he bonded a wire on both the labial and lingual of the previously rotated incisor and the adjacent incisor on both sides, then analyzed histological sections of the gingival tissue around the gingival, middle, and apical sections of the incisor at six timepoints up to 232 days (~8 months) of retention. He found that the gingival fibers at the middle and apical thirds of the root had fully reorganized by the 147-day time point (~5 months of retention), however even at the 232-day timepoint, the free gingival fibers and the transseptal fibers at the gingival third of the root had only partially reorganized. He also looked at bone tissue in the same regions and found that little change was observed in bone tissue reorganization after the first 2 months of retention. He concluded that relapse of rotated teeth seems to be caused mainly by displaced or stretched supracrestal fibers that have a tendency to contract back to the original position even after 8 months of retention.

Little, Wallen, and Reidel published an article in 1981 looking at mandibular anterior alignment at a 10 year follow up period on 65 cases treated with edgewise appliances and first premolar extractions.[5] For the cases included in this study, a one year retention period was prescribed following treatment, either with fixed or removable retainers, then the retainers were removed at the end of the retention period. Little's irregularity index was used to analyze the amount of alignment irregularity present for each case.[6] Results showed that long-term alignment of

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mandibular anterior teeth was varied and unpredictable. They found that at 10 years posttreatment, only 30% of cases in the sample showed an acceptable alignment of mandibular anterior teeth, and 20% of cases showed at least a moderate level of crowding and misalignment. In addition, they found that a majority of cases showed a significant decrease in arch width and length, while simultaneously showing an increase in crowding since treatment completion. Furthermore, in 1988 Little, Reidel, and Artun published a follow up article looking at the same sample 10 – 20 years later.[7] Results of this study were consistent with the previous study, however the rate of post-retention relapse seemed to slow down a bit. This study found that during the 10 – 20 year follow up time frame, only 10% of cases had acceptable mandibular anterior tooth alignment. Based on the results of these two studies, the authors recommend the use of either fixed or removable retainers for lifelong wear. It however should be noted that all cases in the sample for the above studies included four bicuspid extractions. So while the results may be relatable to some malocclusions, the results can't be generalized to all orthodontic patients.

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Retention Protocols

The overall goal of retention following orthodontic treatment is to stabilize teeth in their final position when the orthodontic appliances were removed and active treatment was completed. In order to do this, practitioners will prescribe a retainer of various types (fixed, clear overlay, Hawley, etc.) and instruct the patient to wear the retainers with a selected wear schedule protocol. Many protocols have been developed and used by practitioners worldwide. In recent years, a number of survey type studies have attempted to answer questions about what commonly accepted retention protocols exist. In 2008, Keim et al, conducted a study looking at diagnosis and treatment procedures.[8] In this study, a questionnaire was sent to all members of the American Association of Orthodontics to find out what common appliances are used for active treatment and retention throughout the United States. For retention, they found an increasing use of clear retainers and bonded mandibular 3-3 retainers instead of Hawley and spring-retainers when compared to previous studies. In 2010, Valiathan and Hughes surveyed American Association of Orthodontists as well to investigate the most commonly accepted retention protocols throughout the United States at that time, and found that not only have practitioners trended towards clear vacuform retainers and fixed retainers, but that the most commonly prescribed retainers in the United States were a fixed retainer for the lower arch combined with a clear vacuform retainer for the upper arch to be worn at night time.[9] In 2013, Meade and Millett surveyed 101 orthodontic specialists in Ireland to find answers to the following questions: preferred retainer choice

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in the maxillary and mandibular arches, prescribed wear protocols, VFR (vacuform retainer) characteristics and factors influencing retainer choice.[10] They found that that throughout Ireland, VFRs are the most commonly used retainers with 53% of respondents using them for maxillary retention and 33% using VFRs for mandibular retention. 1.0mm thickness thermoplastic was found to be the most commonly used thickness, and the most commonly accepted wear schedule was full time at first, then scaling back to part time wear indefinitely. Also in 2013, Vandevska-Radunovic et al surveyed members of the Norwegian Association of Orthodontics looking at common types of retainers used as well as commonly accepted duration of retainer wear.[11] Similarly to the above studies, they found that the most common retainer combination was clear thermoplastic retainer for the maxilla, and fixed anterior retainer for the mandible. For duration of retention, 2 to 3 years was the most commonly accepted length of retention, followed by 3 to 5 years. Of those clinicians using a fixed retainer for the mandibular dentition, 70% left the retainers in and relegated the retention responsibility moving forward to the patient and the general practitioner. In 2014, Lai et al sent a survey out to orthodontists in Switzerland asking about common retention protocols as well.[12] It was found that in Switzerland, bonded retainers were the most common retainer of choice for both the maxillary and mandibular arches, and that when expansion or extractions were involved with treatment it was common for a removable thermoplastic retainer to be used in combination with the bonded retainers. They also found that 87% of orthodontists surveyed in Switzerland preferred life-time retention protocols. Also in 2014, Keim et al published a part 2 follow up to their 2008 study

DocuSign Envelope ID: 4818C49B-441B-474B-BC97-07B664C7BE40

when they sent the same survey out again to members of the American Association of Orthodontics.[13] In comparison to the results of the 2008 study, this study found an even stronger trend towards practitioners using clear retainers for maxillary retention and bonded 3-3 retainers for mandibular retention. In 2018, Padmos et al conducted a comprehensive questionnaire based study of orthodontists in the Netherlands.[14] As part of this study, they asked participants about their most commonly used retention protocols, including; type of retainer used in each arch, daily wear schedule for removable retainers, and duration of retention. They found that a majority of orthodontists in the Netherlands prefer to use bonded retainers 3-3 with a removable clear thermoplastic retainer for maxillary retention, and a bonded 3-3 retainer without a removable retainer for the mandibular arch. A majority of surveyed orthodontists preferred to have patients wear the removable retainers (in addition to the bonded retainers) at nighttime only for up to one year, while 23% of practitioners preferred to have patients wear their removable retainers (in addition to the bonded retainers) full time for a period of up to three months. A vast majority of respondents reported they instruct their patients that the wearing of the removable retainers is only for the above listed temporary intervals then they can stop, while the bonded 3-3 maxillary and mandibular retainers are to be continued indefinitely. While the practitioner can monitor the stability of the teeth when the patient comes into the office for appointments, ultimately the stability of the teeth comes down to the patient's willingness to follow the prescribed retention protocol by wearing the retainers as directed. In addition to deciding

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a retainer wear schedule for their patients to follow, practitioners must decide what type of retainers to instruct their patients to wear.

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Common Types of Retainers

Clear Overlay Retainers

Clear overlay retainers are one of the most common choices for post-treatment retention. The idea for using a clear thermoplastic material to cover all the teeth in order to retain the post-treatment tooth position was introduced in 1971 by Robert Ponitz.[15] Clear overlay retainers are fabricated by placing the patient's final models in a vacuform machine. Many companies have developed different thermoplastics to be used for this purpose, and while each company's plastic is slightly different, the general fabrication process is the same as the final product is a clear plastic retainer that is molded to fully cover the crowns of all the teeth. The main advantage of this style of retainer is that fully covering the crowns of all the teeth with a hard-plastic material ensures all the teeth remain in the position they were at when the active treatment was completed. In 2010, Thickett and Power conducted a randomized clinical trial in the UK comparing full time and night time only retainer wear schedules for 60 patients using thermoplastic retainers.[16] They used the irregularity index, intercanine width, intermolar width, arch length, overbite, overjet, and Peer Assessment Rating (PAR) scores were measured on study models using digital calipers to compare results at four time points: Pretreatment (T1), Debond (T2), 6 months retention (T3), and 1 year retention (T4). The results of this study found no significant differences between the groups for all measures except Overbite between T3 and T4. From this it was concluded that a night time only wear schedule with thermoplastic retainers can sufficiently maintain a stable treatment result. Jäderberg et al in 2012 conducted a prospective clinical trial not only looking at

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effectiveness of Essix retainers, but also comparing length of full time vs. night time only wear, and patient perceptions of the retainers.[17] The study included 60 patients split evenly into two groups with both groups receiving maxillary and mandibular Essix retainers. Group A was instructed to wear retainers full time for 3 months then move to nighttime only, while Group B was instructed to wear retainers full time for 1 week before moving to nighttime only wear. Little's irregularity index scores were obtained from dental casts at debond (T1) and at 6 months retention (T2) for all patients. Results found no significant difference in irregularity scores and a 6-month questionnaire found a high level of patient satisfaction with Essix retainers. The authors concluded that Essix retainers are effective in maintaining a stable treatment result, and that a nighttime only wear schedule is sufficient. Some other advantages of clear overlay retainers are that they are cost effective, and can be easily fabricated in house on the day of active appliance removal. There are however some drawbacks to clear overlay retainers. The main drawbacks are that clear overlay retainers are totally dependent on patient compliance, and holding the teeth locked in plastic doesn't allow the teeth to settle. Settling is a phenomenon of micro-shifting of the teeth that occurs when the active appliances are removed as the teeth try to settle into the most comfortable, functional, and stable position with regards to the teeth directly opposing.

Hawley Retainers

Hawley retainers are another common style of retainer. This type of retainer was introduced in the United States by Charles Hawley in 1919 after visiting Dr. McBride of Dresden, Germany in 1906.[18] A Hawley retainer is a lab fabricated appliance that

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may be fabricated in office, or sent to an outside lab for fabrication. The basic design of this type of retainer has three main components: a labial bow around the anterior teeth, hard acrylic on the lingual or palatal side of the teeth, and some kind of retentive clasps on posterior teeth. Many studies have looked into the effectiveness of this style retainer. In 2010, Shawish et al performed a randomized clinical trial in which 67 consecutive patients were randomly designated into two groups to assess differences in Hawley retainer effectiveness worn either full time or part time.[19] One group was instructed to wear the retainers full time for the first 6 months then night time only for 6 months, while the other group was told to wear the retainers only at night for the full year. Dental casts were analyzed at debond and a 1-year retention time point for all patients using Little's Irregularity index. No statistical difference was found between the groups leading the researchers to conclude that a nighttime only wear schedule with Hawley retainers is a sufficient protocol to maintain stable treatment results. In addition to showing effectiveness at maintaining stable treatment results, the main advantage of the Hawley retainer is that there is no or minimal occlusal coverage on posterior teeth which allows the teeth to be free to settle into the most stable occlusion. The main disadvantages are that this style of retainer is more costly than a clear overlay retainer, less effective at maintaining anterior tooth alignment, and it is less esthetic.

