



Effects of Clear Aligner Adjuncts on Patient Experience and Aligner Efficacy

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A thesis proposal submitted to the Division of Orthodontics, Oregon Health & Science University School of Dentistry in partial fulfillment of the requirement for the Degree of Master of Science in Orthodontics.

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Abstract

Objective: The objective of this randomized prospective study was to evaluate whether the use of clear aligner adjunct tools (PULSystem® “BITE ME”) affected reported pain, aligner wear compliance, subject satisfaction, and aligner tray efficacy during the initial phase of orthodontic treatment.

Methods: With OHSU IRB oversight, adult subjects undergoing clear aligner treatment without planned extraction, elastic wear, or interproximal reduction during the first four trays were recruited. Subjects were randomly assigned to the experimental (adjunct with removal hook and bite cushion) or control group (adjunct with removal hook). Subjects completed validated surveys to assess baseline psychosocial scores; and daily and overall pain via a modified McGill Pain Questionnaire, visual analogue scale (VAS), and current pain level score; satisfaction; and compliance. Predicted tooth positions were obtained by scanning tray #4 with a titanium dioxide-based spray and intraoral scanner. Actual positions were captured by digital intraoral scans following the wearing of tray #4. The predicted and actual models were imported into software (Geomagic Control) for best-fit superimposition, and root mean square (RMS) values were calculated to assess maxillary and mandibular arch aligner tracking accuracy. Statistical tests included Wilcoxon, t-, chi-squared, and analysis of variance, where significant differences were defined by $\alpha = 0.05$.

Results: Twelve subjects (n=6 experimental, n=6 control) completed the study; however, 11 were included in the tray-efficacy analysis. Baseline psychosocial scores indicated minimal symptoms with no significant between-group differences. Survey-response compliance varied between groups, with the control group maintaining consistently higher daily completion rates (77–79%) compared to the experimental group, whose rates declined across trays (72% to 50%).

This disparity likely influenced the reliability of late-treatment pain measurements. Across nearly all daily and overall pain measures, the experimental group did not differ significantly from the control group. When comparing the pain scores between weeks 1 and 2 for each tray, both groups generally showed the expected cyclical pain pattern with an initial peak following tray insertion followed by a decline. One exception was observed in tray 4, where the experimental group demonstrated a small percentage increase in VAS pain from week 1 to week 2 (+9%) whereas the control group demonstrated the expected decrease (-46%) and this difference was significant ($p = 0.03$). Compliance and satisfaction were high across groups, with no significant differences in reported hours/day or days/week of aligner wear. RMS analysis revealed no significant differences in tray efficacy between experimental and control groups; however, the mandibular arch exhibited significantly lower RMS values than the maxillary arch (0.62 ± 0.06 mm vs. 0.75 ± 0.09 mm, $p = 0.005$), indicating superior lower-arch tracking.

Conclusions: Use of the clear aligner adjunct with a bite cushion during the first four trays did not significantly affect overall pain, compliance, satisfaction, or tray efficacy. Although most pain outcomes were similar between groups, the experimental group showed a significant increase in VAS percent change during tray 4; however, this result is likely influenced by low survey-entry compliance and disproportionate data representation during the later trays. The significantly better tracking observed in the mandibular arch suggests a potential arch-specific difference in aligner adaptation that warrants further investigation.

Introduction

Within the modern age of dentistry, there is an increasing demand for esthetics, convenience, and comfort. As the field of orthodontics progresses with new innovations and technology, within the past two decades, the use of clear plastic removable dental trays, called “aligners,” to move the teeth has become an increasingly popular alternative to traditional fixed appliances that involve brackets and bands temporarily glued to the teeth and wires that engage the braces to move the teeth. Clear aligners have a lower profile appearance when compared to braces and wires. In addition to esthetics, patient hygiene is easier to maintain, due to the ability to completely remove the aligners when cleaning (Galan-Lopez et al., 2019). Patients receiving clear aligner treatment have reported less pain and fewer negative impacts in their lives during the first week of treatment when compared to patients receiving fixed appliance treatment (Miller et al., 2007). In addition to the benefits brought to the patient, there are numerous advantages that clear aligner treatment brings to the provider. For example, using orthodontic aligners can lead to decreased orthodontic “emergency” visits, longer intervals between appointments, and less chair time (Tamer et al., 2019). This potentially allows clinicians to see more patients, improve productivity, and increase practice revenue.

Clear aligner treatment works to move teeth by utilizing a series of plastic trays manufactured to fit the series of incremental tooth positions in a given dental arch from initial presentation to the desired tooth positions that achieve improved intra- and inter-arch relationships. Thus, each clear aligner should provide the forces necessary to incrementally shift teeth towards the final occlusion in stepwise fashion. Tooth-colored attachments are also glued onto the teeth to help improve the retention of the aligner and to help lead to more predictable tooth movement (Proffit et al., 2007). Although convenient and effective, clear aligner treatment

is accompanied with unique challenges when it comes to accurate tooth movement. Patients treated with clear aligners must be carefully monitored to ensure that the teeth are “tracking” according to the determined treatment plan and predicted final tooth positions. Tracking problems can arise for a variety of reasons. Some examples include: patients not wearing trays for the prescribed amount of time, patients breaking attachments, difficult tooth movements, aligners not seated and closely adapted to the teeth and attachments, and tooth-colored attachments not fitting snugly into the tray (Figure 1) (Bowman et al., 2015). Such tracking problems can result in tooth positions that do not match the intended tooth positions prescribed by the clear aligner treatment plan. In order to quantify tracking success, studies have compared the actual versus predicted tooth movements at specific points throughout treatment by overlapping a predicted virtual tooth setup with an actual final intraoral scan and measuring differences, or by making weekly polyvinyl siloxane impressions and measuring the changes between the dental models (Castroflorio et al., 2023; Drake et al., 2012).

To address tracking problems and improve patient comfort during treatment, clear aligner adjunctive tools have been created. One example of these tools is a disposable plastic cotton roll-shaped tool (Chewies, Ortho Technology, West Columbia, SC) which the patient bites on. If a gap is visible between the tray and teeth, this type of tool is used by the patients throughout the day to focus on the area and achieve a better fit and adaptation of the clear aligner to the teeth (Bowman et al., 2015). Another disposable plastic tool that consists of a stick with biting “cushion” and a loop at one end and hook at the other end (BITE ME, Pul System, San Francisco), is designed similarly for the patient to bite on and improve aligner seating (Figure 2A-C), however, the hook end also aids in aligner removal (Figure 2B). By biting on the plastic

cushion (Figure 2C), the patient can better adapt the aligner to the teeth and minimize gaps (Figure 1).

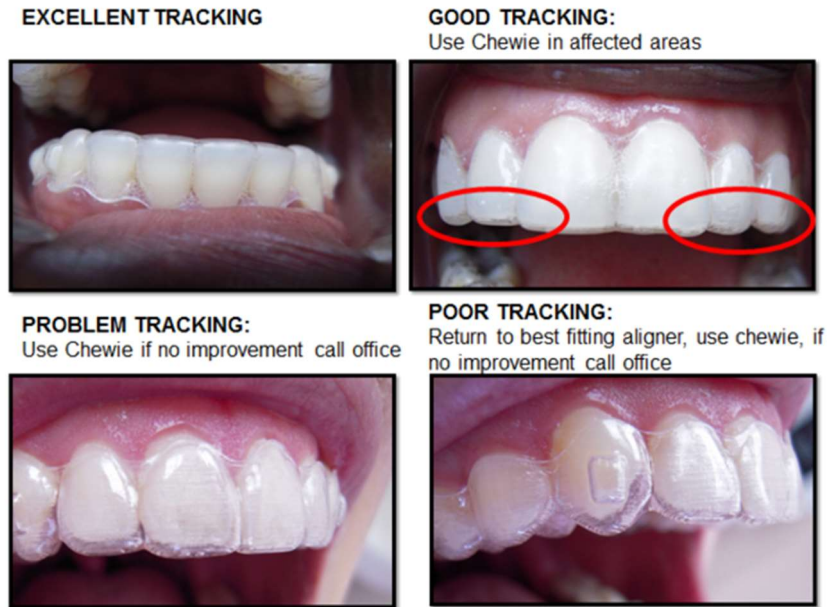


Figure 1. Various types of tracking from “excellent” where aligner is fully seated (upper left), “good” where some gaps between the tray and teeth are indicated by red circles (upper right), “problem tracking” where the gaps start to get larger and the teeth are not following the designed shape of the tray, and “poor tracking” where the gaps are largest and the white bumps on the teeth (attachments) are not seated within the tray anymore. The instructions in this figure refer to use of the “Chewie” adjunctive tool , which is designed to address tracking errors (“Invisalign Aligners | Check Your Fit, n.d.”).

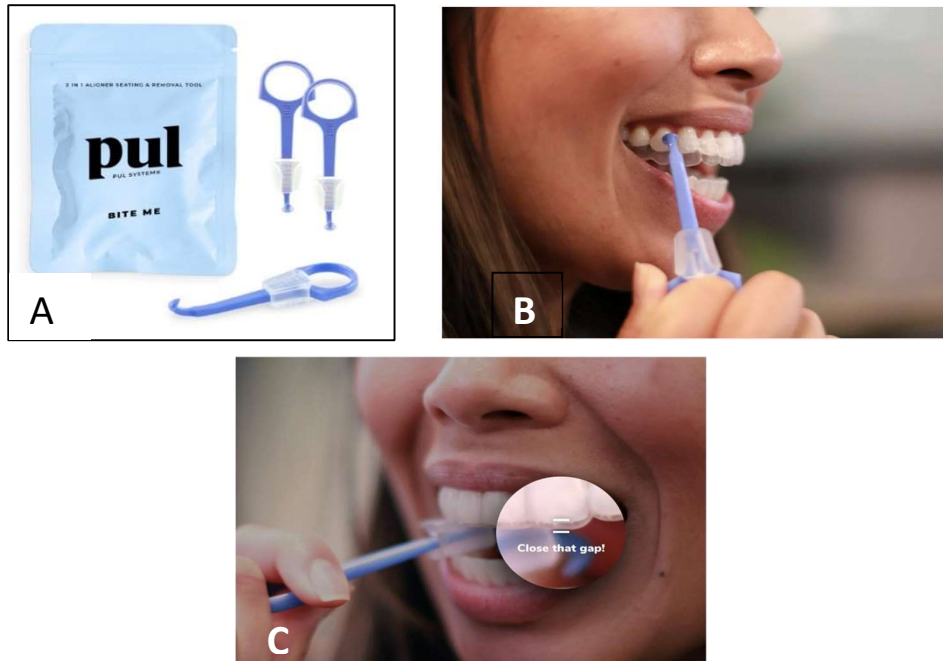


Figure 2A. Commercially available package of clear aligner adjuncts (left) with three examples of these plastic products (right). **2B.** The loop at one end is a handle and the hook at the other end is used to engage an aligner tray edge for removal. **2C.** The clear plastic cushion is for biting to improve seating of the aligner (*BITE ME- 2 in 1 Invisalign Chewies & Removal Tool – PUL, n.d.*).

Dental pain and soreness are well-known side effects of orthodontic tooth movement. Biting pressure is believed to cause temporary displacement of teeth, alleviating orthodontic pressure and relieving pain. Farzanegan et al. developed a study to compare different methods of pain reduction during orthodontic treatment. In this study design, the investigators had 50 girls between the ages of 13 and 18 years. Within the study they compared 5 groups: placebo, ibuprofen, chewing-gum, soft viscoelastic wafer, and hard viscoelastic wafer groups. Each subject was assigned to one of these methods and was told to repeat it every 8 hours if they experienced pain. The subjects measured the pain they felt on a 0-10 Likert scale (0 = no pain, 10 = unbearable pain). The results found that both chewing gum and viscoelastic bite wafers statistically significantly reduced pain during treatment compared to placebo. They found no

statistical difference between the pain experienced between the viscoelastic and ibuprofen groups. It seemed that mechano-stimulation was a suitable substitute for medications such as ibuprofen or acetaminophen (Farzanegan et al., 2012). This study shows one example of how clear aligner adjuncts may play a notable role in pain management, but this needs to be verified through more research and clinical trials.

Despite the increasing availability of clear aligner adjuncts, there is a lack of studies showing whether or not these tools can reduce the pain experienced during clinical orthodontic treatment. To analyze patient's perceived levels of pain, accurate and consistent methods are needed to quantify pain. In addition, it is important to consider conditions that can alter or enhance perceived levels of pain, such as depression, anxiety, and physical symptoms (somatization). A systematic review by Kroenke et al. found that the Patient Health Questionnaire 9 (PHQ9), Generalized Anxiety Disorder 7 (GAD7), and Patient Health Questionnaire 15 (PHQ15) are validated measures for detecting and monitoring depression, anxiety, and somatization, respectively (Kroenke et al., 2010). With regards to measuring perceived pain, a Modified McGill Pain Questionnaire (MMPQ-SF15) has been shown as an effective method to assess localized and generalized aspects of pain in adolescent orthodontic patients (Iwasaki et al., 2013).

A pilot study by Ramanan (OHSU IRB#0022928) established face validity of a set of surveys to measure subjects' pain (MMPQ-SF15), satisfaction, and compliance when using adjuncts during the initial stage of orthodontic tooth movement and established baseline psychological conditions (PHQ9, GAD7, and PHQ15). These surveys were completed through an online platform (Qualtrics, Provo, UT). This pilot study compared two experimental groups and a control group during the initial stages of aligner treatment, when the first four aligner trays

were worn. The experimental group that used the plastic tool that consists of a stick with biting “cushion” (Pul System, San Francisco) (n=4) compared to the control group (n=3) did not, showed that the experimental group had significantly lower levels of frustrating ($p<0.01$) and strange pain ($p<0.05$) and significantly lower reported pain during the second week compared to the first week of aligner wear ($p<0.01$) compared to the control group (Ramanan, 2022). Additionally, the study provided data for a power analysis to determine sample sizes for the current study.

The purpose of this study was to evaluate whether a commercially available clear aligner adjunct tool has a clinically measurable impact on treatment experience and the efficacy of tooth movement. With the findings of the current study, orthodontists can better predict and assess the effects of aligner adjuncts and determine if they should be used to improve aligner tracking and patient experience. Specifically, Aim 1 of the current study was to measure whether or not biting on an adjunct tool (BITE ME, Pul System, San Francisco) (experimental group) had a significant effect on reported pain in the first week of each tray (week 1), the last week of each tray (week 2), and overall pain after the first four trays used during clear aligner treatment (8 weeks) compared to not biting on an adjunct tool (control group). Aim 2 was to measure whether biting on an adjunct tool (experimental group) had a significant effect on aligner wear compliance and satisfaction compared to not biting on an adjunct tool (control group) during the first four trays of clear aligner treatment. Aim 3 was to test whether biting on an adjunct tool (experimental group) had a significant effect on the efficacy of tooth movement during the first four trays of clear aligner treatment compared to not biting on an adjunct tool (control group). The null hypotheses of this study were, for the first four trays of clear aligner treatment:

- 1) There was no significant difference in reported pain during treatment between the experiment and control groups.
- 2) There was no significant difference in aligner wear i) compliance and ii) satisfaction between the experiment and control groups.
- 3) There was no significant difference in tracking success (i.e. minimal difference between predicted vs actual tooth movement) between the experimental and control groups.



Figure 3a. Group 1 adjunctive tool with removal hook and bite cushion. Image downloaded from thepultool.com.



Figure 3b. Group 2 adjunctive tool with removal hook but no bite cushion. Image downloaded from thepultool.com.

Materials and Methods

The protocol for this study was approved by the Oregon Health & Science University (OHSU) Institutional Review Board (Appendix A). This was a randomized prospective study that involved consenting subjects who were patients from the OHSU Orthodontic Clinic who underwent clear aligner treatment.

Subject Recruitment

Patients at the OHSU Orthodontic Clinic who decided to undergo orthodontic clear aligner treatment were screened for eligibility to participate in this study. To be eligible, subjects needed to be adults and not actively growing, which was determined to be 18 years or older and in Cervical Vertebral Maturation (CVM) stage 4 or higher, respectively (McNamara & Franchi, 2018). Exclusion criteria included treatment plans that involved tooth extraction or inter-arch elastic wear during the first 4 aligners; self-reported habits such as nail-biting or digit sucking; relatively short clinical crowns that could compromise retention of aligners; pregnancy, which may increase risk of pregnancy-induced gingivitis and, therefore, could impact the seating of the aligners; and the use of medications for pain, depression, or anxiety. During the period of the research study, subjects did not undergo any elastic wear or interproximal tooth reduction (IPR), to minimize confounding variables.