Fixed Retainers

While other styles of retainers still remain, the other most common style of retainer used is a fixed retainer. A fixed retainer is essentially a wire bonded to the lingual of anterior teeth. Just like the Clear Overlay and Hawley retainers, the Fixed retainer can

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be used on maxillary or mandibular arch, or both arches. Typically for the mandibular arch a fixed retainer is bonded across all six anterior teeth from one cuspid to the other cuspid. In the maxillary arch, typically a fixed retainer is either from one lateral incisor to the other lateral incisor, or sometimes only includes the central incisors. As one of the most profound pioneers of this form of retention, Bjorn Zachrisson has performed extensive research on various fixed retainer techniques and materials. In 2015, he published a summary of his journey with fixed retention, recommending which specific wire his research and clinical experience had found to be the best for long term stability. Through multiple tribulations, Zachrisson has found fixed retainers to be very effective at maintaining stable treatment results long term. In comparison of various wires available, he has found 5-stranded 0.0215 wire to be the best wire as it is less prone to breakage and less prone to unintended consequences of active wires as are single or 3-stranded wires.[20-26]

While several studies have shown fixed retainers to have great effectiveness at maintaining the stability of post-treatment occlusion, there have also been studies over the years that have observed a complication of unintended consequences in which teeth have at times shifted out of alignment as a result of the fixed retainer. In 2007, Katsaros et al looked into this issue by screening post-treatment patients at the orthodontic residency clinic at Radboud University Nijmegen Medical Center in the Netherlands.[27] At this clinic, they routinely attempt to schedule patients for follow up appointments at 1, 2, 5, and 10 years post-treatment. In this study, they screened patients during these follow up appointments who had been fitted with mandibular fixed retainers using

DocuSign Envelope ID: 4818C49B-441B-474B-BC97-07B664C7BE40

flexible spiral wire bonded to all 6 anterior teeth and found 21 patients with flexible spiral wire retainers to have undesired changes in alignment of their mandibular anterior teeth even though all 6 anterior teeth were still bonded to the wire. These 21 patients accounted for 5% of the total patients observed in this study, and half of these 21 patients were determined to be in need of retreatment to correct the misalignment of the dentition. The two most common discrepancies found in this population were a torque difference of two adjacent incisors, and a buccal inclination or movement of at least one of the canines. In 2011, Renkema et al performed a follow up study to Katsaros's study in 2007, in which they analyzed dental cases of 221 consecutively treated patients using Little's irregularity index at debond, and at a 5 year follow up period.[28] They found stable results for 200 patients and found increased irregularity scores for 21 patients (9.5%). Of those 21 patients, 15 were found to have bonding failure of the fixed retainer, and 6 were attributed to unintended consequences of an active retainer wire. Though it is rare, in some cases unintended consequences of fixed retainers can cause teeth to shift so far out of alignment that a dehiscence is created and this ultimately leads to gingival recession. In 2012, Bonetti et al published a case report upon seeing two patients with significant recession observed on a single tooth; both previously had orthodontic treatment followed by retention with a mandibular fixed retainer.[29] Upon questioning, a parafunctional habit of nail-biting was observed in both and the researchers concluded that the parafunctional habit caused the fixed retainers to become active and ultimately shifted the teeth towards the cortical plate. Another case report by Pazera et al in 2012 from a dental clinic in Switzerland found a 20 year old patient who previously had

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orthodontic treatment with a flexible spiral wire fixed retainer on the mandibular anterior teeth that had severe complications as well.[30] The patient presented to the clinic because of a broken retainer wire, and was observed to have 35 degrees of buccal root torque on the mandibular right canine to the point that the apex had almost completely penetrated the cortical plate. In 2016, Kucera and Marek assessed 3500 consecutively treated cases with fixed appliances who were fitted with mandibular fixed retainers for retention.[31] They found 38 patients (1.1%) to have unexpected complications associated with the fixed retainer. Of the 38 patients, 21 experienced what the authors referred to as a twist effect of the wire which resulted in one canine inclining towards the buccal and the other inclining towards the lingual, 12 patients experienced a torque differential develop between adjacent incisors, and 5 experienced what was listed as a nonspecific complication. While complications were found to be pretty rare in this study, there was a correlation between complications and patients with vertical growth patterns. The authors concluded that a pretreatment divergent mandibular growth pattern could be a predictive factor for complications with fixed retainer stability. In 2018, Padmos et al surveyed Dutch orthodontists to look at common retention protocols, as well as possible complications of different fixed retainer wires. From their survey responses, they found Dutch orthodontists most frequently used these wires: SS 3-stranded twisted retainer, SS co-axial 5+1 round wire, and SS braided 8-strand retainer respectively.[32] They also found that 33% of orthodontists reported having seen at least one instance of unintentional tooth moment in their career resulting from an active fixed retainer. The respondents reported the most common reasons for unintended tooth movement were;

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wire properties of round multistranded wires, wire deformation by mastication forces, and wire deflections during placement and repairs respectively. The main advantages of a fixed retainer are that they remove the patient compliance component of retention, and if placed properly having a rigid wire bonding the teeth together will keep those teeth lined up as long as it is in place. There are three main disadvantages to fixed retainers: 1) they are more prone to breakage and to needing repair than removable retainers, 2) fixed retainers make proper oral hygiene more difficult in those areas, and 3) it is possible to unintentionally place an active wire which can cause unwanted tooth movement.

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Comparing Types of Retainers

Looking into the best way to keep treatment results stable is not a new concept. In 1993, Sauget et al looked into changes in occlusal contacts post-treatment comparing clear overlay retainers with Hawley retainers.[33] In this study, they analyzed dental models from 30 patients at the time of debond and retainer delivery, and at a 3 month retention time point. For both the clear overlay and the Hawley groups, they found no significance in changes of occlusal contacts for anterior teeth. However, for posterior teeth they found occlusal contacts to have significantly increased and intensified for the Hawley group, whereas the contacts in the clear overlay group showed little or no change. They attributed the change in the Hawley group to the settling phenomenon as this type of retainer either does not cover, or only minimally covers the occlusal surface of posterior teeth allowing for the teeth to be guided to their most comfortable and stable position. In 2007 Rowland et al conducted a randomized clinical trial at a private practice in the United Kingdom.[34] They analyzed dental casts of 397 patents at debond and at a 6 month retention time point. Patients were randomly designated to either the VFR (vacuform retainer) or Hawley retainer group to have an approximately equal number of patients in each group. Using the Little's irregularity index for comparison, they found significantly higher levels of incisor irregularity for both mandible and maxilla in the Hawley group in comparison to the VFR group.

In 2006, Littlewood et al published a systematic review of randomized clinical trials to evaluate the effect of different retention strategies used following orthodontic treatment with fixed appliances.[35] The goal of the review was to analyze each article

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that met the inclusion criteria to see; how well the teeth were stabilized, failure of retainers, adverse effects on oral health, and participant satisfaction. 15 studies met the inclusion criteria and were used for the review, and these studies were divided into four categories: 2- removable retainers versus fixed retainers, 4- different types of fixed retainers, 8- different types of removable retainers, and 1- study compared a combination of upper thermoplastic and lower bonded versus upper thermoplastic with lower adjunctive procedures versus positioner. Two studies were used to compare fixed retainers with removable retainers. They found that Little's Irregularity Index scores were better when fixed retainers were used than when removable retainers were used, and participant satisfaction was higher with fixed retainers as they were viewed as easier to wear. While results were more stable and patients liked the fixed retainers better than removable retainers, in general the patient's oral hygiene was better in the removable retainer group. The results of the four studies comparing types of fixed retainers showed no statistical difference in stability of dentition or amount of breakage of the retainers. The review included eight studies that compared different types of removable retainers. Upon analyzing these eight studies, the results showed that with either clear overlay retainers or Hawley type retainers, there was no difference in stability whether the patient wore retainers full time or half time. No statistical difference was found in comparing overall stability of dentition for clear overlay retainers compared to Hawley type retainers. However, two studies did find clear overlay retainers superior to Hawley retainers in maintaining the stability of mandibular anterior teeth; in both studies, these differences were statistically

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significant. One study found compliance to be better with clear overlay retainers than with Hawley retainers as the Hawley type retainers were found to be more embarrassing to wear. So while this review provides some good insight into the various types of retention protocols, the authors were unable to conclude that any particular retention protocol or appliance is better than the others.

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Active Treatment with Invisalign

Prior to the retention phase of treatment, the initial malocclusion must be treated during the active phase of treatment. Traditionally fixed orthodontic appliances have been used as the main tool for practitioners to accomplish goals of improving function and esthetics for patients. While these appliances work well, they do not necessarily provide an esthetically pleasing look during treatment. With each generation, demand for an esthetically pleasing look during treatment has continued to increase. As a result, multiple companies launched ceramic brackets to meet patients' demands; however, many patients still desired more esthetic alternatives.

A major breakthrough in esthetic treatment occurred when Invisalign® was introduced in 1999. These entrepreneurs suggested replacing fixed appliances with attachments and replacing metal wire with a clear plastic thermoplastic tray. Ever since Invisalign® was introduced to the orthodontic market, patient demand for this less-intrusive market option has increased.

Moving teeth with a plastic tray is however not a new concept. In the 1940's, Harold Kesling introduced the idea of using a clear aligner to straighten teeth for minor orthodontic treatment, especially in the finishing stage of treatment.[36] Furthermore, Ponitz introduced the invisible retainer concept in 1971, which was the first article to suggest thermoplastic material as a retainer, however it wasn't until Sheridan in 1993 that Essix material was thought of to move teeth rather than just to retain them.[37,38] Considering how esthetics are becoming a driving factor in a

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consumer's choice of appliance, the trend of Invisalign® is likely to continue, if not increase.

The improvement of Invisalign® as a treatment modality and its increasing popularity has led to researchers looking into comparisons with cases treated with fixed appliances. Djeu et al in 2005 compared the treatment outcomes of patients treated with Invisalign and those treated with fixed appliances using the ABO objective grading system.[39] They found that in comparison to fixed appliances, Invisalign was less effective at correcting large anterior-posterior discrepancies and obtaining occlusal contacts, however Invisalign was found to effectively close spaces, correct anterior rotations, and level marginal ridge heights. Li et al in 2015 also used the ABO OGS to compare results of Invisalign treated cases with Fixed Appliance treated cases.[40] They found fixed appliance patients have better overall scores for buccolingual inclination and occlusal contacts, however results of all other categories of the OGS had nonsignificant differences and it was concluded that both Invisalign and Fixed Appliances can be used successfully as tools to treat Class I extraction cases. Grunheid et al in 2016 analyzed mandibular intercanine distance and buccolingual angulation of canines on dental cases of 30 Invisalign cases and 30 cases treated with edgewise appliances.[41] In the Invisalign treated group they found intercanine distance to be increased however buccolingual inclination changes were minimal, where as in the edgewise group the intercanine distance was found to have minimal change and the canines were successfully uprighted. In 2016, Hennessy et al compared the amount of mandibular incisor proclination during alleviation of mild crowding for cases

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treated with Invisalign compared to cases treated with Fixed Appliances and found no significant difference between the groups.[42] In 2018, Lantari et al analyzed PAR score reductions for cases treated employing Invisalign and fixed appliances.[43] They found both groups to have significantly improved PAR scores at treatment completion compared to pretreatment. In addition, over 90% of cases from both groups achieved great improvements, and there was no significant difference in the quality of results between the two groups.