Eligibility to participate in the study was determined by evaluating the initial records of each subject. If the subjects met all requirements and did not meet any exclusion criteria, they were recruited for the study during the consultation appointment. The Subject Recruitment Script (Appendix B) was used to ask all potential subjects about their interest in joining the study. All subjects were recruited at the Oregon Health & Science University School of Dentistry (OHSU) in Portland, OR. If the subject agreed to be a part of the study, informed consent (Appendix C) and baseline surveys were collected. If the subject declined to participate in the study, they proceeded on with the standard treatment after consultation, and any other data collected for the study were immediately destroyed.

Study Groups

This study involved two groups 1) Adjunctive Tool #1 (PUL System BITE ME, Figure 3a), and 2) Adjunctive Tool #2 (Pul System BITE ME without rubber cushion, Figure 3b). Both

adjunctive tools were provided by the manufacturer for the purposes of this study. In addition, the device is available direct-to-consumer on numerous websites and online platforms. Subjects were randomly assigned to Adjunctive Tool #1 (Experimental group) and Adjunctive Tool #2 (Control group) but were first categorized by sex into male and female groups. Within each sex group, subjects were then randomly assigned to either the control or experimental condition in an alternating sequence based on the order of enrollment (Figure 4). All subjects were provided with their assigned tool and group-specific instructions (verbal and written) on how and when to use these tools (Figures 5, 6). Subjects were allowed to keep the devices after the study.

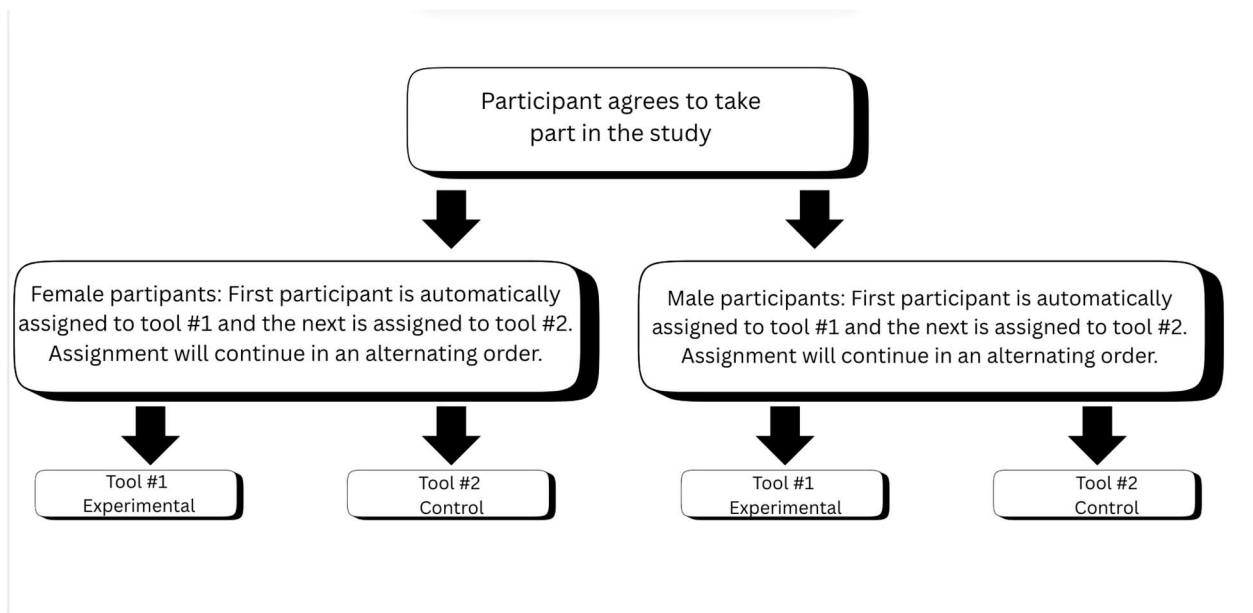


Figure 4. Flowchart displaying how subjects were grouped by sex (male and female), then randomly assigned to Tool #1 or Tool #2.

Thank you for volunteering to be a part of our project!

Today you were provided with **4 clear aligner trays**. Please make sure to:

- Wear the trays at least **22 hours** a day.
- Wear each tray for **14 days**.
- Use the tool when seating your trays.



- Complete the **daily survey**.

How to use the tool:



When **seating** the aligner trays, use the tool by biting on the cushion on the end of the appliance. **Bite solidly between your teeth for 10-15 seconds, release, and repeat.** Move from your front teeth and work your way to the back teeth. If you see a gap in the tray, make sure to bite on the tool until the tray is seated all the way.

When **removing** the aligner trays, use the hook of the tool to engage and remove the trays.



Figure 5. Instruction handout for the Experimental Group who used Adjunctive Tool #1 (PUL System BITE ME)

Thank you for volunteering to be a part of our project!

Today you were provided with **4 clear aligner trays**. Please make sure to:

- Wear the trays at least **22 hours** a day.
- Wear each tray for **14 days**.
- Use the **tool** when removing your trays.



- Complete the **daily survey**.

How to use the tool:

When removing the aligner trays, use the hook of the tool to engage and remove the trays.

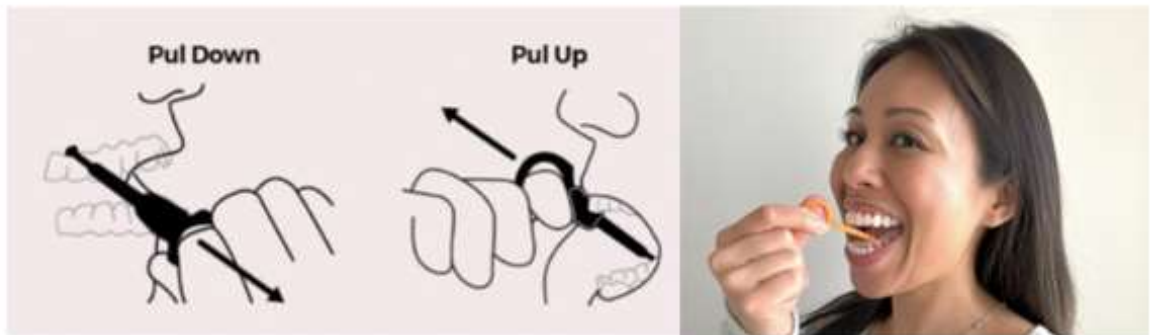


Figure 6. Instruction handout for the Control Group who used Adjunctive Tool #2 (Modified PUL System BITE ME)

Subject Activities

The subjects were provided with pre- and post-treatment surveys (PHQ-9, GAD-7, PHQ-15), as well as daily surveys (pain, satisfaction, and compliance). These were provided online through the OHSU-approved online platform (Qualtrics, Provo, UT). The surveys were either completed at OHSU or at the subject's home. The order of activities in this study included the following:

Records (90 minutes)

Records collected for the purpose of elective clear aligner treatment, include demographics and medical history, x-rays, photographs, plus intra-oral scans of the teeth and intra-oral soft tissues to obtain stereolithography (.stl) data files. These records were screened and evaluated to see if the patient was eligible for this research study.

Consultation (1 hour)

After clear aligner treatment consultation, potentially eligible patients were invited to participate in the study through the subject recruitment script (Appendix B). If a patient chose to participate, the subject consent form was provided (Appendix C).

Baseline Data Collected:

- Intra-oral scans (Trios 4, 3Shape A/S, Copenhagen, Denmark) to obtain open source .stl files if not already available from the Records visit
- Surveys via quick response (QR) code link (Appendix J) to the online platform (Qualtrics, Provo, UT) for:
 - Depression Survey (Patient Health Questionnaire 9, PHQ9) (Appendix D)
 - Anxiety Survey (General Anxiety Disorder 7, GAD7) (Appendix E)
 - Somatization/Physical Symptoms (PHQ15) (Appendix F)

- Medical History and Medications (from Records visit)

Visit 1 (V1): Delivery Visit (20 minutes)

Subjects were provided with a package of adjuncts and instructions for using these with clear aligners and the QR code link for pain, compliance, and satisfaction data surveys (Appendix G, H, I). V1 occurred at the same treatment visit where the first 4 clear aligners were given to the subject. For both groups, the adjuncts were removed from the commercial product packaging and re-packaged in clean autoclave bags using sterile techniques. For the control group, the adjunct was modified by removing the clear plastic cushion (for biting on) using sterile techniques before re-packaging.

Between V1 and V2 (10 minutes daily)

Pain, compliance, and satisfaction surveys were completed daily using the QR code link (Appendix K) provided. This was anticipated to take no longer than 10 minutes a day. For clear aligner therapy, subjects were instructed to wear each of the first 4 clear aligners in sequence for two weeks each. Consequently, the time between V1-V2 was 8 weeks.

V2: 4 Trays-Later Visit

Repeat intra-oral scan for Progress Assessment. Overall pain, compliance, and satisfaction surveys were completed using the QR code link provided (Appendix L). Subjects were reimbursed for their time and effort on a pro-rated basis via a secure debit card system (ClinCard, Greenphire Patient Payments, Suvoda, Philadelphia PA). Study participants were reimbursed \$16 for completing the initial baseline visit (V1). An

additional \$64 was provided upon completion of both the daily survey portion (V1.5) and the concluding appointment (V2), allowing each subject to earn up to \$80 in total.

Data Collection

The data collected included the subjects' pre-treatment age, sex, and medical history; pre-treatment, during treatment, and post-tray 4 survey responses; and pre-treatment and post-tray 4 intra-oral scans.

Depression Survey: Patient Health Questionnaire-9 (PHQ9) (Appendix D)

The PHQ9 is a validated nine-item measure used to assess the severity of depression over a two-week period. Each item is scored on a four-point Likert scale: “0 = not at all,” “1 = several days,” “2 = more than half the days,” and “3 = nearly every day.” The total score can range between 0-36 and defines the level of depression as follows: 0-4 indicates minimal depression, 5-9 indicates mild depression, 10-14 indicates moderate depression, 15-19 indicates moderately severe depression, 20-27 indicates severe depression (Kroenke et al., 2010; Kroenke & Spitzer, 2002). The PHQ-9 was developed by Kroenke and et al. can be accessed online (Kroenke et al., 2001; *Patient Health Questionnaire (PHQ) Screeners. Free Download*, n.d.).

Anxiety Survey: Generalized Anxiety Disorder-7 (GAD7) (Appendix E)

The GAD7 is a validated seven-item survey used to measure anxiety levels over the past two weeks. Each item is scored on a four-point Likert scale: “0 = not at all,” “1 = several days,” “2 = more than half the days,” and “3 = nearly every day” (Löwe et al., 2008). Total scores can range between 0-21 and are categorized as follows: 0-4 indicates minimal anxiety, 5-9 indicates mild anxiety, 10-14 indicates moderate anxiety, and 15-21

indicates severe anxiety (Löwe et al., 2008; Spitzer et al., 2006). The GAD-7 was developed by Spitzer et al. and can be accessed online (*Patient Health Questionnaire (PHQ) Screeners. Free Download*, n.d.; Spitzer et al., 2006).

Somatization/Physical Symptoms: Patient Health Questionnaire- 15 (PHQ15) (Appendix F)

The PHQ15 is a validated 15-item questionnaire used to assess somatic symptoms experienced over the past four weeks. Each item is rated on a three-point Likert scale: “0 = not bothered,” “1 = bothered a little,” and “2 = bothered a lot.” The total score can range between 0-30 and categorizes somatization severity as follows: 0-4 for minimal, 5-9 for mild, 10-14 for moderate, and 15-30 for severe (Kocalevent et al., 2013; Kroenke et al., 2002). The PHQ15 was developed by Kroenke et al. and can be accessed online (Kocalevent et al., 2013; *Patient Health Questionnaire (PHQ) Screeners. Free Download*, n.d.).

Pain Survey (Appendix G)

The modified McGill Pain Questionnaire is a validated three-part survey designed to assess orthodontic pain (Iwasaki et al., 2013). The first part consists of 15 items addressing various aspects of pain, scored on a four-point Likert scale: “0 = no pain,” “1 = mild pain,” “2 = moderate pain,” and “3 = severe pain.” Thus, each of the 15 items had a score and the total MPQ score potentially ranged from 0 – 45, between no pain and severe pain. The second part asks subjects to indicate the severity of their pain using a visual analog scale ranging from “no pain” to “worst pain possible Pain was assessed using a 100-point Visual Analog Scale (VAS) presented as a slider. Participants adjusted the slider to indicate their perceived level of pain. Numerical values were not visible to

participants during the rating process to minimize bias. The third part involves ranking the current pain level (CPL) from “0 = no pain,” “1 = little pain,” “2 = moderate pain,” “3 = bad pain,” “4 = horrible pain,” to “5 = extreme pain” (Iwasaki et al., 2013; Melzack, 1987). This survey was used to assess daily pain while subjects wore aligner trays as well as overall pain throughout the study surveyed at V2.

Compliance Survey (Appendix H)

The compliance questionnaire is a two-part survey that was utilized to assess the compliance of wearing the clear aligners throughout the study. The first part consists of a daily question that uses a sliding bar from 0 to 24 hours a day. The second part involves an overall assessment of daily and weekly wear with multiple sliding bar responses for hours per day and days per week. Subjects also had an optional text-field to add comments at the end.

Satisfaction and Effort Surveys (Appendix I)

The satisfaction survey was offered daily and overall, at the end of the study. This survey contains four questions regarding patients’ comfort and function during aligner wear, including their ability to bite, chew, speak, and eat without discomfort, as well as any irritation caused by the aligners to the oral soft tissues. This survey is a modified version of Miller et al. which, in turn, was adapted from validated Geriatric Oral Health Assessment Index (Miller et al., 2007) and assessed subject satisfaction in the form of a five-point Likert scale. For questions 1, 2, and 4, the scoring was “1 = never”, “2 = seldom”, 3 = sometimes”, “4 = often”, and “5 = always.” For question 3, the scoring was “1 = always”, “2 = often”, 3 = sometimes”, “4 = seldom”, and “5 = never.”

The effort survey was offered overall, at the end of the study, and involved five modified customer effort score survey statements used to assess other aspects of subject satisfaction. This survey involved five questions that asked about the overall ease of using aligners, including patient satisfaction, the ability to seat and remove trays, confidence in aligner tracking, and willingness to recommend aligner treatment to others. The responses were scored in the form of a seven-point Likert scale of “1= strongly disagree”, “2 = disagree”, “3 = somewhat disagree”, “4 = neutral”, “5 = somewhat agree”, “6 = agree”, and “7 = strongly agree.”

There were three additional questions (10-12) that asked about the subject’s usage and perception of the adjunctive tool, including frequency of use, likelihood of recommending the tool to others, and willingness to continue using it in the future. For question 10 the scoring was “1 = Never”, “2 = Few times a week”, “3 = Every day”, and “4 = Multiple times a day.” Questions 11 and 12 were graded on a ten-point Likert scale ranging from 0 (not likely) to 10 (very likely).

Intra-oral Pre-treatment Scan

Pre-treatment 3D representations of the teeth and intra-oral soft tissues were captured using an intra-oral scanner (Trios 4, 3Shape A/S, Copenhagen, Denmark) to create a .stl file. These files were kept in a secure OHSU database.

Intra-oral Post-Tray 4 Scan

Post-Tray 4 (V2) 3D representations of the teeth and intra-oral soft tissues were captured using the same digital intra-oral scanner (Trios 4, 3Shape A/S, Copenhagen, Denmark) to create a .stl file. These files were kept in a secure OHSU database.

Tray Efficacy Analysis (Predicted versus Actual Position at Tray 4)

To determine if there were significant differences between tracking success (i.e. minimal difference between predicted versus actual tooth movement) of the experimental and control groups, predicted tooth positions (from the aligner software) were compared to the actual clinical tooth positions after tray #4 for both the maxillary and mandibular dental arches. Predicted positions refer to the ideal tooth alignment programmed into aligner tray #4, while actual positions refer to the recorded clinical outcome after the subject wore tray #4.

Due to proprietary restrictions of the aligner product's software, .stl files of the prescribed tooth movement were unavailable, so a method to capture the predicted tooth positions was developed using the physical maxillary and mandibular trays #4 for each subject. The intaglio (inner) surfaces of both maxillary and mandibular trays were coated with a titanium dioxide-based scanning spray (Dentsply Sirona Optispray, Bensheim, Germany) to make the transparent aligner sufficiently opaque for intraoral scanning (Figure 7). The trays were then scanned with the intraoral scanner (3Shape, Copenhagen, Denmark). Since the scan captured the negative impression of the teeth (internal surface of the aligner), it was necessary to invert the results of the scan to create a positive, tooth-surface representation. This was achieved by importing the .stl file into a 3D mesh editing software (Autodesk Meshmixer, San Rafael, CA) where the 3D digital image was inverted to simulate predicted tooth positions as they would appear clinically. This resulted in the .stl file that was used to represent predicted tray 4 tooth positions and compared to post-tray 4 tooth positions for the same dental arch.

To compare the predicted and actual post-tray 4 positions for a given arch, the two .stl files were imported to a 3D inspection software (Geomagic Control, 3D Systems, Rock Hill, SC). Using the best-fit surface alignment tool, the predicted and actual model images were

superimposed (Figure 8). A root mean square (RMS) deviation value (mm) was calculated via the software to measure similarity between the two .stl files. An RMS deviation value represented the average difference between corresponding surface points and served as a quantitative measure of how closely the clinical outcome matched the planned aligner movements. A lower RMS value indicated better accuracy and tracking. This method allowed for an objective assessment of tray efficacy and enabled statistical comparisons between control and experimental groups and the maxillary and mandibular dental arches.



Figure 7a. Product (Cerec® Optispray) sprayed onto the intaglio surface of the tray. **Figure 7b.** Maxillary aligner tray #4 sprayed with this product (Cerec® Optispray).

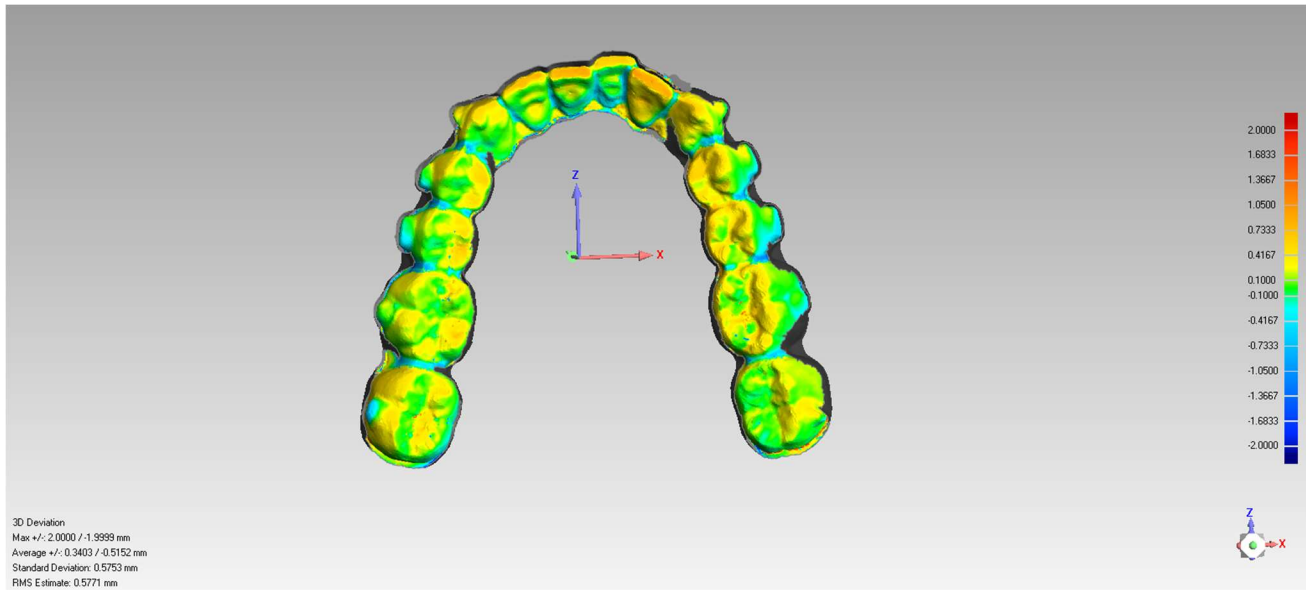


Figure 8. Superimposition of images from inverted tray 4 (predicted) and the post-tray 4 intraoral (actual) scans for the mandibular dental arch in one subject via software (Geomagic Control). Average root mean squared (RMS) deviation values (mm) were generated to determine degree of differences between the two .stl files. Smaller RMS values represent a higher similarity and better tracking.

Data and Statistical Analyses

Fill-in-the blank survey answers were qualitatively analyzed in consultation with statistical expertise, Dr. Dongseok Choi. Dr. Choi received only de-identified data. Classical content analysis was used to analyze any longer answers. De-identified multiple choice survey answers were analyzed statistically. Images of the teeth from intra-oral scans were inspected visually.

Data included: V1 subject demographics including age and sex; V1, V2, and daily between V1-V2 survey responses; and intra-oral digital scans. Means, standard deviations, medians, and ranges were calculated for PHQ9, GAD7, and PHQ15 at baseline, and pain,

compliance, and satisfaction scores at V1, V2, and daily scores between V1 and V2. Daily MMPQ-15 and VAS scores were analyzed to evaluate changes in reported pain between week 1 and week 2 of each aligner tray. For each subject, MMPQ-15 and VAS responses were averaged across week 1 and week 2 for every tray. Group averages were then computed to assess the percent change in scores from week 1 to week 2 across trays 1–4 for both the experimental and control groups. Positive values indicated a percent increase in pain, whereas negative values indicated a percent decrease in pain.

Wilcoxon tests were used to test group differences in baseline psychosocial scores and responses to questions in the overall MMPQ-15, satisfaction, and compliance surveys. T-tests were used to determine whether there were significant differences between groups for pain (MMPQ-15, VAS, and current pain index) scores across each aligner tray (1–4). Chi-squared tests and mixed effects modeling and multivariate analysis were used to test for significant differences in RMS (mm) results between groups and between dental arches. Statistically significant differences were defined by p-value <0.05. Intraclass correlation coefficients were calculated to determine intra-rater reliability in V1-V2 tooth movement measurements. R statistical software was used for all statistical analyses (R Core Team, Auckland, New Zealand).

Results

Eighteen subjects were approached to participate in the study. Twelve subjects, 10 females and two males, met inclusion criteria, gave informed consent and were enrolled in the study. Of the 12 subjects enrolled, eleven were included in the final tray efficacy analysis, as one subject incorrectly proceeded past the fourth tray of aligner treatment. Subjects were categorized by sex and assigned to either the experimental or control group in an alternating sequence based on the order of enrollment. Six subjects (five females, one male) were assigned to the experimental

group and six (five females, one male) were assigned to the control group. Mean age for all the subjects enrolled in the study was 31 ± 10 years. Mean age was 26 ± 6 years for the experimental group and 36 ± 12 years for the control group, and not significantly different between groups ($p=0.13$) (Table 1).

Baseline PHQ-9, GAD-7, and PHQ-15 Survey Analysis (Table 1)

All subjects completed the baseline surveys. Both groups indicated minimal depressive symptoms at baseline, on average 4 ± 6 for the experimental group and 4 ± 3 for the control group, and not significantly different between groups ($p=0.68$, Figure 9). PHQ-9 scores indicating mild depression were found in one subject in each of the experimental (Subject 6, female with PHQ-9 = 5) and control (Subject 3, female with PHQ-9 = 8) groups and one subject in the experimental group (Subject 11, female) had a PHQ-9 score = 16, indicating moderately severe depression.

Both groups indicated minimal anxiety at baseline, on average 3 ± 5 for the experimental group and 3 ± 2 for the control group, and not significantly different between groups ($p=0.67$, Figure 10). GAD-7 scores indicating mild anxiety were found in one subject in each of the experimental (Subject 6, female with GAD-7 = 5) and control (Subject 10, female with GAD-7 = 6) groups and one subject in the experimental group (Subject 11, female) had a GAD-7 score = 12, indicating moderate anxiety.

Both groups indicated minimal somatization and physical symptoms at baseline, on average 4 ± 3 for the experimental group and 2 ± 3 for the control group, and not significantly different between groups ($p=0.33$, Figure 11). PHQ-15 scores indicating mild somatization and physical symptoms were found in one subject in each of the experimental (Subject 6, female with

PHQ-15 = 6) and control (Subject 3, female with PHQ-15 = 7) groups and one subject in the experimental group (Subject 11, female) had a PHQ-15 score = 10, indicating medium severity.

Table 1. Subject numbers by group and sex (percentages of total sample), with mean \pm standard deviation of age and baseline psychosocial scores, and t-test results of between-group comparisons (p-values).

Subject	Total Sample	Experimental	Control	p-value
Number	12	6	6	1.00
Females	10	5 (83%)	5 (83%)	1.00
Males	2	1 (17%)	1 (17%)	1.00
Age in years	31 \pm 10	26 \pm 6	36 \pm 12	0.13
Anxiety (PHQ-9, 0-36)	4 \pm 4 Minimal	4 \pm 6 Minimal	4 \pm 3 Minimal	0.68
Depression (GAD-7, 0-21)	3 \pm 4 Minimal	3 \pm 5 Minimal	3 \pm 2 Minimal	0.67
Physical Symptoms (PHQ-15, 0-30)	3 (\pm 3) Minimal	4 \pm 3 Minimal	2 \pm 3 Minimal	0.33

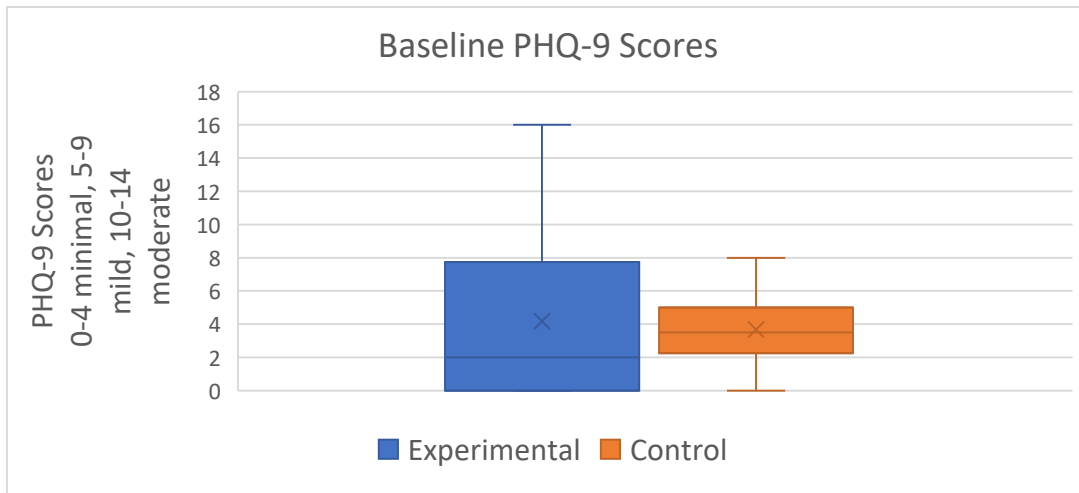


Figure 9. Baseline Patient Health Questionnaire-9 total scores. Lines in the box plot indicate median values for the data set. There was no significant difference found in the PHQ-9 scores between groups ($p=0.68$).

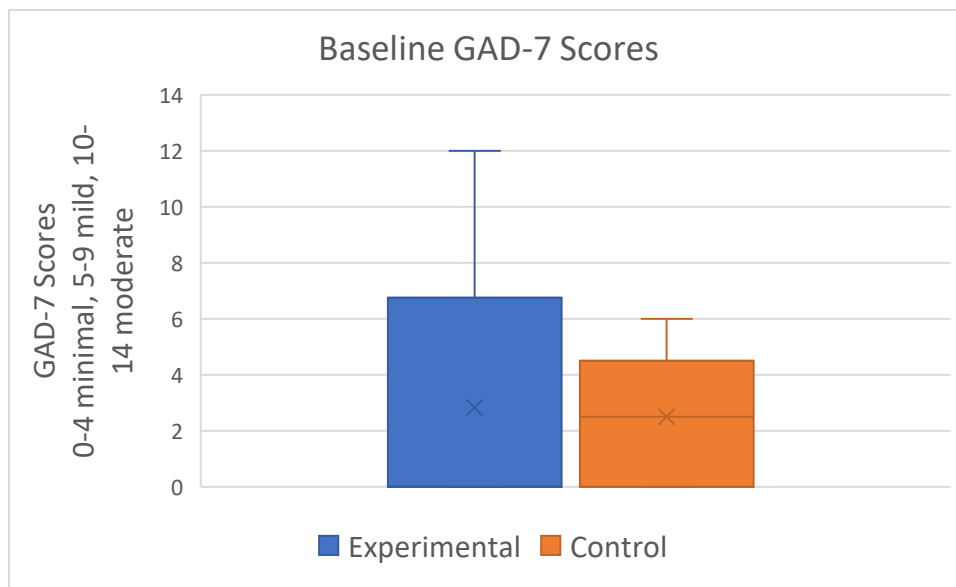


Figure 10. Baseline Generalized Anxiety Disorder-7 total scores. Lines in the box plot indicate median values for the data set. There was no significant difference found in the GAD-7 scores between groups ($p=0.67$).

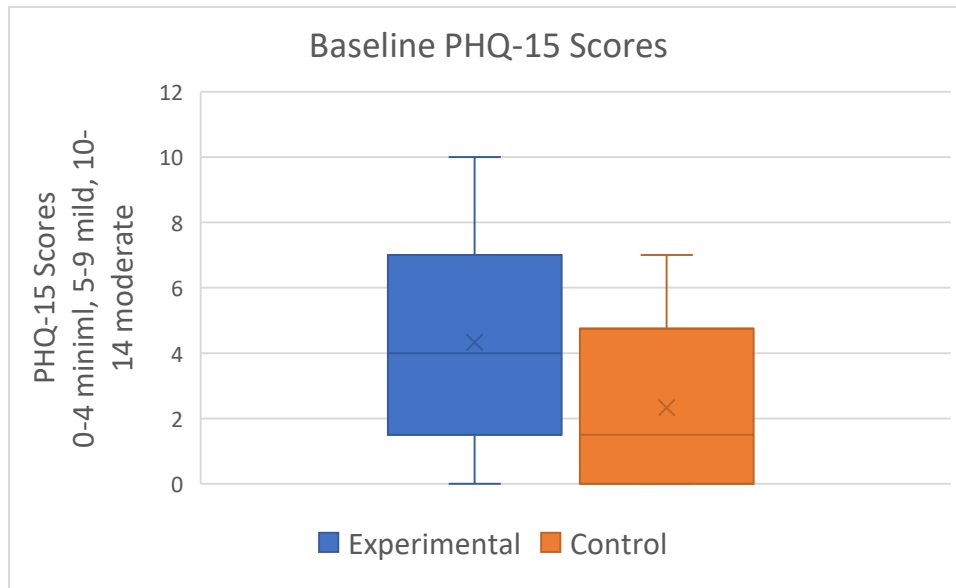


Figure 11. Baseline Patient Health Questionnaire-15 total scores. Lines in the box plot indicate median values for the data set. There was no significant difference found in the PHQ-15 scores between groups ($p=0.33$).

Table 2. Survey response compliance per subject. The table presents the number of days (out of 14) that each subject completed the daily survey for each tray interval. Average response rates (\pm SD) are reported for both the experimental and control groups across trays 1–4.

Subject #	Group	Sex	Number of daily surveys submitted (% compliance) for:			
			Tray 1 days 1-14	Tray 2 days 15-28	Tray 3 days 29-42	Tray 4 days 43-56
1	Experimental	Male	10 (71%)	9 (64%)	8 (57%)	6 (43%)
4	Experimental	Female	12 (86%)	14 (100%)	14 (100%)	14 (100%)
6	Experimental	Female	5 (36%)	0 (0%)	1 (1%)	1 (1%)
8	Experimental	Female	14 (100%)	14 (100%)	14 (100%)	13 (93%)
9	Experimental	Female	5 (36%)	10 (71%)	12 (86%)	4 (29%)
11	Experimental	Female	14 (100%)	8 (57%)	3 (21%)	5 (36%)

Experimental group: average response rate \pm SD			72% \pm 30%	65% \pm 37%	61% \pm 42%	50% \pm 39%
2	Control	Male	11 (79%)	12 (86%)	12 (86%)	12 (86%)
3	Control	Female	13 (93%)	13 (93%)	12 (86%)	12 (86%)
5	Control	Female	7 (50%)	6 (43%)	5 (36%)	5 (36%)
7	Control	Female	10 (71%)	9 (64%)	11 (79%)	12 (86%)
10	Control	Female	13 (93%)	14 (100%)	14 (100%)	14 (100%)
12	Control	Female	NA	NA	NA	NA
Control group: average response rate \pm SD			77% \pm 18%	77% \pm 23%	77% \pm 24%	79% \pm 25%

Daily Pain Surveys

Of the twelve participants enrolled, eleven completed the daily pain surveys. One control subject (Subject 12, female) participated in the baseline and overall assessments but did not complete the daily surveys. Excluding Subject 12, the average daily survey response rate was 62% for the experimental group and 78% for the control group. The experimental group showed a gradual decline in compliance across weeks 1–4 (72%, 62%, 61%, and 50%, respectively), whereas the control group maintained consistently high compliance over the same period (77%, 77%, 77%, and 79%, respectively) (Table 2).