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Comparing Fixed Appliances and Invisalign postretention

When looking at the comparison of Invisalign® and traditional fixed orthodontic appliances, little research has been done looking at long term stability. Kuncio et al. published an article in The Angle Orthodontics Journal in 2007 comparing the two treatment appliances for post-retention outcomes using the American Board of Orthodontics Objective Grading System.[44] 22 patients were split into an Invisalign® and a braces group and their study model casts were assessed at debond and at a 3 year post-debond time point. They found that while both groups showed some adverse tooth movement from T1 to T2, the Invisalign® treated group showed statistically significantly more occlusion relapse than did the braces treated group. Furthermore, the largest amount of relapse observed in both groups was in the mandibular anterior tooth alignment. While the findings of this study provide a nice reference in comparing Invisalign and fixed appliance retention, it should be noted that the results of this study are limited due to a small sample of only 11 patients in the Invisalign group and 11 patients in the fixed appliances group. It should also be noted that the Invisalign sample for this study all completed treatment in 2005, and at that time Invisalign was still a new and limited treatment appliance, so it's possible that treatment results were more prone to relapse tendencies.

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Survey Studies about Patient Compliance with Retainers

In recent years, multiple studies have surveyed patients directly to investigate what factors contribute to post treatment retainer compliances. A study was conducted at the University of Kentucky in 2011 that looked at patient compliance with different types of removable retainers by surveying patients.[45] In this comparison of clear vacuform retainers vs. Hawley type retainers, they found that patient compliance with clear vacuform retainers was better than Hawley retainers for the first two years of retention, however after the two year mark, compliance with clear vacuform retainers decreased at a faster rate than did compliance with Hawley retainers. In 2012, Katherine Vig found similar results from her questionnaire, however she found that esthetics were not the main factor in initial compliance being better for vacuform retainers but long term compliance being better for Hawley the retainer group.[46] She found factors such as subject age, gender, and time since fixed appliances were removed to be larger contributing factors to retainer compliances that esthetics. In 2005, Wong and Freer also surveyed patients about compliance with retainer wear and found compliance was mainly related to comfort level while wearing the removable retainers.[47] Kacer et al in 2010 surveyed a sample of 1,200 patients previously treated at 4 separate private practices in Cleveland, Ohio in an attempt to estimate compliance levels of patients within the first two years following the completion of active treatment. A survey containing questions about the following six items was sent to patients who met the inclusion criteria: type of retainer prescribed, age, sex, length of time since debond, and hours per day and nights per week that patients wore their retainers. The results of the

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survey showed that at 3 months post-treatment, 69% of patients reported wearing their removable retainers every night, and that by 2 years posttreatment, 19% of patients reported not wearing their retainers at all anymore.

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Current Study

Each of the above studies provide us with great insight into common retention protocols and patient's attitudes towards complying with the prescribed retention protocols. However, none of the above studies have attempted to assess if the active orthodontic treatment method chosen by the practitioner plays a role in the patient's retention compliance following active treatment. Previously if a patient presented with a malocclusion, they were prescribed fixed appliances to align their teeth. While fixed appliances are still a very popular treatment modality, more recently the use of clear aligners, most commonly Invisalign®, have been used as a more esthetically driven treatment alternative to align teeth. Throughout an extensive review of the current literature, we have not found any published articles that have compared post-treatment retention compliance for patients treated with Invisalign compared to patients treated with traditional fixed appliances. With Invisalign becoming an increasingly popular treatment modality, we feel it is important to understand how our patients feel about post-treatment retention and assess whether this attitude differs based on the treatment modality used to align their teeth in the active phase of treatment.

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Thesis Objective

The main objective of this study is to analyze and compare post-treatment retention compliance for patients treated with Invisalign compared to patients treated with traditional fixed appliances.

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Hypotheses

Null Hypothesis 1: There is no significant difference between the retention compliance of patients treated with Invisalign in comparison to patients treated with traditional fixed appliances.

Alternative Hypothesis 1: There is a significant difference between the retention compliance of patients treated with Invisalign in comparison to patients treated with traditional fixed appliances.

Null Hypothesis 2: There is no significant difference in the preference of receiving a fixed retainer following treatment between patients treated with Invisalign in comparison to patients treated with traditional fixed appliances.

Alternative Hypothesis 2: There is a significant difference in the preference of receiving a fixed retainer following treatment between patients treated with Invisalign in comparison to patients treated with traditional fixed appliances.

Null Hypothesis 3: There is no correlation between length of time since active treatment completion and patient retainer wear compliance.

Alternative Hypothesis 3: There is a correlation between length of time since active treatment completion and patient retainer wear compliance.

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Manuscript for Publication

Analyzing Patient Retention Compliance: Invisalign vs. Fixed Appliances, a Questionnaire-Based Study

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Abstract

The main objective of this study was to analyze and compare post-treatment retention compliance for patients treated with Invisalign compared to patients treated with traditional fixed appliances.

Respondents participated in a web-based survey consisting of 10 questions; 3 demographic identifiers, and 7 pertaining to treatment and retention compliance. The survey was pilot tested using 6 current patients at the graduate orthodontic clinic located in the Midwest of the United States and revised accordingly. The final survey was distributed via email and text to a private practice on the east side of Cleveland using practice management software to 3,094 eligible participants. 143 participants completed the survey (response rate=4.6%).

Independent t-test revealed Invisalign patients wore removable retainers more days per week (4.88, $p = .039$), more hours per 24-hr day (7.34, $p = .004$), and more nighttime hours per day (7.0 , $p = .008$), compared to Fixed Appliances patients. An association between Treatment Modality and retainer compliance was significant, $X2$ (2, $N = 143$) = 9.8, $p = .008$. Invisalign patients were more likely to desire fixed retainers than patients treated with Fixed Appliances. Female respondents were statistically more likely to desire fixed retainers than male respondents, $X2$ (2, $N = 143$) = 6.7, $p = .035$. Following a One-way ANOVA comparing time since active treatment completion and retainer compliance, a Tukey post hoc test revealed the following: the average reported days the removable retainers were worn in a recent 7-day period was significantly lower for patients who completed their active treatment 4 to 6 years ago (3.16, $p = .014$) than for patients who completed active treatment 1 to 3 years ago (4.93).

Keywords: Retention Compliance, Orthodontics, Invisalign, Fixed Appliances

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Introduction

Ever since its recognition as a specialty in 1929, the goals of orthodontic treatment have been to provide proper function, esthetics, and stability. The general focus of orthodontic treatment is to assess and diagnosis a patient's initial malocclusion, then move teeth around to correct this malocclusion while achieving better function, esthetics and stability in the process. While many studies over the years have looked into stability and retention of orthodontic treatment, many questions still remain in this aspect of the specialty. The Retention Problem is referenced in multiple textbooks, including Graber's Orthodontics Principles and Practice. In Graber's textbook, we learn that malocclusions are stable because the teeth are in balanced harmony between opposing muscular forces.[1,2] No matter how long we attempt to hold teeth in place with a retainer, if the position the teeth following treatment is not in balance with the surrounding musculature, teeth will always have a tendency to shift to a more stable position.

While not often the main focus of orthodontic treatment, long term stability is a very important factor to consider with treatment. In his textbook, Handbook of Orthodontics for the Student and General Practitioner, Moyers defines retention following treatment as, "The holding of teeth following orthodontic treatment in the treated position for the period of time necessary for the maintenance of the result".[3] In 1959, Kaare Reitan took a histological approach to analyzing the reorganization of bone and gingival tissues surrounding teeth that had previously undergone rotational movements, and concluded that relapse of rotated teeth seems to be caused mainly by

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displaced or stretched supracrestal fibers that have a tendency to contract back to the original position even after 8 months of retention.[4] Little, Reidel et al conducted multiple studies looking at long term stability of mandibular incisor alignment following comprehensive treatment.[5,6,7] Each of these long term follow up studies showed significant misalignment of mandibular incisors following treatment if some method of retention is not employed; even when patients underwent a 1 year retention period, teeth still tended to shift following this period. This had led most practitioners to believe that the only way to maintain posttreatment alignment results is with lifetime retention.

With long term stability of treatment results being an important factor and research has shown that teeth won't remain stable without some form of retention, extensive research has been conducted comparing various types of retainers (fixed, clear overlay, Hawley, etc), as well as what are the most widely accepted retention protocols. Many studies comparing thermoplastic retainers and Hawley retainers have found that in general, thermoplastic retainers are better at maintaining anterior arch alignment than are Hawley retainers, however Hawley retainers have been found to better allow for settling and an improvement of posterior occlusal contact during retention in comparison to retention with thermoplastic retainers.[8,9] In addition to the above findings, a systematic review by Littlewood et al in 2006 found there to be no statistical difference in stability between full time or nighttime only wear of removable retainers.[10]

In recent years, multiple studies have been conducted in which surveys were sent out to orthodontists to find out what the most commonly used retainers are as well as the

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most commonly accepted wear schedules.[11-15] A majority of these studies have found an increasing trend away from Hawley or Spring type retainers and moving more towards using thermoplastic and fixed retainers. Based on the above studies, the current most commonly accepted retention protocol in the United States and multiple European countries is using a fixed 3-3 retainer for the mandibular arch, and using a removable thermoplastic retainer for the maxillary arch to be worn at nighttime indefinitely. In 2014, while also finding a strong preference in life-time retention, Lai et al found slightly different results for retainer preference among orthodontists in Switzerland in that, bonded retainers were the most common retainer of choice for both the maxillary and mandibular arches, and that when expansion or extractions were involved with treatment it was common for a removable thermoplastic retainer to be used in combination with the bonded retainers.[16] In 2018, Padmos et al found similar results to Lai et al as their survey of orthodontists in the Netherlands showed a preference for indefinite retention using fixed 3-3 retainers for both maxillary and mandibular arches, as well as a removable thermoplastic retainer to be warn at nighttime in addition for the maxillary arch for up to 1 year posttreatment.[17] While the practitioner can monitor the stability of the teeth when the patient comes into the office for appointments, ultimately the stability of the teeth comes down to the patient's willingness to follow the prescribed retention protocol by wearing the retainers as directed. In addition to deciding a retainer wear schedule for their patients to follow, practitioners must decide what type of retainers to instruct their patients to wear.