Subjects reported daily pain using the Modified McGill Pain Questionnaire, which included three measures of pain: the MMPQ-15 total score, the Visual Analog Scale (VAS), and the Current Pain Index. Analysis of these responses (Figure 12) illustrates trends in daily pain over the 56 days of aligner wear, with each row representing one of the three pain measures. Across all three measures, trends were observed in both groups, where noticeable spikes in pain

occurred approximately every 14 days in some subjects, coinciding with the switch to a new aligner tray (days 1, 15, 29, and 43). Following each tray change, pain levels typically declined within several days, stabilizing at lower levels before the next tray switch.

Overall, both experimental and control participants demonstrated a gradual reduction in pain intensity over time, with the most pronounced peaks occurring within the first one to two days after each tray change. The magnitude of pain spikes appeared slightly more variable in the experimental group, with some subjects exhibiting greater fluctuations, whereas the control group's responses were generally more uniform and lower in intensity. When analyzing individual subject responses, it seemed that one subject in the experimental (Subject 11, female) and one subject in the control (Subject 10, female) that had generally higher tray one pain scores in all three measures of pain. Another subject in the experimental (Subject 6, female) had an initial drop in pain after the first tray, but a slow and steady increase in pain until the end of the study.

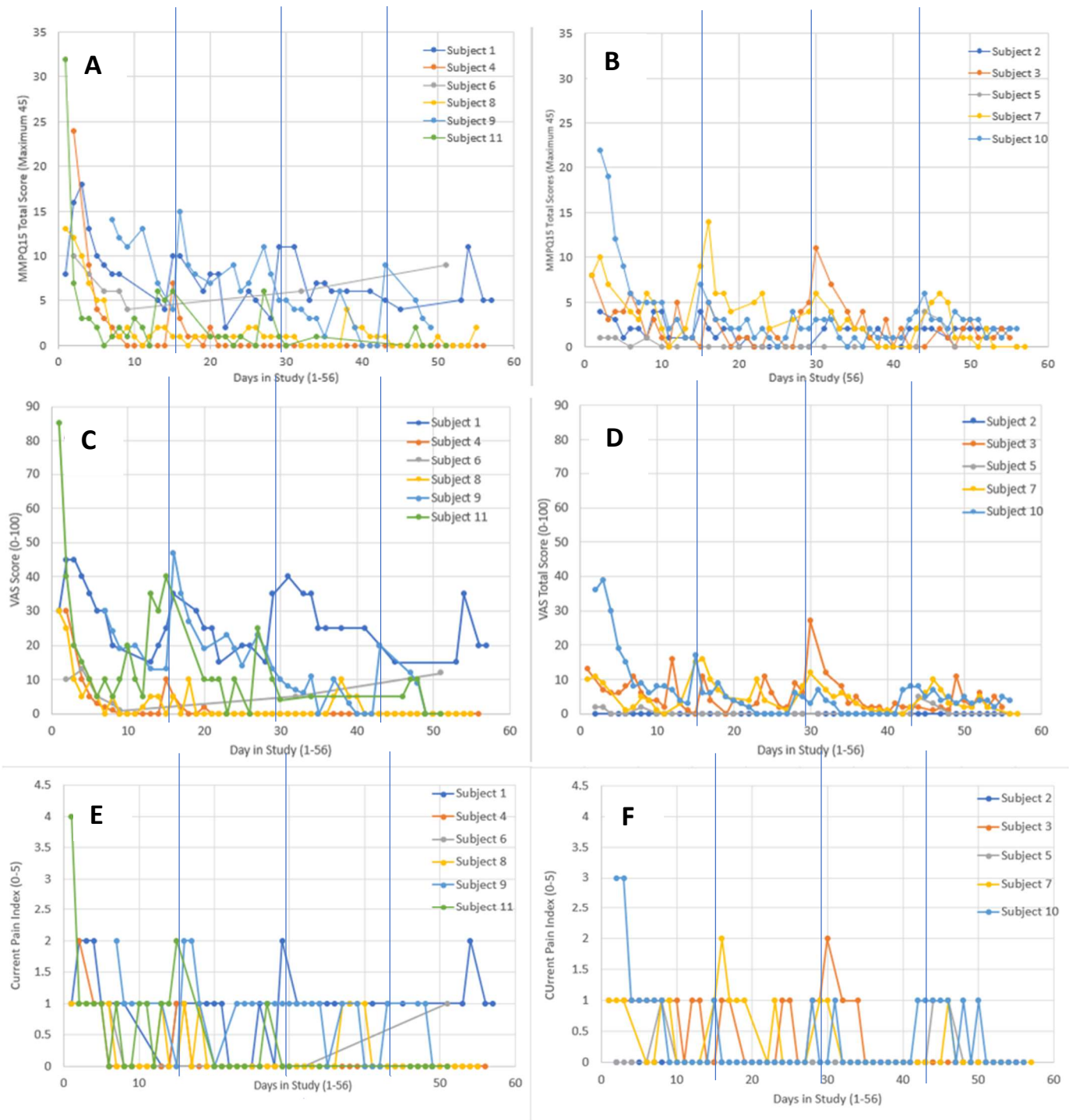


Figure 12. Daily pain scores (top to bottom: MMPQ15, VAS, and Current Pain Index) plotted versus days of the study (1-56). The graphs on the left (A, C, E) represent the experimental group, while graphs on the right (B, D, F) represent the control group. Each vertical solid blue line represents the beginning of a new tray.

Comparisons of Pain Between Each Tray (Table 2)

Analysis of daily survey results allowed for evaluation of pain scores across each aligner tray (1–4). MMPQ-15, VAS, and current pain index scores were compared between experimental and control groups for all trays. For trays 1–4, the experimental group reported average MMPQ-15 scores of 7 ± 3 , 4 ± 4 , 3 ± 3 , and 4 ± 4 , while the control group reported 4 ± 2 , 2 ± 2 , 2 ± 1 , and 2 ± 1 , respectively. Average VAS scores for the experimental group were 14 ± 12 , 12 ± 13 , 9 ± 13 , and 9 ± 9 , compared with 8 ± 8 , 5 ± 5 , 3 ± 3 , and 3 ± 2 for the control group. Current pain index averages for trays 1–4 were 1 ± 0 , 0 ± 0 , 0 ± 0 , and 1 ± 1 in the experimental group, and 1 ± 0 , 0 ± 0 , 0 ± 0 , and 0 ± 0 in the control group. Across all trays, the experimental group demonstrated higher average pain scores than the control group in each of the three measures. However, these differences were not statistically significant for MMPQ-15 ($p=0.10, 0.39, 0.27, 0.24$), VAS ($p=0.37, 0.34, 0.40, 0.23$), or current pain index ($p=0.41, 0.43, 0.26, 0.16$) across trays 1–4 (Figure 13).

Table 2. Averages \pm standard deviations for experimental and control groups and between group comparison of pain scores per tray (MMPQ-15, VAS, and current pain index per trays 1-4).

Subject	Experimental Average	Control Average	p-value
MMPQ-15 (0-45)			
Tray 1	7 ± 3	4 ± 2	0.10
Tray 2	4 ± 4	2 ± 2	0.39
Tray 3	3 ± 3	2 ± 1	0.27
Tray 4	4 ± 4	2 ± 1	0.24
VAS (0-100)			
Tray 1	14 ± 12	8 ± 8	0.37
Tray 2	12 ± 13	5 ± 5	0.34
Tray 3	9 ± 13	3 ± 3	0.40
Tray 4	9 ± 9	3 ± 2	0.23

Current Pain Index (0-5)			
Tray 1	1 ± 0	1 ± 0	0.41
Tray 2	0 ± 0	0 ± 0	0.43
Tray 3	0 ± 0	0 ± 0	0.26
Tray 4	1 ± 1	0 ± 0	0.16

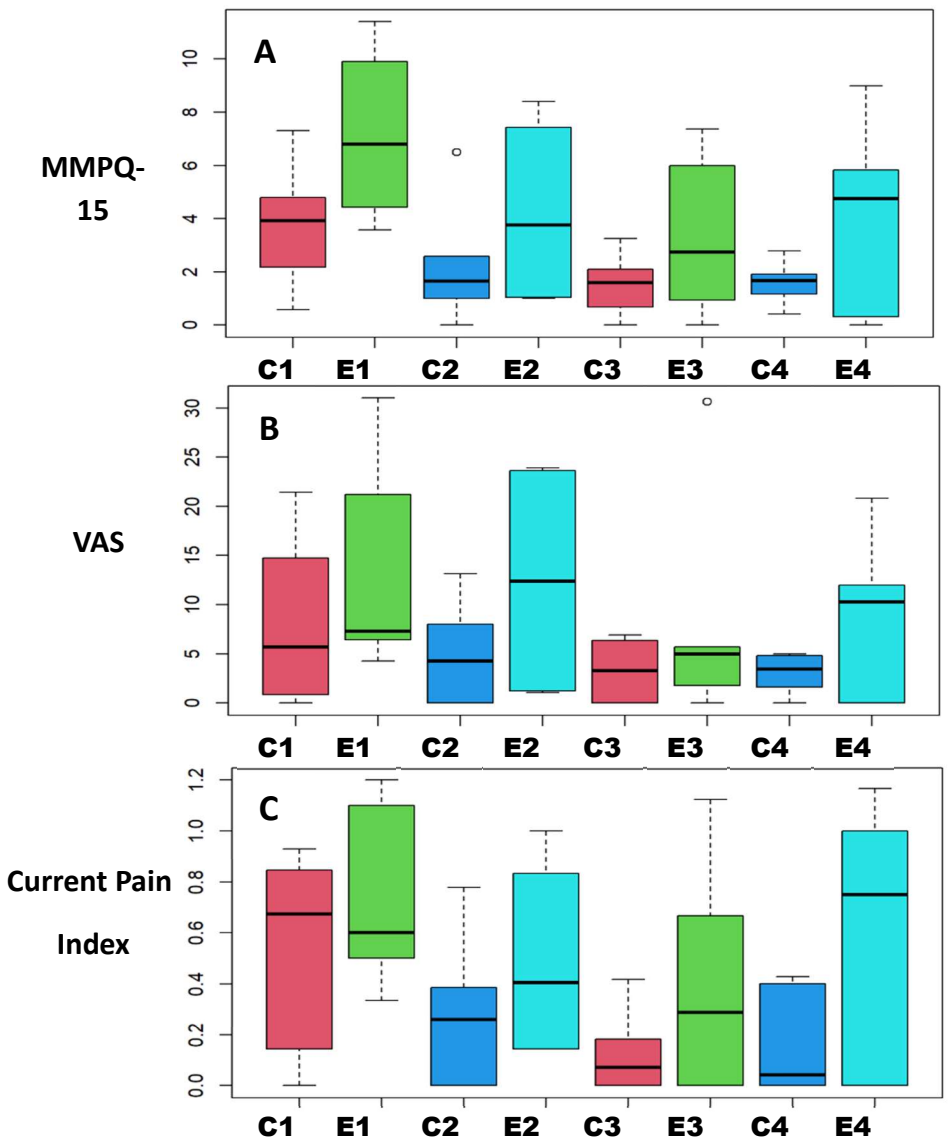


Figure 13 Box plots showing average daily survey results for **A** MMPQ-15, **B** VAS, and **C** Current Pain Index from control (C) and experimental (E) groups for trays 1, 2, 3, and 4. The boxes represent the interquartile range (IQR), the horizontal line within each box marks the median, and the dashed vertical whiskers extend to the minimum and maximum values within 1.5× IQR. Points beyond the whiskers indicate outliers.

Changes in Pain from Week 1 to Week 2 of Each Tray

Daily MMPQ-15 (Figure 14A) and VAS scores (Figure 14B) were analyzed to evaluate percentage changes in reported pain between week 1 and week 2 of each aligner tray. For trays 1–4, the experimental group exhibited MMPQ-15 percent changes of -58%, -27%, +27%, and +64%, respectively. The control group showed percent changes of -52%, -62%, -46%, and -37%, respectively. Overall, the experimental group demonstrated decreasing pain scores between weeks 1 and 2 of the first two trays, followed by increasing scores in the final two trays. In contrast, the control group showed consistent decreases in pain across all four trays. However, there were no significant differences between groups in weekly percent change for trays 1 - 4 ($p=0.73, 0.34, 0.28, \text{ and } 0.13$, respectively). Similarly, when examining for trays 1–4, the experimental group demonstrated VAS percent changes of -68%, -65%, -31%, and +9%, respectively, while the control group showed changes of -40%, -26%, -45%, and -46%, respectively (Figure 14B), after Subject 8 (experimental group) was identified as an outlier. The experimental group exhibited decreasing pain between weeks 1 and 2 for the first three trays, followed by a slight increase during the final tray. Within the experimental group, Subject 8's percent change value for tray 3 was identified as an outlier due to the extremely low baseline pain score. In week 1, this subject reported a pain score of 0. During week 2, the score increased to 3.6. Although the absolute increase in pain was minimal, the percentage-change calculation (from 0 to 3.6) produced an artificially inflated value of 360%. This disproportionately large percentage occurred because even small absolute changes become exaggerated when the initial value was near zero. For this reason, these data were excluded from the final comparison. In regards to the control group VAS changes between weeks 1 and 2, this group demonstrated gradual decreases in pain across all trays. There were no significant differences between groups

in weekly percent change for trays 1 - 3 ($p=0.10, 0.17, 0.62$, respectively). However, the percentage change in VAS scores between weeks 1 and 2 for tray 4 was significantly different, where it increased for the experimental group by +9% and decreased for the control group by -46% (Figure 14B).

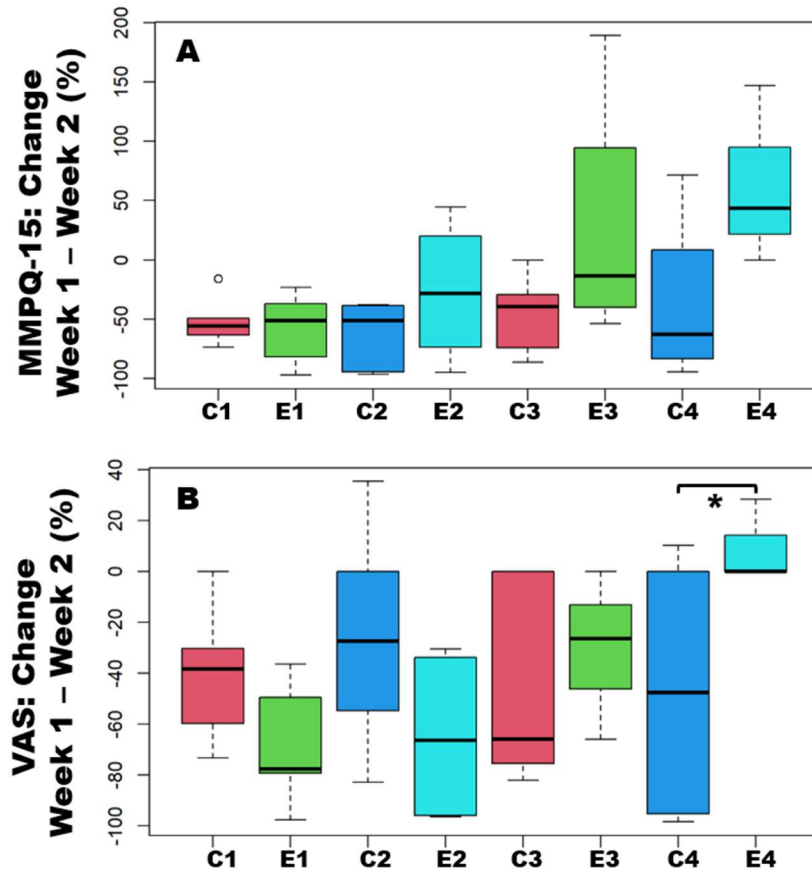


Figure 14 Box plots showing percent change between weeks 1 and 2 for **A** MMPQ-15 and **B** VAS in control (C) and experimental (E) groups for trays 1, 2, 3, and 4. The boxes represent the interquartile range (IQR), the horizontal line within each box marks the median, and the dashed vertical whiskers extend to the minimum and maximum values within $1.5 \times$ IQR. Points beyond the whiskers indicate outliers. The * represents a significant difference between the control and experimental group at tray 4 ($p=0.03$).