No matter how much research goes into finding the best methods to retain

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posttreatment results, if patients are not compliant with retainer wear schedules, the practitioner's efforts are limited. In recent years, multiple studies have surveyed patients directly to analyze what factors contribute to post treatment retainer compliances. In 2005, Wong and Freer found compliance to be better with thermoplastic retainers than Hawley retainers due to patient comfort and satisfaction levels being higher with thermoplastic retainers.[18] In 2010, Kacer et al found that at 3 months posttreatment, 69% of patients reported wearing their removable retainers every night, and that by 2 years posttreatment, 19% of patients reported not wearing their retainers at all anymore.[19] In 2011, Pratt et al found compliance to be better with thermoplastic retainers than Hawley retainers because of esthetics.[20] However in 2012, Katherine Vig found esthetics not to be a major compliance factor, but rather subject age, gender, and time since fixed appliances were removed to be larger contributing factors to retainer compliance.[21]

Each of the above studies provide us with great insight into common retention protocols and patient's attitudes towards complying with the prescribed retention protocols. However, none of the above studies have attempted to assess if the active orthodontic treatment method chosen by the practitioner plays a role in the patient's retention compliance following active treatment. Previously if a patient presented with a malocclusion, they were prescribed fixed appliances (braces) to align their teeth. While fixed appliances are still a very popular treatment modality, more recently the use of clear aligners, most commonly Invisalign which was founded in 1999, have been used as a more esthetically driven treatment alternative to align teeth. Very little research has been conducted comparing differences in retention between patients treated with fixed

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appliances and patients treated with Invisalign. Kuncio et al in 2007 compared stability of cases treated with fixed appliances to cases treated with Invisalign and found that while both groups showed some occlusal relapse at a 3-year posttreatment timepoint, the Invisalign group showed a statistically significant result for having more relapse than the fixed appliance group.[22]

Throughout an extensive review of the current literature, we have not found any published articles that have compared post-treatment retention compliance for patients treated with Invisalign compared to patients treated with traditional fixed appliances. With Invisalign becoming an increasingly popular treatment modality, we feel it is important to understand how our patients feel about posttreatment retention and assess whether this attitude differs based on the treatment modality used to align their teeth in the active phase of treatment.

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Materials and Methods

The procedures and protocols for this study were approved by the Institutional Review Board at a University located in the midwest of the United States. After we critically reviewed the literature, our initial survey instrument was designed with the ‘‘tailored design method.’’[23] The questionnaire was pilot tested on 6 patients in the graduate orthodontic clinic of the Department of Orthodontics. The responses were reviewed, and minor revisions were made to form a preliminary survey instrument. The preliminary survey was converted to electronic form and hosted on Qualtrics.com. The electronic version was again tested and revised as needed to arrive at the final survey instrument. The final survey consisted of 10 questions; 3 demographic identifiers, 1 treatment modality, and 6 pertaining to retention compliance.

Participants

Recruitment was conducted over a 3-week period in October, 2020. Participation was voluntary and respondents were recruited from an opportunity sample. The patient population chosen for this study came from Wenger Orthodontics, a local private practice on the east side of Cleveland. A single private practice was chosen for this study as an attempt to minimize variation in treatment mechanics and ensure that treated patients underwent a consistent retention protocol following active treatment. Following completion of active treatment, all patients received maxillary and mandibular removable clear overlay retainers and were instructed to wear them full time for the first 6 weeks, then transition to nighttime only wear indefinitely. The following inclusion criteria was used to establish the population of eligible participants: 1) patients who have completed treatment with either Invisalign® or fixed orthodontic appliances with an

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active treatment completion date within the range of 01/01/2010 – 01/01/2020, 2) must have a valid email address and/or mobile phone number in order to contact patients for participation in study, 3) patients must have received removable clear overlay type retainers upon completion of the active phase of treatment, and 4) subjects who are over the age of 13 in order to exclude patients who have only been treated for Phase I treatment. Using the practice management software with the above parameters, a search found 3,094 eligible participants who met the inclusion criteria. In order to recruit participants, a recruitment letter providing a brief explanation of the study to participants and a link to the survey was emailed to eligible participants. For eligible participants who have text messages setup as their primary communication method a text was sent to them with a link to the same recruitment letter that was sent by email. A participation reminder email was sent to all eligible participants 2 weeks after the initial recruitment letter was sent out in an attempt to increase participation.

Test Design

After agreeing to the consent form, participants were redirected to the beginning of the survey. This web-based survey via Qualtrics XM[24] consisted of 10 questions; 3 demographic identifiers including gender, ethnic identification, and age, followed by 7 questions pertaining to treatment and retention compliance. Participants were asked whether their active treatment was completed with Invisalign or fixed Appliances, and how long ago their active treatment was completed. They were then asked questions in regards to how much they currently wear their retainers, how long they feel is a sufficient length of retention to maintain treatment results, who they feel is responsible for

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maintaining a stable result, and if they would have preferred to receive a fixed retainer upon active treatment completion.

Statistical Design

Statistical analysis was conducted using IBM SPSS analysis software. Independent T-tests were used to compare mean responses from and within gender and treatment modality variable groups. Pearson Chi Square tests were used to assess for associations between Treatment Modality, Gender, Ethnicity, Age, and Time since active treatment completion with the following categorical variables; patient perception of length of retention, patient perception of the importance of a stable treatment result, patient's desire for receiving fixed retainers instead of removable retainers following active treatment, and patient perception of who is responsible for maintaining a stable treatment result. One-way ANOVA tests were used to compare the mean responses among the following groups; Ethnicity, Age, and Time since active treatment completion. Two-way ANOVA tests were used to assess the effect of Treatment Modality within groups for Ethnicity, Age, and Time since active treatment completion. Post hoc test was used for each ANOVA to determine significance between factors.

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Results

3094 total eligible participants received the recruitment letter, 1465 by email, and 1629 by text message. A total of 147 survey responses were received. Out of 147 participants, 4 participants exited the survey prior to responding to all questions, so those responses were disregarded. The majority of the respondents were female, 88 responses (62%) compared to 55 (38%) male participants. 125 (87%) participants identified as White, 10 (7%) identified as Asian, 4 (3%) identified as Black or African American, and 4 (3%) identified as other. The most prevalent respondent age group was 18 – 60 years old with 105 (73%) responses, followed by the under 18 group with 23 (16%) responses, and 15 (11%) responses from participants 60 years or older. Of the 143 respondents, 113 (79%) reported that their active treatment was completed using fixed appliance, and 30 (21%) subjects reported their treatment was completed with Invisalign. The final independent variable reported was time since completion of active treatment. For this question, response choices were the following: less than 1 year ago, 1 – 3 years ago, 4 – 6 years ago, 7 – 9 years ago, and more than 10 years ago. 60 (42%) respondents reported 1 – 3 years ago, 49 (34%) reported 4 – 6 years ago, 18 (13%) reported 7 – 9 years ago, 10 (7%) reported over 10 years ago, and 6 (4%) reported less than 1 year ago. A 95% Confidence Interval was used to demonstrate significance level for statistical tests.

Retainer compliance within last 7-day week

The question that reads, "How often did you wear your removable retainers **last week** (over a 7 day period)?" differed from all other questions in that it asked participants to answer all four components of the question. In an attempt to find out not only how

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many days per week patients are wearing their removable retainers but also to find out when they are wearing the retainers, respondents were asked to respond to each of the following with a fill in the blank answer; number of days retainers were worn (0 – 7), number of hours per day worn (0 – 24), number of nighttime hours worn per day (0 – 8), number of daytime hours worn per day (0 – 16).

In looking at treatment modality, this study found that patients treated with Invisalign on average wore their retainers more than patients treated with fixed appliances. Independent t-tests revealed Invisalign patients wore their removable retainers more days per week (4.88, $p = .039$), more hours per 24-hr day (7.34, $p = .004$), and more nighttime hours per day (7.0 , $p = .008$), compared to fixed appliance patients who wore their removable retainers on average for 3.87 days per week, 5.61 hours per 24-hr day, and 5.12 nighttime hours per day worn.

No statistically significant differences were found in this study in regards to gender. However, in comparing gender groups within treatment modality groups, a statistically significant difference was found in the Invisalign group, as male patients treated with Invisalign reported wearing their removable retainers for an average of 9.4 hours per 24-hr day, compared to female Invisalign patients who reported an average of 6.65 hours per day ($p = .016$). Also within the Invisalign patients' group, a statistically significant difference was found as male patients treated with Invisalign reported wearing their removable retainers for an average of 7.9 nighttime hours, compared to female Invisalign patients who reported an average of 6.4 nighttime hours ($p = .038$). No other statistical difference was found between male and female patients who were treated with fixed appliances.

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There was a statistically significant difference between ethnic groups as determined by one-way ANOVA (F = 3.360, p = .021). A Tukey post hoc test revealed that the average reported hours the removable retainers were worn per 24-hour day in a recent 7-day period were statistically significantly higher for patients in the Black or African American group (11.50, p = .021) compared to all other groups including; White (5.62, p = .048), Asian (4.00, p = .025), and Other (2.75, p = .030). There were no other statistically significant differences between the groups.

A statistically significant difference was also found between age groups as determined by one-way ANOVA (F = 4.718, p = .010). A Tukey post hoc test revealed that the average reported days the removable retainers were worn in a recent 7-day period was statistically significantly lower for patients both in the under 18 years old group (3.96, p = .048), and the 18 to 60 years old group (3.80, p = .007) in comparison to the over 60 years old group (6.23). There were no other statistically significant differences between the groups.

With respect to time since active treatment completion, there was a statistically significant difference between groups as determined by one-way ANOVA (F = 3.196, p = .015). A Tukey post hoc test revealed that the average reported days the removable retainers were worn in a recent 7-day period was statistically significantly lower for patients who completed their active treatment 4 to 6 years ago (3.16, p = .014) than for patients who completed active treatment 1 to 3 years ago (4.93). No statistically significant differences were found within Ethnic groups, Age groups, or Time since active treatment completion groups in relation to treatment modality.

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Patient Perception- necessary length of retention for stability

For this question, respondents had four possible choices: less than 1 year, 1 – 3 years, 3 – 10 years, or lifetime. 95 (67%) respondents reported lifetime retention is necessary to maintain a stable treatment result, 26 (18%) respondents felt 3 – 10 years of retention is sufficient to maintain a stable result, 19 (13%) reported 1 – 3 years is sufficient, and 3 (2%) respondents felt less than 1 year of retainer wear following active treatment is sufficient to maintain treatment results.

Chi-square tests of independence were performed to examine the relationship between patients' perceptions for how long retention should be to maintain a stable treatment result and the following variables; Treatment Modality, Gender, Ethnicity, Age, and Time since active treatment completion. The relation with Ethnicity was significant, X^2 (9, N = 143) = 24.8, p = .003. A closer look at the results shows that 40% of Asian respondents reported they believe the ideal length of retention should be 1 – 3 years, which was three times higher than the next highest ethnic group response. The results also show that 100% of respondents from the Other ethnic group believe that lifelong retainer wear is the ideal length to maintain a stable result, which was over 30% higher than the next closest ethnic group's response.

Patient Perception- importance of stability

The four response choices for the importance of stability question included: Extremely Important, Rather Important, Unsure, or Not Important. The responses were as follows: 109 (76%) respondents chose extremely important, 27 (19%) chose rather

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important, 6 (4%) chose unsure, and 1 (1%) respondent felt a stable result was not important.

Chi-square tests of independence were performed to examine the relationship between patients' perceptions on the importance of a stable treatment result and the following variables: Treatment Modality, Gender, Ethnicity, Age, and Time since active treatment completion. The relation with Ethnicity was significant, X^2 (9, N = 143) = 26.9, p = .001. Around 75% of respondents from each ethnic group reported that a stable result is extremely important, except the Black or African American group where only 25% of respondents reported that a stable result is extremely important. No other statistically significant associations were found in relation to patient perception on the importance of a stable result.

Patient Perception- prefer Fixed or Removable retainers

In order to qualify as an eligible participant for this study, patients must have received a removable clear overlay retainer following active treatment completion. While most patients receive this type of retainer for both arches, if the criteria of a pretreatment anterior space or diastema is met, a patient may receive a fixed retainer in that specific arch and a removable clear overlay retainer for the opposing arch. For this reason, to avoid confusion for those patients participating, the answer choices for this question included the following: Yes, No, Unsure, or Not applicable as I did not receive a removable retainer. 80 (56%) respondents indicated they would not prefer to have fixed or bonded retainers instead of their removable retainers, 40 (28%) reported they

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would have preferred fixed retainers, 23 (16%) said they are unsure whether they would have preferred fixed retainers or removable retainers.

Chi-square tests of independence were performed to examine the relationship between patients' desire for fixed retainers instead of removable retainers following completion of active treatment and the following variables: Treatment Modality, Gender, Ethnicity, Age, and Time since active treatment completion. The relation with Treatment Modality was significant, X^2 (2, N = 143) = 9.8, p = .008. Patients treated with Invisalign were more likely than patients treated with fixed appliances to desire fixed retainers. Also, the relation with Gender was significant, X^2 (2, N = 143) = 6.7, p = .035. Female respondents were more likely than male respondents to desire fixed retainers. No associations were found for Ethnicity, Age, and Time since active treatment completion.

Patient Perception- who is responsible for stability of result

There were four response choices for who the patient feels has the responsibility for the treatment stability: Patient, General Dentist, Orthodontist, or Both patient and orthodontist. 72 (50%) responses reported that the patient is responsible for stability of results, 68 (48%) reported that both the patient and orthodontist are responsible for stability of treatment results, 2 (1.3%) participants felt it is the sole responsibility of the orthodontist to maintain a stable treatment result, and 1 (0.7%) participant felt the general dentist is responsible for stability.

Chi-square tests of independence were performed to examine the relationship between patients' perceptions on who is responsible for stability of treatment result and the following variables: Treatment Modality, Gender, Ethnicity, Age, and Time since

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active treatment completion. No associations were found between patients' perceptions on who is responsible for stability of treatment result and any of the above variables.

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Discussion

The main objective of this study is to analyze and compare post-treatment retention compliance for patients treated with Invisalign compared to patients treated with traditional fixed appliances.

Based on the results obtained in this study, we can accept our first hypothesis, there is a significant difference between the retention compliance of patients treated with Invisalign in comparison to patients treated with traditional fixed appliances. The results from the survey found a statistically significant difference showing that patients whose active treatment was completed using Invisalign reported higher levels of compliance with removable retainer wear in terms of days per week worn, total hours worn per 24-hour day, and nighttime wear hours as compared to patients treated with fixed appliances. Invisalign treated patients mean reported removable retainer wear responses were 4.88 days per 7-day week, 7.24 hours per 24-hour day, and 7.0 hours of nighttime wear per day, as compared to fixed appliance patients whose mean reported removable retainer wear responses were 3.87 days per 7-day week, 5.61 hours per 24-hour day, and 5.12 hours of nighttime wear per day respectively. We believe this significance may be associated with Invisalign patients having little to no adjustment moving from active treatment to retention with clear overlay retainers. Whereas patients treated with fixed appliances may not be used to using a compliance driven appliance, so there is a larger adjustment period in moving from active treatment to retention.

While we were able to accept our first alternative hypothesis, this result was in fact the opposite of what we expected to find in this study. Based on anecdotal clinical information, we predicted that we would find removable retainer wear compliance would

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be higher for patients treated with fixed appliances than for patients treated with Invisalign. We believed there would be a stronger level of patient burnout in retention compliance with Invisalign patients because the clear overlay removable retainers they received are more similar to the appliance they received for their active treatment. Whereas for patients treated with fixed appliances, we initially believed since the clear overlay retainer they received following active treatment was more esthetic and hygienic than their fixed appliances, that the patient burnout factor would play less of a role. It may be possible that the patients in this sample who were treated with Invisalign displayed more compliance with clear overlay retainer wear because this style of retainer is more similar to the Invisalign appliance they were already used to using, so following completion of active treatment there was little to no adjustment to the new appliance.

In comparison to Kacer et al., 2011, the removable retainer compliance level found in our study was similar to that of their previous study, however they did not account for any potential difference between fixed appliance treated patients and Invisalign treated patients. Whereas in this current study, it was found that in our sample, patients treated with Invisalign showed better long-term compliance with removable retainers than did patients treated with fixed appliances.

When analyzing gender differences within treatment modality groups, statistically significant differences were found for both retainer wear total hours per 24-hour day, as well as for nighttime wear. Within the Invisalign patients' group, male participants reported higher levels of retainer wear compliance than did female patients who were treated with Invisalign. Male Invisalign patients' mean reported 24-hour day and

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nighttime wear hours were 9.4 and 7.9 hours respectively. This is statistically significantly higher than female Invisalign patients, whose mean responses were 6.65 and 6.4 hours respectively. There is no clear indication as to why this finding was observed, however we do have a couple theories. In comparing the average normal routines of males and females before bed and in the morning, typically women have longer routines involving hair and makeup in addition to the daily tasks that both men and women typically perform. With additional tasks and responsibilities, it's possible that female patients may be more likely to forget to wear their removable retainers more frequently than male patients. Another theory is that in general females have been shown to be more health conscious than males and may be more put off by the idea of putting their fingers in their mouth to put in and remove their removable retainers, so as a result they don't wear the retainers as often.

Additionally, statistically significant results were found between ethnic groups, as well as age groups for retention compliance. Looking at Ethnicity differences, the average reported hours the removable retainers were worn per 24-hour day in a recent 7-day period were statistically significantly higher for patients in the Black or African American group (11.50) compared with the White (5.62), Asian (4.00), and Other (2.75) groups. There were no other statistically significant differences between the groups. Looking at differences between age groups, the average reported days the removable retainers were worn in a recent 7-day period was statistically significantly lower for patients both in the under 18 years old group (3.96), and the 18 to 60 years old group (3.80) in comparison to the over 60 years old group (6.23). There were no other statistically significant differences between the groups. While there may be some

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validity to this finding, in both subsample groups we are limited by a small subsample size which may have resulted in a false positive statistical finding.

The results from the survey found a statistically significant association between Treatment Modality (Fixed Appliances or Invisalign) used for patient's active treatment and patient's desire to receive a fixed retainer following treatment instead of a removable retainer. 50% of patients whose active treatment was completed using Invisalign reported a desire for receiving a fixed retainer instead of a removable retainer following completion of active treatment, as compared to 22% of patients treated with fixed appliances reporting they would prefer to have a fixed retainer. We don't know for sure why the above result was observed. It may be possible that even though patients who were treated with Invisalign showed to be more compliant with removable retainers, we believe there is an element of patient burnout that contributed to this significant finding. Since these patients were treated with a removable compliance driven appliance, they prefer to have retainers in the post treatment retention phase that don't depend on compliance.

In addition to treatment modality, a statistically significant association was found between Gender and the patient's desire to receive a fixed retainer following treatment instead of a removable retainer. 35% of female respondents reported a desire for receiving a fixed retainer following active treatment completion as compared to 16% of male respondents reporting the same desire. Similarly to our theory as to why male Invisalign patients were more compliant with removable retainers than female Invisalign patients, it may be possible that females reported they would prefer fixed retainers because then retainer wear would be one less thing to worry about during their daily

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routine. It could also be possible that females may feel more confident in their oral hygiene than males, and therefore feel better about their ability to care for something fixed to their teeth.

Participants were also asked how long ago their active treatment was completed with the following five answer options: Less than 1 year ago, 1 – 3 years ago, 4 – 6 years ago, 7 – 9 years ago, and More than 10 years ago. 76% of responses to the survey came from either the 1 – 3 years ago or the 4 – 6 years ago groups. The results found a statistically significant association between time since active treatment completion and removable retainer wear compliance for the amount of days retainers were worn in a recent 7-day period. Patients who completed active treatment 1 – 3 years ago reported wearing their removable retainers an average of 4.93 ± 2.80 days, as compared to a mean result of 3.16 ± 2.79 days reported by the 4 – 6 years ago group. Given the above statistically significant result, we were able to reject our third null hypothesis that stated the following: There is no correlation between length of time since active treatment completion and patient retainer wear compliance. These results are consistent with Pratt et al. 2011, Vig 2012, and Kacer et al. 2010, which all showed good initial compliance with clear overlay retainers followed by a decline in compliance overtime. Both Kacer et al. 2010, and Pratt et al. 2011 showed good compliance initially following completion of active treatment, then a moderate to high level of decline in compliance at the two-year post-treatment time point. Our study revealed participants showing good compliance up to three years post treatment, then a moderate to high level of decline in compliance between 4 - 6 years post treatment.

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For the survey question in regards to patient perception for how long retainers should be worn to maintain a stable treatment result, participants had four answer choices: less than 1 year, 1 – 3 years, 3 – 10 years, or lifetime. A statistically significant association was found with ethnic identification. The results show that 40% of Asian respondents reported they believe the ideal length of retention should be 1 – 3 years, which was three times higher than the next highest ethnic group response. The results also show that 100% of respondents from the Other ethnic group believe that lifelong retainer wear is the ideal length to maintain a stable result, which was over 30% higher than the next closest ethnic group's response. Here again, there may be some validity issues with this finding due to the small subsample sizes, which may have resulted in a false positive statistical finding.

A statistically significant result was also found when participants were asked about their perception regarding the importance of a stable treatment result. These were the four choices for this question: not important, unsure, rather important, and extremely important. No significance was found between groups for treatment modality, gender, age, or time since active treatment completion, however a statistically significant association was found with ethnicity. Around 75% of respondents from each ethnic group reported that a stable result is extremely important, except the Black or African American group where only 25% of respondents reported that a stable result is extremely important. Again, this statistical finding may have been caused or affected by a small subsample size which may have resulted in a false positive statistical finding.