Overall Pain Analyses (Table 3)

The three measurements used to report overall pain were MMPQ-15 total, VAS, and current pain index surveyed at V2. The MMPQ-15 total (possible range 0-45) average was 4 ± 2 for the experimental group and 5 ± 4 for the control group. The overall pain for the visual analogue scale (VAS) from 0-100 (no pain-maximum pain) was 13 ± 8 for the experimental group and 6 ± 5 for the control group. The current pain index average (0-5) was 1 ± 0 for the experimental and 0 ± 0 for the control. There were no statistically significant differences between MMPQ-15 total ($p=0.47$), VAS ($p=0.71$), or current pain index scores ($p=0.71$; Table 3).

Within the modified McGill pain questionnaire, pain was broken down into 15 categories: pressure, sore, aching, throbbing, tight, cutting, burning, tingling, pulling, dull, uncomfortable, strange, frustrating, annoying, and miserable. Across 15 categories, most of the categories showed an experimental group pain score that was lower than control group pain scores. When comparing the pain categories of the two groups, the experimental group scored lower in 8 categories, scored similar in 6 categories, and scored higher in 1 category. The throbbing, burning, tingling, dull, uncomfortable, and miserable pain scores were equal amongst the two groups, while the experimental group had higher strange pain than the control group (Figure 15). There were no significant differences found between any of the MMPQ-15 pain categories (range $p=0.13$ to 1.00).

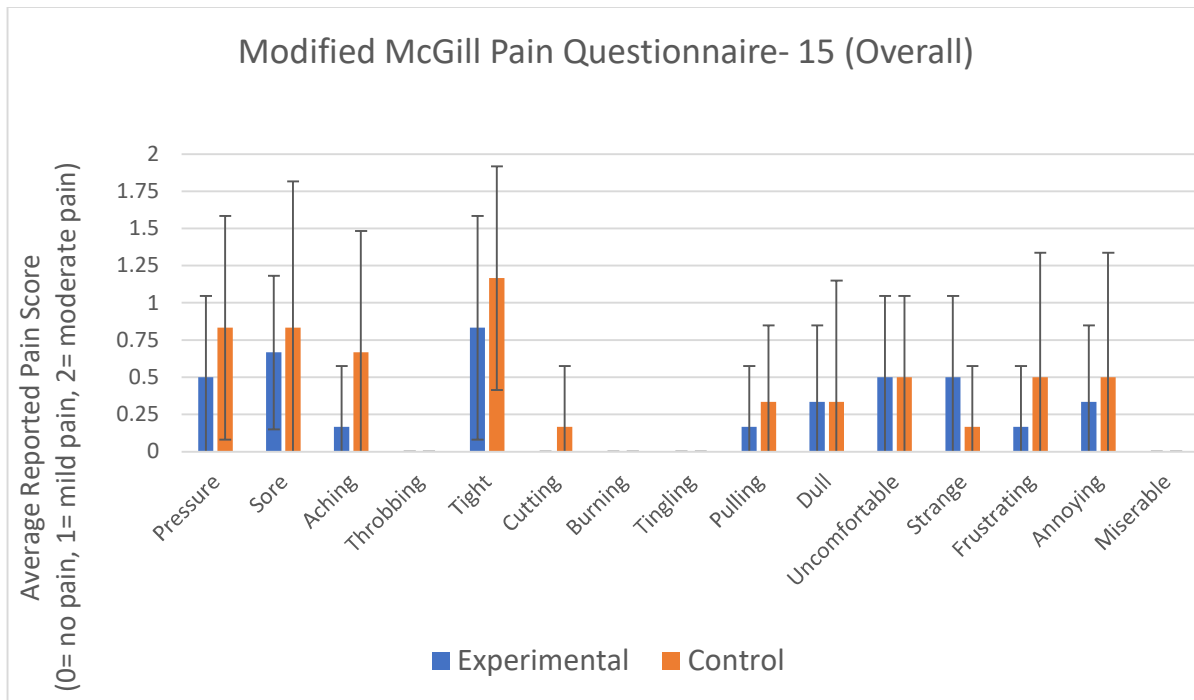


Figure 15. Average reported pain score in each of 15 MMPQ categories for experimental (blue) and control (orange) groups. There were no significant differences found between the groups in any of the 15 categories (range p=0.13 to 1.00).

Table 3. Averages \pm standard deviations for overall reported pain at V2 via MMPQ-15 total score, Visual Analogue Scale, and Current Pain Index for total sample, and experimental and control groups, with between-group comparisons (p-values).

Subject	Total Sample	Experimental	Control	p-value
Overall MMPQ-15 Total (0-45)	5 \pm 4	4 \pm 2	6 \pm 5	0.47
Overall VAS Pain (0-100)	10 \pm 7	13 \pm 8	6 \pm 5	0.21
Overall Current Pain Index (0-5)	0	1	0	0.71

Compliance Analysis (Table 4)

Both groups reported high compliance for aligner wear for hours per day at 21 ± 1 hours/day for the experimental group and 19 ± 8 hours/day for the control group. In terms of the days per week, compliance for aligner wear was 7 ± 0 days/week for the experimental group 6 ± 2 days/week for the control group. The experimental group had higher average durations of aligner wear than the control group, however, there were no significant differences in the aligner wear for hours/day ($p=0.72$) and days/week ($p=0.41$) between groups.

Table 4. Overall compliance reported at V2 for experimental and control groups in average hours per day and days per week with results of between-group comparisons via t-tests (p-value), where SD=standard deviation, Min=minimum, Max=maximum.

Compliance	Control (N=6)	Experimental (N=6)	p-value
Hours worn per day			
Mean (SD)	19 (8)	21 (1)	0.72
Median (Min, Max)	22 (3, 22)	22 (19, 22)	
Days worn per week			
Mean (SD)	6 (2)	7 (0)	0.41
Median (Min, Max)	7 (1, 7)	7 (7, 7)	

Satisfaction Analysis (Table 5 & 6)

Daily satisfaction was assessed through survey responses evaluating each subject's daily aligner experience. Each participant responded to four questions addressing 1) trouble biting or chewing food, 2) preventing speaking, 3) being able to eat without discomfort, and 4) discomfort with the cheek, tongue, or lip; where average daily satisfaction results for experimental subjects were: 1) seldom, 2) seldom, 3) often, and 4) seldom, and for control subjects were: 1) never, 2) seldom, 3) often, and 4) never (Table 5). Global satisfaction scores were calculated by averaging the four daily satisfaction questions for each subject. In this scoring system, lower values (closer to 1) reflect higher satisfaction, whereas higher values (closer to 5) indicate lower satisfaction. Both the experimental and control groups demonstrated similar results, with an average global satisfaction score of 2 ± 1 , indicating generally high satisfaction across all subjects.

Satisfaction was also evaluated through overall survey responses assessing each subject's general aligner experience at V2, where average responses to the four questions for the experimental subjects were: 1) seldom, 2) sometimes, 3) often, and 4) seldom, and for control subjects were: 1) seldom, 2) seldom, 3) sometimes, and 4) seldom. No statistically significant differences were found between the two groups for satisfaction questions 1 – 4 ($p = 0.74, 0.77, 1.00, \text{ and } 1.00$, respectively) (Table 6).

Table 5. Daily surveys on satisfaction from each subject and experimental and control groups, showing averages \pm standard deviations for each of four questions and global score that represents overall level of satisfaction (average of results for the four questions). The lower the global score, the higher the satisfaction.

Subject #	Group	Sex	Average ± standard deviation for:				
			1) Trouble biting / chewing	2) Prevent speaking	3) Eat without discomfort	4) Discomfort with cheek, lip or tongue	Global Score representing Daily Satisfaction 1= High Satisfaction 5= Low Satisfaction
1	Experimental	Male	2 ± 1	2 ± 1	2 ± 1	2 ± 1	2 ± 1
4	Experimental	Female	1 ± 0	1 ± 0	1 ± 1	1 ± 0	1 ± 0
6	Experimental	Female	1 ± 0	4 ± 0	1 ± 1	3 ± 0	3 ± 0
8	Experimental	Female	2 ± 1	3 ± 0	2 ± 0	2 ± 1	2 ± 0
9	Experimental	Female	3 ± 1	2 ± 1	2 ± 1	2 ± 1	2 ± 1
11	Experimental	Female	2 ± 1	1 ± 0	2 ± 1	1 ± 0	2 ± 1
Experimental group: daily average ± SD			2 ± 1 (Seldom)	2 ± 1 (Seldom)	2 ± 1 (Often)	2 ± 1 (Seldom)	2 ± 1
2	Control	Male	2 ± 1	2 ± 1	4 ± 0	2 ± 1	2 ± 0
3	Control	Female	1 ± 1	1 ± 0	1 ± 0	1 ± 0	1 ± 0
5	Control	Female	1 ± 0	1 ± 1	1 ± 1	1 ± 0	1 ± 0
7	Control	Female	1 ± 0	1 ± 0	1 ± 1	1 ± 1	1 ± 0
10	Control	Female	2 ± 1	4 ± 0	2 ± 1	2 ± 1	2 ± 1
12	Control	Female	NA	NA	NA	NA	NA
Control group: daily average ± SD			1 ± 0 (Never)	2 ± 1 (Seldom)	2 ± 1 (Often)	1 ± 0 (Never)	2 ± 1

Table 6. Overall satisfaction reported at V2 for total sample and experimental and control groups, showing averages scores \pm standard deviations and between group comparisons (p-values).

Overall Satisfaction Survey 1= High Satisfaction 5= Low Satisfaction	Total Sample	Experimental	Control	p-value
1) Trouble biting or chewing	2 \pm 1 (Seldom)	2 \pm 1 (Seldom)	2 \pm 1 (Seldom)	0.74
2) Preventing from speaking	2 \pm 1 (Seldom)	3 \pm (Sometimes)	2 \pm 1 (Seldom)	0.77
3) Eat without discomfort	2 \pm 1 (Often)	2 \pm 1 (Often)	3 \pm 2 (Sometimes)	1.00
4) Discomfort with cheek, lip, or tongue	2 \pm 1 (Seldom)	2 \pm 1 (Seldom)	2 \pm 1 (Seldom)	1.00

Overall Customer Effort Survey and Overall Adjunct Satisfaction Survey

Customer effort survey was collected at the end of the study (V2) to assess subject’s experience with aligner treatment. On average, both experimental groups and control groups 1) somewhat agreed that they would recommend aligner treatment to a friend, 2) somewhat agreed that they were satisfied with their aligner treatment, 3) somewhat agreed that it was easy to seat their aligner trays, and 4) somewhat agreed that it was easy to remove their aligner trays. There were no significant differences between groups for responses to these survey questions 1– 4 (p=1.00, 0.46, 0.46, and 1.00, respectively) (Table 7).

Overall adjunct satisfaction was also collected at the end of the study to assess subject's experience with the adjunct appliance. On average, the experimental group 1) used the appliance every day, 2) scored a 9 ± 2 in likelihood to recommend the adjunct appliance, and 3) scored a 9 ± 2 in likelihood to continue using the adjunct after the study. On average, the control group 1) used the appliance multiple times a day, 2) scored a 10 ± 1 in likelihood to recommend the adjunct appliance, and 3) scored a 9 ± 1 in likelihood to continue using the adjunct appliance after the study. There were no significant differences between these survey questions 1-3 ($p=0.18, 0.86, \text{ and } 1.00$, respectively) (Table 8).

Table 7. Overall effort reported at V2 for total sample and experimental and control groups, showing averages scores \pm standard deviations and between group comparisons (p-values).

Overall Effort Survey 1=Strongly disagree 7=Strongly agree	Total Sample	Experimental	Control	p-value
I would recommend aligner treatment to a friend	5 ± 0 (Somewhat Agree)	5 ± 0 (Somewhat Agree)	5 ± 0 (Somewhat Agree)	1.00
I am satisfied with my aligner experience	5 ± 0 (Somewhat Agree)	5 ± 0 (Somewhat Agree)	5 ± 0 (Somewhat Agree)	0.46
It was easy to seat my aligner trays	5 ± 0 (Somewhat Agree)	5 ± 0 (Somewhat Agree)	5 ± 0 (Somewhat Agree)	0.46
It was easy to remove my aligner trays	5 ± 0 (Somewhat Agree)	5 ± 0 (Somewhat Agree)	5 ± 0 (Somewhat Agree)	1.00

Table 8. Overall satisfaction with adjunct tool reported at V2 for total sample and experimental and control groups, showing averages scores \pm standard deviations and between group comparisons (p-values).

Overall Adjunct Satisfaction	Total Sample	Experimental	Control	p-value
How often did you use the adjunct appliance? (1-4)	4 \pm 1 (Multiple times a day)	3 \pm 1 (Every day)	4 \pm 0 (Multiple times a day)	0.18
How likely are you to recommend the adjunct appliance? (1-10)	9 \pm 1	9 \pm 2	10 \pm 1	0.86
How likely are you to continue using the adjunct appliance after the study? (1-10)	9 \pm 2	9 \pm 2	9 \pm 1	1.00

Efficiency Analysis

Of the twelve subjects enrolled, 11 were included in the efficiency analysis: five in the experimental group and six in the control group. One experimental subject (Subject 4, female) was excluded for progressing beyond tray 4 before a scan could be obtained. Both maxillary and mandibular arches were analyzed in the efficiency assessment. Nine of the 11 included subjects underwent treatment of both arches, while two subjects received aligners only for the mandibular arch. Additionally, one control subject (Subject 12, female) had the maxillary arch excluded due to a poor-quality .stl file that prevented accurate comparison. In total, 19 scans were analyzed: 11

mandibular and eight maxillary arches. The control group contributed six mandibular and three maxillary scans, while the experimental group contributed five mandibular and five maxillary scans.

The mean RMS value was 0.69 ± 0.09 mm for the experimental group and 0.66 ± 0.11 mm for the control group, and not statistically significantly different between the groups ($p = 0.56$; Figure 16). A separate analysis comparing mandibular and maxillary arches revealed a significantly lower RMS of 0.62 ± 0.06 mm for the mandibular teeth compared to 0.75 ± 0.09 mm for the maxillary teeth ($p=0.005$; Figure 17).

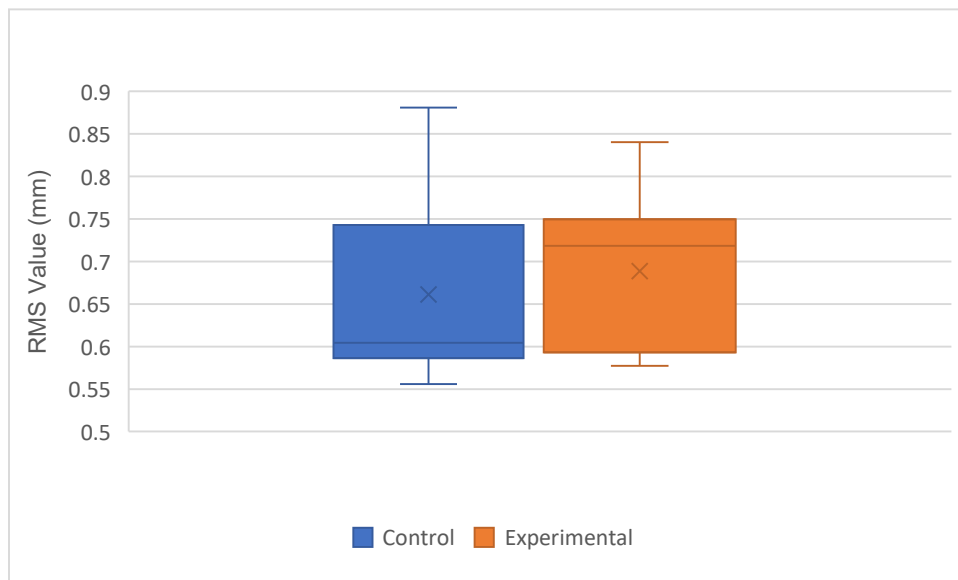


Figure 16. RMS values for control and experimental groups. Lines in the box plot indicate median values for the data set. There were no significant differences in RMS values between control and experimental groups ($p=0.56$).

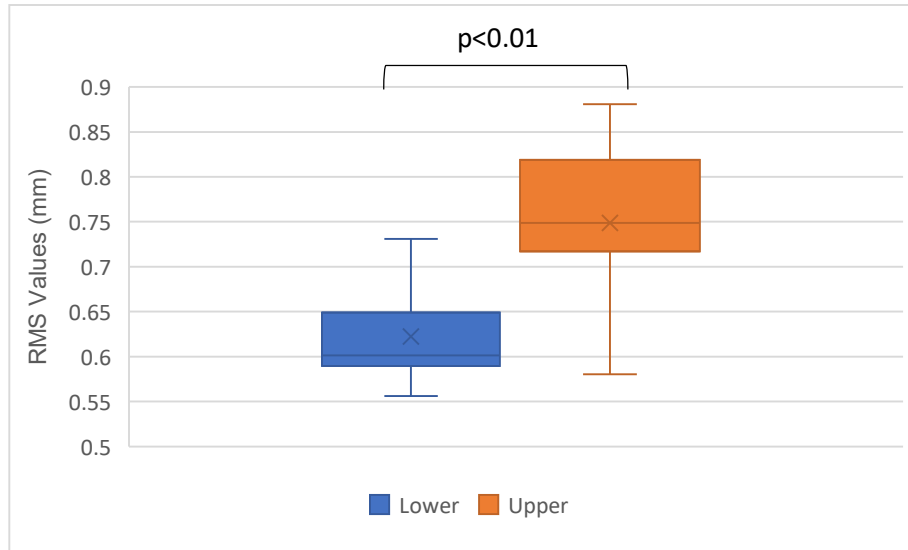


Figure 17. RMS values for upper (maxillary) and lower (mandibular) teeth. Lines in the box plot indicate the median values for the data set. The lower dental arch presented with smaller RMS values and there was a significant difference when compared to the upper dental arch ($p=0.005$).

Discussion

The purpose of this study was to discover the effects that clear aligner adjuncts have on subject's compliance, satisfaction, pain, and tray efficacy. Compliance, satisfaction, and pain were assessed through daily and overall surveys, which provided a detailed view of the subjects' experiences throughout aligner wear for the first four trays. Tray efficacy was estimated by comparing predicted and actual outcomes using .stl files after four trays of aligner wear. As a prospective study, this design allowed for the evaluation of adjunct effects under consistent treatment conditions. Results from 12 subjects, six in each of the experimental and control groups showed most variables measured were not significantly different between the groups and some interesting trends that warrant future investigation in a larger scale study.

Pain Analysis

When discussing pain, it is important to recognize factors that may influence pain perception. Previous research has suggested that there is a link between pain sensitivity and both genetic and environmental factors, including stress, anxiety, and depression (Fillingim, 2017; Thompson et al., 2016). For this reason, it was important for this study to collect pre-treatment data regarding subject's depression (PHQ-9), anxiety (GAD-7), and somatization (PHQ-15) to help contextualize pain responses during orthodontic treatment. The average PHQ-9, GAD-7 and PHQ-15 scores showed minimal symptoms with no significant differences between experimental and control groups at baseline. However, two experimental subjects (Subject 6, female; Subject 11, female) and one control subject (Subject 10, female) exhibited elevated PHQ-9, GAD-7, and PHQ-15 scores that corresponded with higher reported daily pain levels. Subject 6 demonstrated mild depression, anxiety, and somatization symptoms and showed an initial decrease in pain during the first tray, followed by a gradual increase in pain across subsequent trays. However, it is also important to note that Subject 6 had very low levels of daily survey compliance, which artificially biases the data and renders the results unreliable. Subject 11 had the highest psychosocial symptom scores of the sample and exhibited moderate depression, moderate anxiety, and medium somatization, with pain scores during the initial tray notably higher than those of all other participants. Similarly, Subject 10 demonstrated mild anxiety, and showed the highest pain during the first tray of aligners than any other subject in the control group (Figure 12). These findings are consistent with prior research indicating that psychosocial factors can influence pain perception and tolerance (Fillingim, 2017). However, the absence of significant between-group differences in overall pain suggests that the data were unaffected by these outlier subjects.

Adjunctive therapies that generate chewing-level forces have been proposed to help alleviate orthodontic pain (Ramanan, 2022). One proposed mechanism suggests that orthodontic pain originates from periodontal ligament compression during tooth movement, which triggers the release of inflammatory mediators such as bradykinin and histamine, activating nociceptors within the ligament. Farzenagan et al. (2012) proposed that applying intermittent biting forces may help relieve this discomfort by mechanically loosening the compressed periodontal fibers and restoring normal blood flow and lymphatic drainage within the periodontal ligament, thereby reducing local inflammation and pressure. Another framework for pain modulation is described by the Gate Control Theory of Pain (Melzack & Wall, 1965). This model proposes that the substantia gelatinosa of the dorsal horn functions as a neural “gate” that regulates the transmission of pain signals to the central nervous system. Pain impulses carried by small-diameter afferent fibers (A-delta and C fibers) can be inhibited when large-diameter afferent fibers (A-beta fibers), which transmit sensations of pressure and touch, are simultaneously activated. In this way, masticatory pressure or mechanical stimulation, such as that provided by chewing or biting on an adjunct, can reduce the perception of orthodontic pain by distinguishing pain signal transmission at the spinal level. With these proposed mechanisms in mind, this study had the goal of examining the interaction between the aligner adjunct and experienced pain. However, no significant differences were found in overall MMPQ-15 total, VAS, and current pain index scores between the control and experimental groups. Although not significant, the experimental group had higher averages for VAS and current pain index than the control group. In addition, there were no significant differences between the 15 categories of pain. Analysis of the Modified McGill Pain Questionnaire (MMPQ-15) revealed the experimental group reported lower average pain in eight of the 15 categories, whereas the control group reported lower pain

in only one. The remaining categories showed similar scores between the two groups. Despite these trends, none of the category-specific pain comparisons reached statistical significance.

Interestingly, the control group reported higher average VAS and current pain index scores, contrary to prior findings by Farzanegan et al. (2012) and Ramanan et al. (2019), which suggested that bite adjuncts can reduce orthodontic pain. Based on those studies, it was anticipated that the experimental group, who had access to the bite cushion, would experience lower overall pain. However, the categorical MMPQ findings more closely align with theoretical expectations, as the experimental group reported lower pain in the majority of categories. These categories included pressure, sore, aching, tight, cutting, pulling, frustrating, and annoying. This pattern raises the possibility that the adjunct may influence specific qualities of pain rather than reducing pain overall. Moreover, broader pain measures such as the MMPQ-15 total score, VAS, and current pain index may not fully capture the nuances of patients' pain experiences or distinguish between different sensory dimensions of pain. These findings highlight the need for future research to explore which specific qualities of pain may be most influenced by clear aligner adjuncts and whether certain pain domains respond more favorably to mechanical stimulation. Overall, this trend supports the possibility that biting on the adjunct may have stimulated large-diameter A-beta fibers, thereby reducing pain signal transmission through the mechanism described by the Gate Control theory. Nevertheless, the findings of the current study cannot confirm this effect.

Further analysis of daily survey data examined whether pain decreased from week one to week two within each tray cycle. The experimental group demonstrated decreased MMPQ-15 total scores for the first two trays, followed by increases in the last two trays. VAS pain scores decreased through the first three trays, with a mild increase in the fourth. Conversely, the control

group exhibited steady decreases in both MMPQ-15 total and VAS pain scores across all four trays. Although no statistically significant differences were observed between groups for any tray, these trends were contrary to expectations, as we anticipated that the experimental group would demonstrate greater reductions in pain across trays. Notably, the experimental group exhibited a +9% increase in VAS pain from week one to week two during the fourth tray.

This late-stage rise in pain is unexpected, as patients typically adapt to aligner forces over time, resulting in lower discomfort across trays. However, interpretation of this finding must be made cautiously, as tray 4 had the lowest survey compliance of the entire study—only 50% of daily entries were recorded in the experimental group. Low response rates can bias pain estimates in several ways. In this context, it is possible that participants with little or no pain simply stopped reporting during the later stages of the study, while subjects who continued to experience discomfort remained more active in recording their symptoms. Additionally, reduced compliance at the end of treatment introduces variability that makes the data less reliable and less representative of the experimental group. Missing entries prevent a complete depiction of the daily pain trends, limit the ability to detect true patterns, and increase the likelihood that observed changes reflect reporting bias rather than true group differences.

Compliance & Satisfaction Analysis

Both the experimental and control groups reported high levels of compliance throughout their aligner experience. The experimental group had an average of 21 ± 1 hours per day and 7 ± 0 days per week of aligner wear. Similarly, the control group had an average of 19 ± 8 hours per day and 6 ± 2 days per week of aligner wear. These values closely align with the standard instruction provided to all participants; to wear aligners for 22 hours per day, 7 days per week. There were no significant differences in reported hours of wear per day or days per week,

suggesting that the presence of the adjunct appliance did not influence tray wear compliance. The overall high compliance observed may be attributed to the relatively short study duration, as participants only completed four trays of aligners. Because comprehensive aligner therapy often extends over one to two years, future studies examining long-term compliance may yield more representative findings. It is also important to note that self-reported compliance measures may be subject to bias, as participants are unlikely to strictly monitor hourly or weekly wear time. This limitation reflects the inherent challenges in accurately measuring aligner wear outside of a controlled environment.

Satisfaction ratings were similarly high in both groups. Satisfaction scores revealed little difficulty for biting speaking, and discomfort for both groups. Additionally, both groups were able to eat without discomfort. including ease of tray insertion and removal, and minimal reported issues with biting, chewing, speaking, or eating. The absence of significant differences in any satisfaction measures suggests that the bite cushion did not affect user satisfaction. It is possible that the adjunct appliance used for tray removal alone was sufficient to maintain high levels of satisfaction in both groups.

Tray Efficacy Analysis

Tray efficacy was an important focus of this study due to the inclusion of the bite cushion. Previous research by (Bowman et al., 2015) has suggested that bite cushion appliances can help seat aligners more intimately against the teeth and attachments. The current study aimed to evaluate whether the clear aligner adjunct influenced tooth movement. To assess this, we applied a 3D comparison technique using software, referencing methods described by (Dhingra et al., 2022), who set a 0.25 mm tolerance threshold to detect significant deviations between .stl files. Using this technique, our study found no significant differences between the control and

experimental groups, indicating that the bite cushion had no measurable impact on tray efficacy. It is possible that with the limited treatment duration, there is not a significant amount of tooth movement that occurred to observe the long-term differences and effects of the bite cushion.

A notable finding was the significantly smaller RMS values observed in the mandibular arch compared to the maxillary arch, suggesting better tracking and tray adaptation in the mandibular dentition. This finding was unexpected, as it is generally accepted that the mandibular cortical bone is denser than the maxillary bone, which would theoretically slow tooth movement (Devlin et al., 1998). Furthermore, the lower bone density and thinner cortices of the maxilla should facilitate faster remodeling and, therefore, improve tracking. Supporting this assumption, a 2013 study using animal models found that maxillary teeth demonstrated greater overall movement compared with mandibular teeth over a 12-week period, attributing this difference to the thinner cortices of the maxilla that allowed more rapid bone remodeling (Dudic et al., 2013).

Limitations

There were several important limitations that should be acknowledged with respect to this study. Regarding subject recruitment, a major limitation of this study was the small sample size. Although 18 individuals were approached, only 12 agreed to participate, reflecting approximately 33% attrition at recruitment. Our power calculations indicate that to detect a clinically meaningful difference in RMS of 0.25 mm with a medium effect size and 80% power at $\alpha = 0.05$ would require roughly 114 participants. An attrition rate of 33%, as in the current study, would mean that about 170 potential subjects would be needed. Consequently, the limited number of participants in the present study reduced the statistical power and restricted the ability to draw definitive conclusions from the findings.

Another limitation involved the compliance regarding filling out the daily surveys (Table 2). The average experimental group response rate per trays 1-4 were 72%, 65%, 61%, and 50%, respectively. The experimental group showed a steady decline in response rates throughout the entire study. Subject 6 showed especially low compliance with every tray of the daily surveys, with responses as low 0% for tray 3. The average control group response rate for trays 1-4 were 77%, 77%, 77%, and 79%, respectively. The control group showed steady daily compliance rates overall, however, Subject 5 had response rates that were as low as 36% for trays 3 and 4. Low and inconsistent survey compliance weakened the ability to draw accurate conclusions for several reasons. First, daily pain experiences with clear aligners follow a highly time-sensitive pattern, typically peaking within the first 24–48 hours of tray insertion and declining thereafter. Missing early-week data can influence the true magnitude and timing of pain peaks. Second, incomplete data reduces the reliability of weekly averages and percentage change calculations, making it difficult to distinguish true trends from pieces of missing data. Third, subjects with very low compliance may influence group averages, especially in a small sample, creating bias in pain interpretation. Finally, differences in compliance between groups, such as the declining response rates in the experimental group and the stable rates in the control group, introduce the potential for bias. In this study, observed differences may reflect variations in reporting behavior rather than true differences in pain.

A separate methodological limitation involves the process used to generate predicted .stl files for tray efficacy analysis. Because the aligner manufacturer does not provide direct access to the original predicted .stl files, the study relied on a creative solution: spraying the intaglio surface of tray 4, scanning it with an intraoral scanner, and digitally inverting the scan. Each of these steps introduced new variables, such as spray thickness, uneven coating, scanner interpretation of

reflective surfaces, and geometric inaccuracies during inversion. All of these may have introduced measurement error. This may explain, in part, why some subjects exhibited better “tracking” in one arch than the other or why RMS variability differed across individuals. Access to the original predicted .stl files, directly exported from the aligner software, would greatly increase precision.

Finally, subjects wore a total of four aligner trays, each for a two-week period. This extended wear interval and limited number of trays may have reduced the likelihood of detecting meaningful tracking discrepancies. Typical clinical protocols for aligner treatment involve patients wearing trays for seven-days, which is more sensitive to early tracking issues because the aligner has less time to fully express its programmed movements. In contrast, a two-week protocol provides substantially more time for tooth movement, allowing minor seating inefficiencies to self-correct overtime and diminish differences between groups. This study did not apply this seven-day protocol because of the desire to measure changes in pain from week one to week two. Additionally, evaluating only four trays represents a very small portion of typical orthodontic treatment, which commonly involves dozens of aligner trays. With such limited time in treatment, long-term tracking issues did not have sufficient time to accumulate, further reducing any meaningful differences in tray efficacy.

Future Direction

For future studies, extending the recruitment period beyond one year would greatly improve the ability to enroll a sufficient sample size. The limited one-year recruitment window, combined with the relatively low number of clear aligner cases treated at the study site, restricted the ability to reach the number of participants required for adequate statistical power. Increasing the recruitment duration to multiple years, or collaborating with additional orthodontic clinics,

would allow future studies to easily achieve the 170 potential participants needed as indicated by the power analysis.

Additionally, future research should incorporate strategies to strengthen daily survey compliance. In the present study, subjects were reimbursed for completing baseline surveys and records (V1), daily surveys (V1.5), and final surveys and records (V2). Despite this compensation, daily compliance still declined overtime, especially in the experimental group. A more effective approach may be to provide compensation only when subjects maintain a compliance threshold, such as $\geq 75\%$ of daily entries per tray. If the subject meets this requirement, then the disbursement would be given. This structure would encourage consistent participation throughout the study. Alternatively, reimbursement per entry could be used, in which participants receive compensation proportional to the number of daily surveys completed. Given the 56-day duration of the study, compensating subjects on a per-day basis may further enhance engagement and reduce missing data. Finally, incorporating daily text-message reminders would likely improve compliance substantially. Automated reminders could be sent at the end of each day to participants who have not yet completed their survey, reducing forgetfulness and increasing daily survey compliance.

Another important direction for future research involves a deeper exploration of the findings within the individual MMPQ-15 pain categories. In this study, the experimental group demonstrated lower scores in seven specific pain domains (pressure, sore, aching, tight, pulling, frustrating, and annoying), suggesting that the bite cushion may preferentially reduce certain qualitative aspects of discomfort rather than generally decreasing overall pain. This pattern raises the possibility that mechanostimulation from the adjunct may modulate particular sensory pathways more effectively than others. Studies incorporating larger samples and more accurate

pain tracking tools may help identify which specific sensory characteristics of aligner discomfort are modifiable through adjunctive therapy. Such insights could lead to more individualized pain-management strategies.

Regarding methods for measuring tray efficacy, the most accurate and efficient approach would be to directly obtain the predicted tray 4 .stl files from the aligner software. Access to these files would eliminate the additional variables introduced by the workaround technique used in this study. Tray spraying, intraoral scanning of the intaglio surface, and digital inversion all introduce opportunities for geometric distortion and measurement error. Direct comparison between the original predicted .stl and the post-tray intraoral scan would provide a more precise assessment of tracking accuracy. Because the commercial aligner systems used in this study did not permit export of predicted .stl files, future studies would benefit from the use of in-house aligner systems. Many orthodontic software platforms now allow clinicians to digitally stage tooth movements and fabricate clear aligners directly through 3D printing workflows. Overall, in-house aligners would allow full access to .stl files, standardize the movement of staging, and increase flexibility for future research.