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Limitation

There were some limitations in this study. One major limitation was sample size and survey response rate. For a power of 80% to be represented in this study, a sample size of 149 participants was required, and we only obtained 143 participants. The survey was sent to a total of 3,094 eligible participants, and 143 responses were fully completed for a response rate of only 4.6%. There were 147 total responses, however 4 responses were incomplete where it appeared that the respondent exited the survey in the middle, so those 4 responses were disregarded. Another issue was in the distribution of the sample. 113 fixed appliance patients were recorded, while only 30 Invisalign patients responded to the survey. A large majority of responses (87%) came from the White ethnic group, while all other ethnic groups had less than 10 responses and as little as 4 responses. Additionally, 73% of responses came from the 18 – 60 age group, and only 16% and 11% coming from the other two age groups respectively. Therefore, while multiple variables found associations or significant differences between ethnic groups, it's possible there was a type 1 error at play due to the small sample sizes. The results of this study may have benefited greatly from a larger sample size, more varied age group choices, and future studies may consider using multiple office patient populations to increase the number and diversity of the sample.

Conclusion

Patients treated with Invisalign are more compliant with wearing removable clear overlay retainers following completion of active treatment than patients treated with fixed appliances. Patients who were treated with Invisalign showed a stronger desire for

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receiving a fixed retainer following completion of active treatment than did patients who were treated with fixed appliances. Similarly, female patients showed a stronger desire for receiving a fixed retainer following completion of active treatment. Finally, patients who were 4 – 6 years removed from active treatment completion showed less compliance with wearing removable retainers than did patients who were only 1 – 3 years removed from completion of active treatment.

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IRB APPROVAL

IRB Administration Offices

UH IRB Phone: 216.844.1529
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INITIAL APPROVAL

Principal Investigator:	Manish Valiathan
Title:	Analyzing Patient Retention Compliance: Invisalign vs. Fixed Appliances, a Questionnaire-Based Study
Submission Number:	STUDY20200639
IRB Office:	CWRU IRB
Approval Date:	9/22/2020
Effective Date:	10/2/2020
Approval End Date	N/A
Type of Submission:	Initial Study
Type of Review:	Expedited
Documents Reviewed:	• Questionnaire For Study.pdf, Category: Other; • Analyzing Patient Retention Compliance: Invisalign vs. Fixed Appliances, a Questionnaire-Based Study, Category: IRB Protocol; • Informed Consent Document.pdf, Category: Consent Form; • COI Form, Category: Other; • Dr. Wenger Consent Form, Category: Other; • Assent Document.pdf, Category: Consent Form; • HIPAA Waiver Form, Category: Consent Form; • Recruitment Letter, Category: Recruitment Materials;

The IRB has reviewed this submission.

- Per Federal regulation, changes MAY NOT be made to any element of the current research without prior IRB approval, except to eliminate an immediate and apparent hazard to subjects enrolled in the study.
- Per Federal regulation, the research may not continue beyond the Approval End date. You must submit a continuing review form 6-8 weeks before this Approval End date in order to maintain IRB approval. Failure to maintain IRB approval is human subjects non-compliance. Please note that even if your study falls into a category that does not require an Approval End date, the institution may require a yearly "check-in" to confirm the status of the study.

The UH IRB operates under HHS Federalwide Assurance (FWA) number 00003937 and IRB registration numbers 00000684, 00001691 and 00008600. The CWRU IRB operates under DHHS FWA00004428 and IRB registration number 00000683.

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IRB Administration Offices

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CWRU IRB Phone: 216.368.6925

***Approval by the IRB does NOT mean that you have permission to start your study. Prior to starting your study, you may be required to obtain (1) a coverage analysis for studies that involve patient care, regardless of source of funding, and/or (2) a contract with the Sponsor of your study or an agreement with any third-party collaborator that may receive UH or CWRU patient information in any format. Please ensure that all required approvals are obtained before initiation of research activity. ***

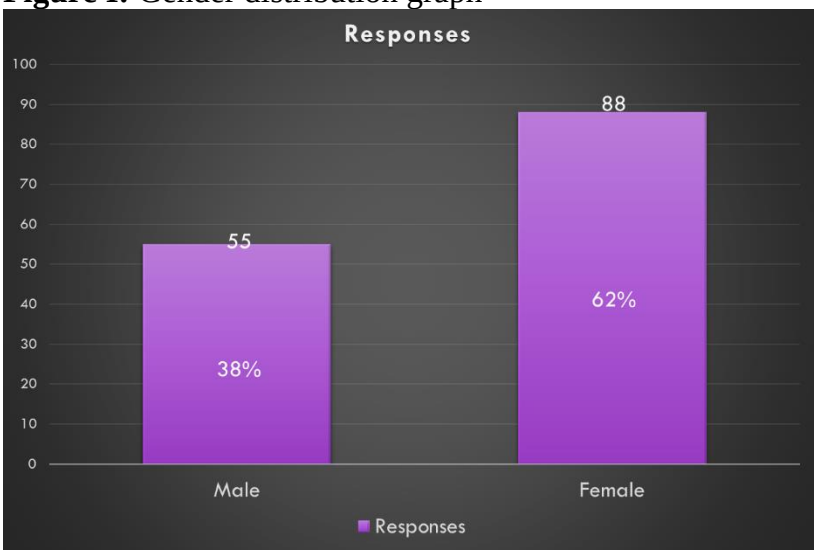
The UH IRB operates under HHS Federalwide Assurance (FWA) number 00003937 and IRB registration numbers 00000684, 00001691 and 00008600. The CWRU IRB operates under DHHS FWA00004428 and IRB registration number 00000683.

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Survey Questions and Responses:

1. Gender
    a. Male
    b. Female

Figure I: Gender distribution graph



2. Ethnic Identification
    a. White
    b. Black or African American
    c. American Indian or Alaska Native
    d. Asian
    e. Native Hawaiian and Pacific Islander
    f. Other

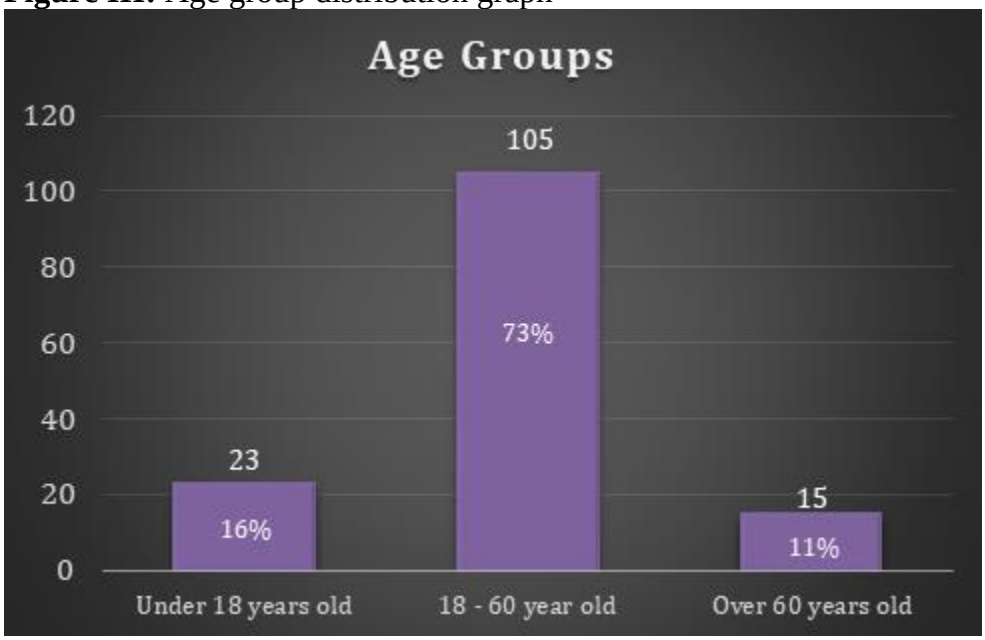
Figure II: Ethnic Identification distribution graph



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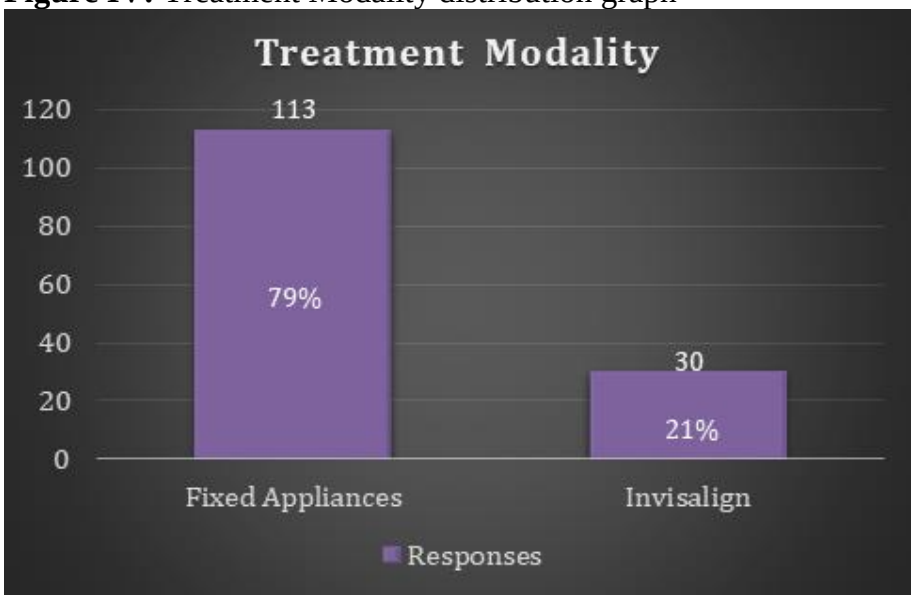
3. Age:
    a. Under 18 years old
    b. 18 – 60 years old
    c. Over 60 years old