Finally, for future studies primarily focused on evaluating the tracking effects of the bite cushion, it would be advantageous to utilize the more common seven-day aligner wear protocol rather than the 14-day protocol used in this study. Shorter wear intervals would allow us to more accurately capture early tracking discrepancies before the aligner has fully expressed its programmed movements. In a 14-day protocol, additional days of wear may compensate and “mask” minor tracking errors, reducing the ability to detect whether the bite cushion truly influences tooth movement efficiency. A shorter wear protocol would also allow the analysis of more aligner stages within the same study period, such as eight trays instead of four. This would

provide a better representation of real-world orthodontic treatment, where errors compound over multiple stages.

Conclusion

In this prospective clinical study, several key findings were identified regarding the use of a clear aligner adjunct with a bite cushion:

Pain:

The experimental group demonstrated no significant differences in reported pain levels compared with the control group across all pain measures.

Compliance and Satisfaction:

- i. The use of the bite cushion did not significantly affect aligner-wear compliance.
- ii. Satisfaction outcomes were also similar between groups, with no significant differences observed in subjects' overall aligner experiences.

Tray Efficacy (Tracking):

- i. The bite cushion did not significantly improve or diminish tray efficacy, as measured by RMS (mm) comparisons of predicted and actual tooth positions.
- ii. A notable finding was that mandibular teeth exhibited significantly better tracking than maxillary teeth, indicating better tray efficacy in the mandibular arch.

Overall, use of the bite cushion adjunct was not associated with differences in pain, compliance, satisfaction, or tray efficacy within the four-tray study period. However, the significantly better tracking in the mandibular dental arch compared to maxillary dental arch highlights an area for further investigation in future research.

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Appendices

Appendix A. Oregon Health & Science University Institutional Review Board approval.



APPROVAL OF SUBMISSION

September 23, 2024

Dear Investigator:

On 8/30/2024, the IRB reviewed the following submission:

IRB ID:	STUDY00027513
Type of Review:	Initial Study
Title of Study:	Effects of Clear Aligner Adjunct use on Patient Experience and Aligner Efficacy
Principal Investigator:	Corey Sheek
Funding:	Name: OHSU Foundation, PPQ #: Fiske Fund
IND, IDE, or HDE:	None
Documents Reviewed:	<ul style="list-style-type: none"> • Compliance Surveys • GAD 7 • PHQ 9 • PHQ 15 • HIPAA - Prep to Research Form_CAT adjuncts_072624.docx • BITE ME Packaging.pdf • Consent and Authorization Forms - Clinical (06.01.2024)_LI_090624a.pdf • Control Instructions • Experimental instructions • McGill Pain Questionnaire • Protocol • PUL_System - 2 pack _ Invisalign USA Store.pdf • PULTOOL_ - 1 pack _ Invisalign USA Store.pdf • Recruitment Script • Satisfaction Survey

The IRB granted final approval on 9/23/2024. The study is approved until 8/29/2025.

Review Category: Expedited Category # 9

Version Date: 03.04.2024

Page 1 of 2

Copies of all approved documents are available in the study's **Final Documents** (far right column under the documents tab) list in the eIRB. Any additional documents that require an IRB signature (e.g., IIAs and IAAs) will be posted when signed. If this applies to your study, you will receive a notification when these additional signed documents are available.

Ongoing PI Responsibilities:

- Six to ten weeks before the expiration date, submit a continuing review to request continuing approval.
- Submit changes to the project for IRB approval prior to implementation.
- Submit Reportable New Information per OHSU policy.
- Submit a continuing review to close the study when the research is completed.

Guidelines for Study Conduct

In conducting this study, you are required to follow the guidelines in the document entitled, "[Roles and Responsibilities in the Conduct of Research](#)," as well as all other applicable OHSU [IRB Policies and Procedures](#).

Requirements under HIPAA

If your study involves the collection, use, or disclosure of Protected Health Information (PHI), you must comply with all applicable requirements under HIPAA. See the [HIPAA and Research](#) website and the [Information Privacy and Security](#) website for more information.

IRB Compliance

The OHSU IRB (FWA00000161; IRB00000471) complies with 45 CFR Part 46, 21 CFR Parts 50 and 56, and other federal and Oregon laws and regulations, as applicable, as well as ICH-GCP codes 3.1-3.4, which outline Responsibilities, Composition, Functions, and Operations, Procedures, and Records of the IRB.

Sincerely,

The OHSU IRB Office

Appendix B. Subject recruitment script.

Effects of Clear Aligner Adjunct use on Patient Experience and Aligner Efficacy

Participant Recruitment Script

My name is _____ and I want to speak to you about the opportunity to volunteer in the study. This study is run here in the OHSU Orthodontics Department, and we think you would be a great candidate for it. It is completely voluntary, and you may choose to leave the study at any time.

- ◇ This study will be for the first 4 trays of your treatment. If you choose to participate, we will give you an additional appliance to use with your trays. You will be asked to complete survey questions before, during, and after wearing the first 4 trays of your treatment. At the following appointment, we will do an additional intraoral scan that will help us track your teeth after 4 trays of treatment. Does this sound like something you may be interested in?

If yes → have a consent form here that we can go through together.

If no → Thank you for your time.

Appendix C. Subject consent form.



Medical Record Number _____
 Name _____
 Date of Birth _____



Medical Record Number _____
 Name _____
 Date of Birth _____

OHSU Clinical Consent and Authorization Form

SUMMARY OF KEY INFORMATION ABOUT THIS STUDY

STUDY TITLE: Effects of Clear Aligner Adjunct use on Patient Experience and Aligner Efficacy

OHSU eIRB STUDY NUMBER: 00027513

PRINCIPAL INVESTIGATOR (Study Doctor): Corey Shook, DMD, MSD 503-346-4709

INTRODUCTION:

You are being asked to join a research study. This consent form contains important information to help you decide if you want to join the study or not. This is a voluntary research study. You do not have to join the study. Even if you decide to join now, you can change your mind later. Please ask the study doctor if you have any questions about the study or about this consent form.

PURPOSE:

The purpose of the study is to learn more about if tools used with clear aligners can improve results and satisfaction with the clear aligner (orthodontic) treatment.

Please take your time and read this document carefully before deciding. You should not join this research study until all of your questions have been answered to your satisfaction.

DURATION:

Your participation in the study will generally consist of 2 visits over 2 months. These visits will be scheduled with your regular visits for orthodontic treatment and add about 20 minutes to each visit.

Your participation in this research is completely voluntary. You can choose not to participate. If you decide to participate, you can change your mind and stop participation at any time, for any reason.

PROCEDURES:

If you decide to take part in this study, you will get a tool to use with your clear aligners. You will be asked to answer survey questions and undergo a progress scan of your teeth during your regularly scheduled visit.

This study does not include genetic testing. This study does not include future research with samples/information.

RISKS: Risks of being in this study include:

- Discomfort from holding your mouth open during scanning of your teeth
- Frustration of survey questions
- Breach of confidentiality.

BENEFITS:

You may or may not directly benefit from taking part in this research. However, by being a participant, you may help us learn how to help patients in the future.

ALTERNATIVES:

The standard treatment for your condition of "crooked" or mis-aligned teeth, may include clear aligners without any tools or other forms of "braces." You may choose not to participate in this study and receive the standard treatment.

If you decide to be a part of this research study, we will give you a copy of this signed and dated consent form to keep.

END OF CONSENT SUMMARY

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INTRODUCTION & PURPOSE

STUDY TITLE: Effects of Clear Aligner Adjunct use on Patient Experience and Aligner Efficacy

PRINCIPAL INVESTIGATOR (STUDY DOCTOR): Corey Shook, DMD, MSD 503-346-4709

WHO IS PAYING FOR THE STUDY? Bruce Fiske Orthodontic Resident Support Fund, OHSU Foundation

WHO IS PROVIDING OTHER SUPPORT FOR THE STUDY? PUL System, San Francisco, CA

INTRODUCTION

This is a clinical trial, a type of research study. The primary purpose of research studies is not to provide medical treatment. Rather, research studies test new ways to diagnose, prevent, and treat disease. Specifically, the purpose of research studies is to learn more about how well new tests and treatments work, what risks they have and how best to use them. Because of this, you may or may not benefit by being in this study. Please take your time to make a decision about taking part in this research study. You can discuss your decision with your family and friends. You can also discuss it with your health care team or another doctor. If you have any questions, ask the study doctor.

WHAT IS THE PURPOSE OF THIS STUDY? WHY AM I BEING ASKED TO JOIN THIS RESEARCH STUDY?

You have been invited to be in this research study because you are receiving orthodontic treatment with clear aligners at the OHSU Orthodontic Clinic. The purpose of this study is to see if clear aligner tools are helpful.

WHAT ARE MY OTHER CHOICES IF I DO NOT TAKE PART IN THIS STUDY?

If you decide not to take part in this study, you can have standard orthodontic treatment with clear aligners.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

As many as 72 people will take part in this study which will be conducted at Oregon Health & Science University. Of these participants, we expect 80 will be screened and 72 will participate in the study at OHSU.

PROCEDURES

WHAT ARE THE STUDY GROUPS?

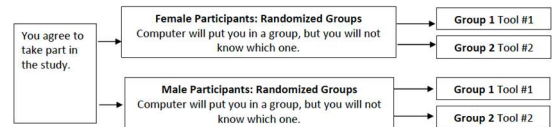
This study has two study groups. Each group will have about equal numbers of female and male participants.

- Group 1 will get clear aligner tool #1.
- Group 2 will get clear aligner tool #2.

A computer will assign you to a group in no particular order. This is called randomization. One-half of participants in this study will get tool #1 and one-half will get tool #2. You will have an equal chance of being in either group.

You will not know which type of adjunctive tool you will receive. The study is done this way because knowing if you are getting a specific tool can change the results of the study.

Below is a chart that shows what will happen to you during this study. Start reading from the left side and read across to the right, following the arrows.



HOW LONG WILL I BE IN THIS STUDY?

If you agree to be in this study, you will participate for 2 visits over the next 2 months that are combined with your regularly scheduled orthodontic treatment visits. It will add an additional 20 minutes to each visit. After you finish the study, your orthodontic provider will continue your clear aligner treatment as discussed at the treatment consultation visit.

WHAT TESTS AND PROCEDURES WILL I HAVE IF I AM PART OF THIS STUDY?

Before the study: For your orthodontic treatment, you will need to have the following records made and these will be used to in the study (for):

- Demographics (for age and sex)
- Medical History (for medications, allergies, habits, and pregnancy, if applicable)
- Scans of your upper and lower teeth (for measuring tooth positions)

During the study:

At your orthodontic treatment consultation visit, you will be asked to do the following baseline surveys:

- Depression Survey (PHQ9)

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- Anxiety Survey (GAD7)
- Somatization/Physical Symptom Survey (PHQ15)
- Modified McGill Pain Questionnaire (MMPQ-SF15)

You may be asked to have second scans made of your upper and lower teeth depending on which scanner was used to make your first set of scans. This is to make sure we use the same type of scanner during the study.

At study visits 1 (V1) and 2 (V2) and daily at home or another convenient location, you will be asked to complete surveys about your comfort, opinions, and use of the clear aligners and tools. These surveys will take about 10 minutes to complete. All surveys will be online and provided through a quick response (QR) code.

See the workflow below for a summary of the procedures that will be done before and during the study.

STUDY PROCEDURES

CONSULTATION VISIT FOR TREATMENT (+20 minutes for study)

At this visit, the plans for your clear aligner treatment will be presented and discussed. Additionally, for the study, we will ask you to complete 4 baseline surveys and you may be asked to have a second set of scans made of your teeth. These procedures will add 20 minutes to your consultation visit.

V1: CLEAR ALIGNER DELIVERY VISIT (+20 minutes for study)

You will receive some of your clear aligners and instructions on how and when to wear these at this visit as part of your treatment. For the research study, you will receive your assigned clear aligner tool and instructions on how to use this tool. You will be provided the QR code link and instructions for daily surveys.

Between V1 and V2

You will use the QR code link provided to complete daily surveys. This will take 10 minutes or less a day.

V2: 4-TRAYS-LATER VISIT (+20 minutes)

At this visit, your teeth will be scanned for the study to assess your treatment progress and you will be asked to complete some final surveys. These procedures will add 20 minutes to your regular treatment visit.

RISKS

WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?

Risks of study tests and procedures:

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- **Scanning of your teeth:** Temporary discomfort can occur from holding your mouth open during scanning of your teeth. If this occurs, you can inform the study provider and you will be allowed to rest.
- **Survey questions:** You may feel frustrated by the number and frequency of survey questions. You may refuse to answer any of the questions that you do not wish to answer.
- **Breach of confidentiality:** We will take steps to keep your personal information confidential, but we cannot guarantee total privacy.

What to do if you become pregnant:

You must tell the study doctor if you become pregnant. You will be removed from the study if you become pregnant because hormones during pregnancy can sometimes cause your gums to swell temporarily (gingivitis), which may interfere with seating of clear aligners.

GENETIC TESTING

WILL THIS STUDY INVOLVE GENETIC TESTING AND WHAT ARE THE RISKS OF GENETIC TESTING?

There is no genetic testing in this study.

TESTING RESULTS (Non-Genetic Testing)

WILL I RECEIVE RESULTS FROM THE NON-GENETIC TESTING IN THIS STUDY AND WHAT ARE POSSIBLE CONSEQUENCES?

We will give your provider the results from the scanning of your teeth. These results will be placed in your orthodontic record. We will not give you or your provider the results of the surveys because we do not know what these results mean to your health.

FUTURE RESEARCH

WILL MY INFORMATION BE USED FOR FUTURE RESEARCH?

Aside from sharing data as required by the publishers, your information and samples will not be used for future research.

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CONFIDENTIALITY, PRIVACY, & HIPAA AUTHORIZATION

WHAT INFORMATION IS BEING COLLECTED, USED, AND SHARED AND WHY?

We will create and collect health information about you as described throughout this form in order to conduct and oversee this research study.

HOW WILL MY INFORMATION BE PROTECTED?

We will take steps to keep your personal information confidential, but we cannot guarantee total privacy. Scans of your teeth that are used for your orthodontic care will have information that will identify you and will be placed in your orthodontic record. A code number will be assigned to you, your research surveys, and data. Only the study team will be able to link the code number back to you.

WHO WILL MY HEALTH INFORMATION BE SHARED WITH?

We may share this information with others outside of OHSU who are involved in conducting or overseeing this research, including:

- The Food and Drug Administration
- The Office for Human Research Protections, a federal agency that oversees research involving humans

When we send information to someone outside of OHSU, it may no longer be protected under confidentiality laws, so we cannot promise that they will keep it private.

DO I HAVE TO SIGN THIS AUTHORIZATION?

You do not have to sign this authorization, but if you do not, you cannot be in the study because we need to use the health information to do this study. If you decide not to take part in this study, it will not affect your ability to get health care services, enroll in any health plans, or get payment or insurance coverage for services.

HOW LONG WILL MY INFORMATION BE USED OR SHARED?

We may continue to use and share your information as described above until the end of the study.

WHAT IF I CHANGE MY MIND?

You may change your mind at any time about participating in the study or any part of the study.

If you no longer want your health information to be used and shared:

Send a written request or email to the address below stating that you are taking back your permission (authorization):

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Dr. Corey Shook
 OHSU School of Dentistry
 SDORTHO
 2730 SW Moody Ave,
 Portland, OR 97201
 Email: shookco@ohsu.edu

Your request will be effective on the date we receive it. However, we will not be able to remove information that has already been used or shared with others.

BENEFITS

WHAT BENEFITS CAN I EXPECT FROM TAKING PART IN THIS STUDY?

You will not directly benefit from being in this study. However, by being a participant, you may help us learn how to help patients in the future.

PARTICIPANT'S RIGHTS

DO I HAVE TO TAKE PART IN THIS STUDY AND CAN I CHANGE MY MIND LATER?

Your participation in this study is voluntary:

- You do not have to join this or any research study.
- If you join the study and later change your mind, you have the right to quit at any time.
- We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.
- You do not have to be in research studies offered by your doctor.

Your health care provider may be one of the study doctors of this research study and, as a researcher, is interested in both your clinical care and the conduct of this study. Before entering this study, or at any time during the study, you may ask for a second opinion about your care from another doctor who is not involved in this study.

WHAT HAPPENS IF I DECIDE I DON'T WANT TO CONTINUE, OR IF THE STUDY DOCTOR HAS TO TAKE ME OUT OF THE STUDY?