Figure III: Age group distribution graph



4. Was your orthodontic treatment completed with Braces or Invisalign?
    a. Braces
    b. Invisalign

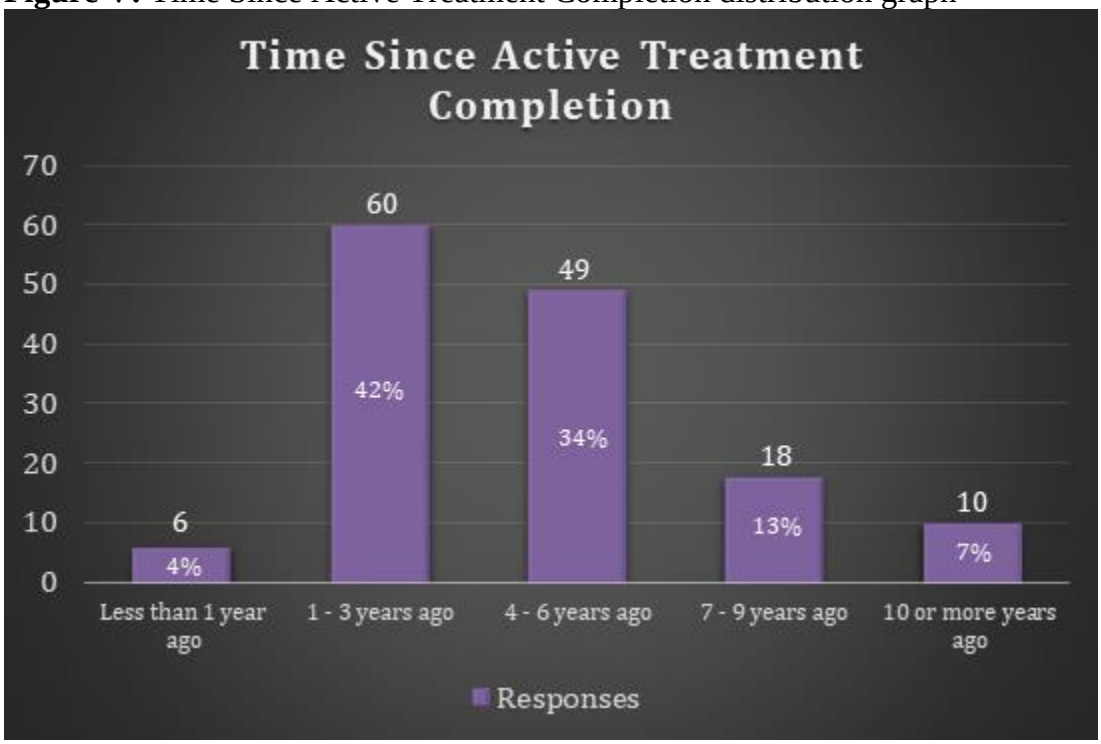
Figure IV: Treatment Modality distribution graph



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5. When did you finish your active treatment (Removal of braces or completion of Invisalign trays)?
    a. Less than 1 year ago
    b. 1 to 3 years ago
    c. 4 to 6 years ago
    d. 7 to 9 years ago
    e. 10 or more years ago

Figure V: Time Since Active Treatment Completion distribution graph



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6. How often did you wear your removable retainers **last week** (over a 7 day period)?
   Number of days (0 – 7 days): _____
   Hours per day when worn (0 – 24 Hrs): _____
   Nighttime hours per day worn (0 – 8 Hrs): _____
   Daytime hours per day worn (0 – 16 Hrs): _____

Figure VI: Recent 7-day Period Removable Retainer Wear graph

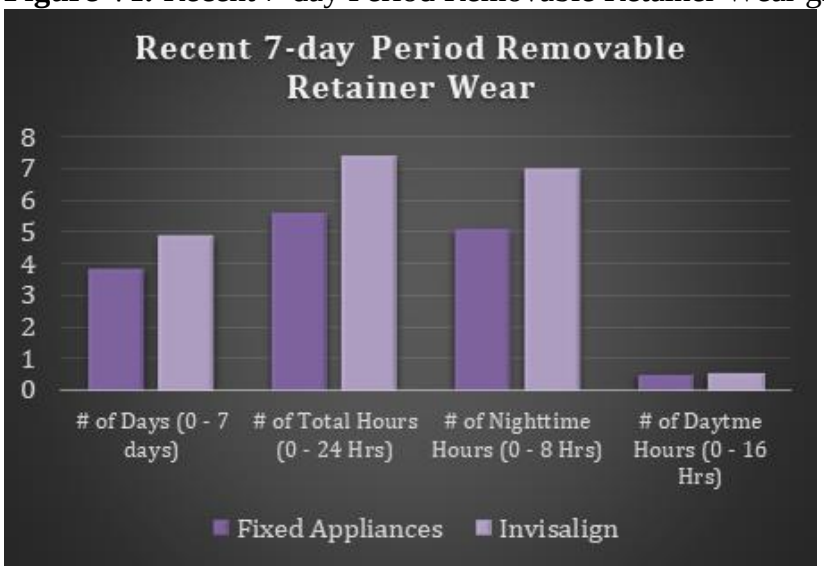


Table I: Independent Sample T-test comparing Treatment Modalities for Retainer Compliance

		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
Days Worn	Equal variances assumed	3.400	0.067	-1.687	141	0.094	-1.016	0.602	-2.207	0.175
	Equal variances not assumed			-1.795	49.796	0.079	-1.016	0.566	-2.153	0.121
Hours Worn	Equal variances assumed	16.292	0.000	-2.456	141	0.015	-2.247	0.915	-4.056	-0.438
	Equal variances not assumed			-2.848	57.560	0.006	-2.247	0.789	-3.827	-0.668
Night Hours Worn	Equal variances assumed	20.131	0.000	-2.128	141	0.035	-1.423	0.669	-2.744	-0.101
	Equal variances not assumed			-2.602	63.882	0.011	-1.423	0.547	-2.515	-0.330
Day Hours Worn	Equal variances assumed	0.017	0.896	-0.053	140	0.958	-0.022	0.416	-0.844	0.800
	Equal variances not assumed			-0.055	48.593	0.956	-0.022	0.398	-0.823	0.779

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Table II: One-way ANOVA comparing Ethnicity groups for Retainer Compliance

		Sum of Squares	df	Mean Square	F	Sig.
Hours Worn	Between Groups	197.368	3	65.789	3.360	0.021
	Within Groups	2721.450	139	19.579		
	Total	2918.818	142			

Table III: Post hoc comparing between Ethnic groups for Retainer Compliance

Dependent Variable			Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Hours Worn	White	Black or African American	-5.880*	2.248	0.048	-11.72	-0.04
		Asian	1.620	1.454	0.682	-2.16	5.40
		Other	2.870	2.248	0.579	-2.97	8.71
	Black or African American	White	5.880*	2.248	0.048	0.04	11.72
		Asian	7.500*	2.618	0.025	0.69	14.31
		Other	8.750*	3.129	0.030	0.61	16.89
	Asian	White	-1.620	1.454	0.682	-5.40	2.16
		Black or African American	-7.500*	2.618	0.025	-14.31	-0.69
		Other	1.250	2.618	0.964	-5.56	8.06
	Other	White	-2.870	2.248	0.579	-8.71	2.97
		Black or African American	-8.750*	3.129	0.030	-16.89	-0.61
		Asian	-1.250	2.618	0.964	-8.06	5.56

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Table IV: One-way ANOVA comparing Age groups for Retainer Compliance

		Sum of Squares	df	Mean Square	F	Sig.
Days Worn	Between Groups	78.135	2	39.068	4.718	0.010
	Within Groups	1159.190	140	8.280		
	Total	1237.325	142			

Table V: Post hoc comparing between Age groups for Retainer Compliance

Dependent Variable			Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Days Worn	Under 18 years old	18 to 60 years old	0.157	0.662	0.970	-1.41	1.73
		Over 60 years old	-2.277*	0.955	0.048	-4.54	-0.01
	18 to 60 years old	Under 18 years old	-0.157	0.662	0.970	-1.73	1.41
		Over 60 years old	-2.433*	0.794	0.007	-4.31	-0.55
	Over 60 years old	Under 18 years old	2.277*	0.955	0.048	0.01	4.54
		18 to 60 years old	2.433*	0.794	0.007	0.55	4.31

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Table VI: One-way ANOVA comparing Time Since Active Treatment Completion for Retainer Compliance

ANOVA						
		Sum of Squares	df	Mean Square	F	Sig.
Days Worn	Between Groups	104.895	4	26.224	3.196	0.015
	Within Groups	1132.430	138	8.206		
	Total	1237.325	142			
Hours Worn	Between Groups	140.237	4	35.059	1.741	0.144
	Within Groups	2778.581	138	20.135		
	Total	2918.818	142			
Night Hours Worn	Between Groups	85.696	4	21.424	2.030	0.093
	Within Groups	1456.122	138	10.552		
	Total	1541.818	142			
Day Hours Worn	Between Groups	26.121	4	6.530	1.635	0.169
	Within Groups	547.034	137	3.993		
	Total	573.155	141			

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Table VII: Post hoc comparing between Time Since Treatment Completion groups for Retainer Compliance

Multiple Comparisons							
Tukey HSD							
Dependent Variable			Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Days Worn	1 to 3 years ago	Less than 1 year ago	0.100	1.227	1.000	-3.29	3.49
		4 to 6 years ago	1.770*	0.552	0.014	0.25	3.29
		7 to 9 years ago	0.739	0.770	0.873	-1.39	2.87
		Over 10 years ago	2.133	0.978	0.193	-0.57	4.84
	4 to 6 years ago	Less than 1 year ago	-1.670	1.239	0.662	-5.09	1.75
		1 to 3 years ago	-1.770*	0.552	0.014	-3.29	-0.25
		7 to 9 years ago	-1.031	0.790	0.688	-3.21	1.15
		Over 10 years ago	0.363	0.994	0.996	-2.38	3.11

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7. How long after active treatment do you think patients should have to wear retainers to keep teeth straight?
    a. Less than 1 year
    b. 1 - 3 years
    c. 3 - 10 years
    d. Lifelong

Figure VII: Patient Perception of Ideal Length of Retention graph

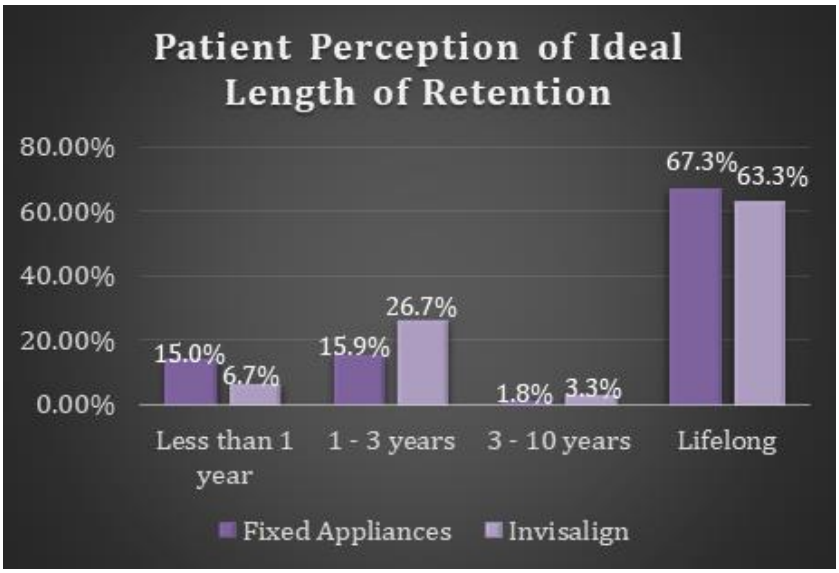


Table VIII: Pearson Chi-Square of Ethnicity group responses to Ideal Length of Retention

Crosstab							
			Retention Length				Total
			1 - 3 years	3 - 10 years	Less than 1 year	Lifelong	
Ethnicity	Asian	Count	4	0	1	5	10
		% within Ethnicity	40.0%	0.0%	10.0%	50.0%	100.0%
		% within Retention Length	21.1%	0.0%	33.3%	5.3%	7.0%
		% of Total	2.8%	0.0%	0.7%	3.5%	7.0%
	Black or African American	Count	0	1	1	2	4
		% within Ethnicity	0.0%	25.0%	25.0%	50.0%	100.0%
		% within Retention Length	0.0%	3.8%	33.3%	2.1%	2.8%
		% of Total	0.0%	0.7%	0.7%	1.4%	2.8%
	Other	Count	0	0	0	4	4
		% within Ethnicity	0.0%	0.0%	0.0%	100.0%	100.0%
		% within Retention Length	0.0%	0.0%	0.0%	4.2%	2.8%
		% of Total	0.0%	0.0%	0.0%	2.8%	2.8%
	White	Count	15	25	1	84	125
		% within Ethnicity	12.0%	20.0%	0.8%	67.2%	100.0%
		% within Retention Length	78.9%	96.2%	33.3%	88.4%	87.4%
		% of Total	10.5%	17.5%	0.7%	58.7%	87.4%
Total		Count	19	26	3	95	143
		% within Ethnicity	13.3%	18.2%	2.1%	66.4%	100.0%
		% within Retention Length	100.0%	100.0%	100.0%	100.0%	100.0%
		% of Total	13.3%	18.2%	2.1%	66.4%	100.0%

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8. How important is a stable result for you?
    a. Not important
    b. Unsure
    c. Rather important
    d. Extremely important

Figure VIII: Patient Perception on Importance of a Stable Result

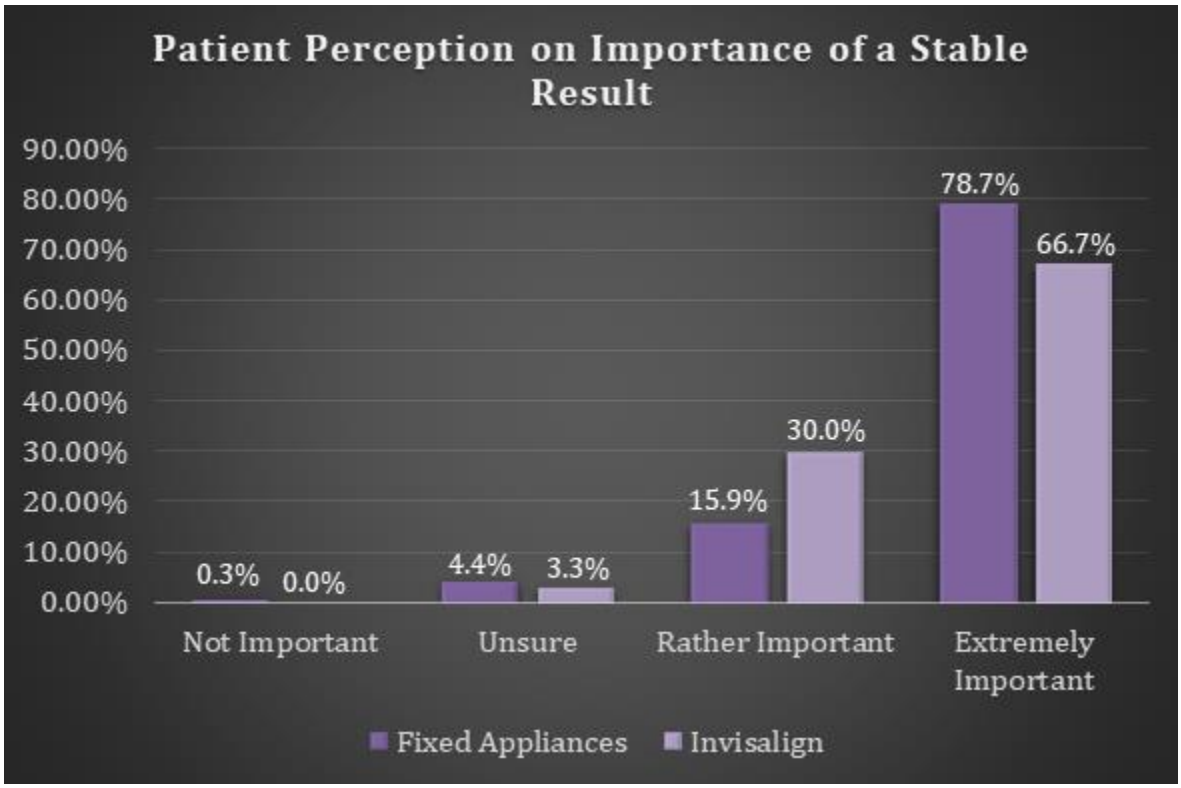


Table IX: Pearson Chi-Square of Ethnicity group responses to Importance of Stability

Chi-Square Tests			
	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	26.926[a]	9	0.001
Likelihood Ratio	15.639	9	0.075
N of Valid Cases	143		
a. 12 cells (75.0%) have expected count less than 5. The minimum expected count is .03.			

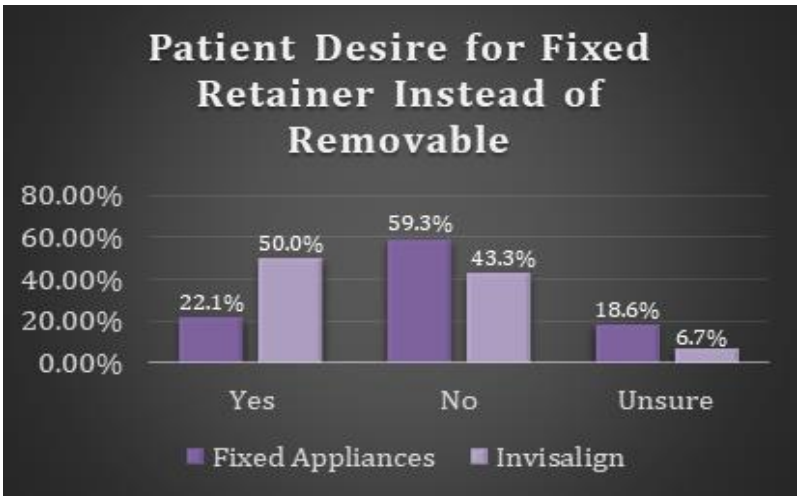
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Table IX: Pearson Chi-Square of Ethnicity group responses to Importance of Stability

Crosstab							
			Importance of Stability				Total
			Extremely important	Not important	Rather important	Unsure	
Ethnicity	Asian	Count	8	1	1	0	10
		% within Ethnicity	80.0%	10.0%	10.0%	0.0%	100.0%
		% within Importance of Stability	7.3%	100.0%	3.7%	0.0%	7.0%
		% of Total	5.6%	0.7%	0.7%	0.0%	7.0%
	Black or African American	Count	1	0	2	1	4
		% within Ethnicity	25.0%	0.0%	50.0%	25.0%	100.0%
		% within Importance of Stability	0.9%	0.0%	7.4%	16.7%	2.8%
		% of Total	0.7%	0.0%	1.4%	0.7%	2.8%
	Other	Count	3	0	0	1	4
		% within Ethnicity	75.0%	0.0%	0.0%	25.0%	100.0%
		% within Importance of Stability	2.8%	0.0%	0.0%	16.7%	2.8%
		% of Total	2.1%	0.0%	0.0%	0.7%	2.8%
	White	Count	97	0	24	4	125
		% within Ethnicity	77.6%	0.0%	19.2%	3.2%	100.0%
		% within Importance of Stability	89.0%	0.0%	88.9%	66.7%	87.4%
		% of Total	67.8%	0.0%	16.8%	2.8%	87.4%
Total		Count	109	1	27	6	143
		% within Ethnicity	76.2%	0.7%	18.9%	4.2%	100.0%
		% within Importance of Stability	100.0%	100.0%	100.0%	100.0%	100.0%
		% of Total	76.2%	0.7%	18.9%	4.2%	100.0%

9. Following your orthodontic treatment, you received a removable retainer; would you have preferred a bonded retainer?
    a. Yes
    b. No
    c. Unsure
    d. Not applicable as I did not receive removable retainers

Figure IX: Patient Perception of Desire for Fixed Retainer Instead of Removable



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Table XI: Pearson Chi-Square of Treatment Modality group responses to Desire for Fixed Retainer

Chi-Square Tests			
	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	9.758[a]	2	0.008
Likelihood Ratio	9.390	2	0.009
N of Valid Cases	143		
a. 1 cells (16.7%) have expected count less than 5. The minimum expected count is 4.83.			

Table X: Pearson Chi-Square of Treatment Modality group responses to Desire for Fixed Retainer

Crosstab						
			Desire for Fixed Retainer			Total
				No	Yes	
Treatment Appliance	Braces	Count	21	67	25	113
		% within Treatment Appliance	18.6%	59.3%	22.1%	100.0%
		% within Desire or Fixed Retainer	91.3%	83.8%	62.5%	79.0%
		% of Total	14.7%	46.9%	17.5%	79.0%
	Invisalign	Count	2	13	15	30
		% within Treatment Appliance	6.7%	43.3%	50.0%	100.0%
		% within Desire for Fixed Retainer	8.7%	16.3%	37.5%	21.0%
		% of Total	1.4%	9.1%	10.5%	21.0%

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Table XIII: Pearson Chi-Square of Gender group responses to Desire for Fixed Retainer

Chi-Square Tests			
	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	6.684[a]	2	0.035
Likelihood Ratio	6.965	2	0.031
N of Valid Cases	143		
a. 0 cells (.0%) have expected count less than 5. The minimum expected count is 8.85.			

Table XIV: Pearson Chi-Square of Gender group responses to Desire for Fixed Retainer

Crosstab						
			Desire for Fixed Retainer			Total
				No	Yes	
Gender	Female	Count	11	46	31	88
		% within Gender	12.5%	52.3%	35.2%	100.0%
		% within Desire for Fixed Retainer	47.8%	57.5%	77.5%	61.5%
		% of Total	7.7%	32.2%	21.7%	61.5%
	Male	Count	12	34	9	55
		% within Gender	21.8%	61.8%	16.4%	100.0%
		% within Desire for Fixed Retainer	52.2%	42.5%	22.5%	38.5%
		% of Total	8.4%	23.8%	6.3%	38.5%

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10. Who do you consider responsible for the stability after orthodontic treatment?
    a. Patient
    b. General Dentist
    c. Orthodontist
    d. Both patient and orthodontist

Figure X: Patient Perception of Who is Responsible for Stability