Talk to the study doctor if you change your mind and want to withdraw from the study.

The study doctor may remove you from all or part of the study for any of these reasons:

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- You become pregnant.
- You do not follow the study team's instructions.

The study doctor will talk to you about any testing, follow-up, or additional treatment you might need to make sure you stop the study safely. You can decide whether to let the study doctor continue to collect your health information from additional routine follow-up for study purposes.

WHAT WILL HAPPEN TO MY INFORMATION IF I WITHDRAW FROM THE STUDY?

If in the future you decide you no longer want to participate in this research, we will ask if we can continue to use your information as described in this form until the end of the study. However, we will not be able to remove information that has already been used or shared with others.

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT MY RIGHTS IN THIS STUDY?

This research has been approved and is overseen by an Institutional Review Board (IRB), a committee that protects the rights and welfare of research participants.

You may talk to the OHSU Research Integrity Office/IRB at (503) 494-7887 or irb@ohsu.edu for any of the following reasons:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at: <https://secure.ethicspoint.com/domain/media/en/gu/18915/index.html> or by calling toll-free (877) 733-8313. Messages can be anonymous, and voicemail is available 24 hours a day, seven days a week.

COSTS & LIABILITY

WHAT WILL I (OR MY INSURANCE COMPANY) BE BILLED FOR IF I PARTICIPATE IN THIS STUDY?

There will be no cost to you or your insurance company to participate in this study.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

Payment for participation is considered taxable income, even if the payment is by gift card or ClinCard debit card. We may request your social security number or tax ID so that we can process payments for your participation in this study.

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We may pay you with a debit card. There may be fees (for example, if the card is inactive for an extended period of time), which will be deducted from the balance on your card. We will give you a separate card member agreement and FAQ sheet with details on how to use the card.

You will be reimbursed \$16.00 at the end of V1 (CLEAR ALIGNER DELIVERY VISIT) and \$64.00 at the end of V2 (4-TRAYS-LATER VISIT), for a total of \$80.00 if you complete all aspects of the study.

WHAT HAPPENS IF I AM INJURED OR HURT BECAUSE I TOOK PART IN THIS STUDY?

If you believe you have been injured or harmed as a result of participating in this research and require treatment, contact one of the study investigators: Corey Shook, DMD, MSD (503) 346-4709, David Bui, DDS (909) 638-9525, or Laura Iwasaki, DDS, MSc, PhD (503) 494-8903.

If you are injured or harmed by the study procedures, you will be treated. OHSU does not offer any financial compensation or payment for the cost of treatment if you are injured or harmed as a result of participating in this research. Therefore, any medical treatment you need may be billed to you or your insurance. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim.

If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

WILL ANY OF MY INFORMATION OR SAMPLES FROM THIS STUDY BE USED FOR COMMERCIAL PROFIT?

This study is not paid for by a company and there are no plans to develop anything with commercial value in this study. However, it is possible that research in the future could lead to a discovery that might have potential commercial value to a company, OHSU, or its researchers. In that case, you will not have property rights or ownership or receive any financial benefits for these discoveries. You will also not be legally responsible for anything that occurs because we used your information or samples.

WHERE TO FIND MORE INFORMATION ABOUT THE STUDY

WHERE CAN I GET MORE INFORMATION?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Outside of regular clinic hours, you can speak with a health care provider on-call. Refer to the beginning of this consent form for contact names and phone numbers. If you have any questions,

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concerns, or complaints regarding this study now or in the future, please contact Corey Shook, DMD, MSD (503) 346-4709.

SIGNATURE		
<p>I have read (or someone has read to me) this form and have been able to ask questions and have them answered. By signing below, I agree to be in this study and authorize the use and sharing of my health information for research as described in this form. I will be given a copy of this signed form.</p>		
Participant Printed Name	Participant Signature	Date
Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

Appendix D. Depression PHQ survey downloaded from Pfizer Inc. (*Patient Health Questionnaire (PHQ) Screeners. Free Download, n.d.*).

Patient Health Questionnaire - 9

Over the last 2 weeks, how often have you been bothered by the following problems?
Please place a check mark in the box to indicate your answer.

	Not at all 0	Several days 1	More than half the days 2	Nearly every day 3
1. Little interest or pleasure in doing things	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Feeling down, depressed, or hopeless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Trouble falling or staying asleep, or sleeping too much	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Feeling tired or having little energy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Poor appetite or overeating	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Trouble concentrating on things, such as reading the newspaper or watching television	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Moving or speaking so slowly that other people could have noticed? Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Thinking that you would be better off dead or of hurting yourself in some way	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
TOTAL SCORE =				

If you checked off <u>any</u> problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?			
Not difficult at all	Somewhat difficult	Very Difficult	Extremely difficult
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Source instrument available at <http://www.phqscreeners.com/>
Consortium version 12May2013. Available at <http://www.rdc-tmdinternational.org/>

Appendix E. Anxiety GAD7 survey downloaded from Pfizer Inc. (*Patient Health Questionnaire (PHQ) Screeners. Free Download, n.d.*).

GAD - 7

Over the last 2 weeks, how often have you been bothered by the following problems?
Place a check mark in the box to indicate your answer.

	Not at all 0	Several days 1	More than half the days 2	Nearly every day 3
1. Feeling nervous, anxious or on edge	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Not being able to stop or control worrying	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Worrying too much about different things	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Trouble relaxing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Being so restless that it is hard to sit still	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Becoming easily annoyed or irritable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Feeling afraid as if something awful might happen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
TOTAL SCORE =				

If you checked off <u>any</u> problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?			
Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Source instrument available at <http://www.phqscreeners.com/>
Consortium version 12May2013. Available at <http://www.rdc-tmdinternational.org/>

Patient Health Questionnaire-15: Physical Symptoms

During the last 4 weeks, how much have you have been bothered by any of the following problems? Please place a check mark in the box to indicate your answer.

	Not bothered 0	Bothered a little 1	Bothered a lot 2
1. Stomach pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Back pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Pain in your arms, legs, or joints (knees, hips, etc)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Menstrual cramps or other problems with your periods [women only]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Headaches	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Chest pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Dizziness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Fainting spells	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Feeling your heart pound or race	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Shortness of breath	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Pain or problems during sexual intercourse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Constipation, loose bowels, or diarrhea	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Nausea, gas, or indigestion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Feeling tired or having low energy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Trouble sleeping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
TOTAL SCORE =			

Appendix G1. Daily pain survey modified McGill Pain Questionnaire validate for orthodontic patients by Iwasaki et al (Iwasaki et al., 2013).

Modified McGill Pain Questionnaire (daily)

(Validated for orthodontic patients by Iwasaki et. al in Angle Orthodontist Vol 83, No 5, 2013)

The words below are sometimes used to explain how your mouth feels while you have clear aligners. Mark the column to indicate the level of pain you feel for each word.

	0 No Pain	1 Mild	2 Moderate	3 Severe
Pressure				
Sore				
Aching				
Throbbing				
Tight				
Cutting				
Burning				
Tingling				
Pulling				
Dull				
Uncomfortable				
Strange				
Frustrating				
Annoying				
Miserable				

Mark along this line to indicate how bad your pain is – the left of the line means no pain at all and the right end means worst pain possible.

No Pain ----- Worst Pain Possible

Mark the space that best indicates your level of pain right now – only mark one.

0	No Pain	
1	Little Pain	
2	Moderate Pain	
3	Bad Pain	
4	Horrible Pain	
5	Extreme Pain	

Appendix G2. Overall pain survey modified McGill Pain Questionnaire validated for orthodontic patients by Iwasaki et al (Iwasaki et al., 2013).

Modified McGill Pain Questionnaire (overall)

(Validated for orthodontic patients by Iwasaki et. al in Angle Orthodontist Vol 83, No 5, 2013)

The words below are sometimes used to explain how your mouth feels while you have clear aligners. Mark the column to indicate the level of pain you feel for each word **for your treatment overall**.

	0 No Pain	1 Mild	2 Moderate	3 Severe
Pressure				
Sore				
Aching				
Throbbing				
Tight				
Cutting				
Burning				
Tingling				
Pulling				
Dull				
Uncomfortable				
Strange				
Frustrating				
Annoying				
Miserable				

Mark along this line to indicate how bad your pain was **throughout your treatment** – the left of the line means no pain at all and the right end means worst pain possible.

No Pain ----- Worst Pain Possible

Mark the space that best indicates your level of pain **throughout treatment** – only mark one.

0	No Pain	
1	Little Pain	
2	Moderate Pain	
3	Bad Pain	
4	Horrible Pain	
5	Extreme Pain	

Appendix H1. Daily compliance survey

Compliance Survey (daily)

Date? _____

How many hours did you wear your aligners? _____

Additional Comments:

Appendix H2. Overall compliance survey

Compliance Survey (overall)

On average, how many hours a day did you wear your aligners? _____

On average, how many days a week did you wear your aligners? _____

Additional Comments:

Appendix I1. Daily satisfaction survey modified from Miller et al. which is adapted from Geriatric Oral Health Assessment Index (Miller et al., 2007).

Satisfaction Survey (daily)

Satisfaction Survey modified from that used in Miller et al. (2007). Adapted from the well-validated Geriatric Oral Health Assessment Index

1. Did you have trouble biting or chewing food?

Never Seldom Sometimes Often Always

2. Did your teeth or aligners prevent you from speaking the way you wanted?

Never Seldom Sometimes Often Always

3. Were you able to eat without feeling discomfort?

Never Seldom Sometimes Often Always

4. Did your aligners cause discomfort to your cheeks, lips, or tongue?

Never Seldom Sometimes Often Always

Additional Comments:

Appendix I2. Overall satisfaction survey modified from Miller et al. which is adapted from validated Geriatric Oral Health Assessment Index. Customer Effort Score survey questions modified for adjunctive aligner therapies (Miller et al., 2007).

Satisfaction Survey (overall)

Satisfaction Survey modified from that used in Miller et al. (2007). Adapted from the well-validated Geriatric Oral Health Assessment Index

- 1. Did you have trouble biting or chewing food?
Never Seldom Sometimes Often Always
- 2. Did your teeth or aligners prevent you from speaking the way you wanted?
Never Seldom Sometimes Often Always
- 3. Were you able to eat without feeling discomfort?
Never Seldom Sometimes Often Always
- 4. Did your aligners cause discomfort to your cheeks, lips, or tongue?
Never Seldom Sometimes Often Always

Additional Comments:

Customer Effort Score Survey (overall)

- 5. I would recommend aligner treatment to a friend.
Strongly Disagree Disagree Somewhat Disagree Neutral Somewhat Agree Agree Strongly Agree
- 6. I am satisfied with my aligner experience.
Strongly Disagree Disagree Somewhat Disagree Neutral Somewhat Agree Agree Strongly Agree
- 7. It was easy to seat my aligner trays.
Strongly Disagree Disagree Somewhat Disagree Neutral Somewhat Agree Agree Strongly Agree
- 8. It was easy to remove my aligner trays.
Strongly Disagree Disagree Somewhat Disagree Neutral Somewhat Agree Agree Strongly Agree
- 9. I am confident my aligner trays were tracking.
Strongly Disagree Disagree Somewhat Disagree Neutral Somewhat Agree Agree Strongly Agree
- 10. How often did you use the tool provided?
Never
Few times a week
Every day
Multiple times a day
Other: _____
- 11. How likely are you to recommend the tool provided?
0 1 2 3 4 5 6 7 8 9 10
Not Likely Very Likely
- 12. How likely are you to continue to use the tool provided?
0 1 2 3 4 5 6 7 8 9 10
Not Likely Very Likely

Additional Comments:

Appendix J. Consultation appointment survey as formatted in Qualtrics (pre-treatment survey)

Over the last two weeks, how often have you been bothered by the following problems?

	Click to write Column 1			
	Not at all	Several days	More than half the days	Nearly every day
Little interest or pleasure in doing things	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling down, depressed or hopeless	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trouble falling asleep or staying asleep, or sleeping too much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling tired or having little energy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Poor appetite or overeating	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling bad about yourself -- or that you are a failure or have let yourself or your family down	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trouble concentrating on things, such as reading the newspaper or watching television	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Moving or speaking so slowly that others could have noticed? Or the opposite -- being so fidgety or restless that you have been moving around a lot more than usual	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Thinking that you would be better off dead or hurting yourself in some way	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

- Not difficult at all
- Somewhat difficult
- Very difficult
- Extremely difficult

Over the last two weeks, how often have you been bothered by the following problems?

	Click to write Column 1			
	Not at all	Several days	More than half the days	Nearly every day
Feeling nervous, anxious, or on edge	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Not being able to stop or control worrying	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Worrying too much about different things	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trouble relaxing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Being so restless that it is hard to sit still	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Becoming easily annoyed or irritable	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling afraid as if something awful might happen	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If you checked off any above problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

- Not difficult at all
- Somewhat difficult
- Very difficult
- Extremely difficult

During the last 4 weeks, how much have you been bothered by any of the following problems?

	Click to write Column 1		
	Not bothered	Bothered a little	Bothered a lot
Stomach pain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Back pain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pain in your arms, legs, or joints (knees, hips, etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Menstrual cramps or other problems with your periods (if Not Applicable, please select 'Not bothered')	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Headaches	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chest pain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dizziness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fainting spells	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling your heart pound or race	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Shortness of breath	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pain or problems during sexual intercourse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Constipation, loose bowels, or diarrhea	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Nausea, gas, or indigestion	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling tired or having low energy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trouble sleeping	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Appendix K. Between V1 and V2 appointments survey as formatted in Qualtrics (daily survey).



The words below are sometimes used to explain how your mouth feels while you have clear aligners. Mark the column to indicate the level of pain you felt for each word for **the past 24 hours**.

	0= No Pain	1= Mild	2= Moderate	3= Severe
Pressure	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sore	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Aching	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Throbbing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Tight	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cutting	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Burning	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Tingling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pulling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dull	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Uncomfortable	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Strange	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Frustrating	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Annoying	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Miserable	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Mark along this line to indicate how bad your pain was for **the past 24 hours**- 0 means no pain at all and 100 means worst pain possible.

0 10 20 30 40 50 60 70 80 90 100

Overall Pain



What best indicates your level of pain for **the past 24 hours**?

No Pain

Little Pain

Moderate Pain

Bad Pain

Horrible Pain

Extreme Pain

Please answer the following questions about **the past 24 hours**:

	Never	Seldom	Sometimes	Often	Always
Did you have trouble biting or chewing food?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Did your teeth or aligners prevent you from speaking the way you wanted?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Were you able to eat without feeling discomfort?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Did your aligners cause discomfort to your cheeks, lips, or tongue?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

In the past 24 hours, how many hours did you wear your aligners?

0 2 4 7 9 11 13 15 17 20 22 24

Hours Worn



Appendix L. V2: 4-Trays-Later appointment survey as formatted in Qualtrics (overall values).



Please write your first and last name (ex. John Smith)

The words below are sometimes used to explain how your mouth feels while you have clear aligners. Mark the column to indicate the level of pain you felt for each word for your treatment **overall**.

	Click to write Column 1			
	0 - No pain	1 - Mild	2 - Moderate	3 - Severe
Pressure	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sore	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Aching	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Throbbing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Tight	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cutting	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Burning	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Tingling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pulling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dull	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Uncomfortable	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Strange	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Frustrating	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Annoying	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Miserable	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Mark along this line to indicate how bad your pain was **throughout** your treatment - 0 means no pain at all and 100 means worst pain possible.

0 10 20 30 40 50 60 70 80 90 100

Overall Pain

Over the past 8 weeks, how many hours a day did you wear your aligners?

0 2 4 6 8 10 12 14 16 18 20 22 24

Hours Worn

Over the past 8 weeks, how many days a week did you wear your aligners?

0 1 1 2 3 4 4 5 6 6 7

Days Worn

How often did you use the adjunct appliance given to you?

Never

Few times a week

Every day

Multiple times a day

Answer the following questions about the adjunct appliance you were provided:

0 1 2 3 4 5 6 7 8 9 10

How likely are you to recommend the adjunct appliance?

How likely are you to continue to use the adjunct appliance after this study?

Please answer the following questions about the past 8 weeks of treatment:

	Never	Seldom	Sometimes	Often	Always
Did you have trouble biting or chewing food?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Did your teeth or aligners prevent you from speaking the way you wanted?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Were you able to eat without feeling discomfort?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Did your aligners cause discomfort to your cheeks, lips, or tongue?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please answer the following questions:

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
I would recommend aligner treatment to a friend.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I am satisfied with my aligner experience.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
It was easy to seat my aligner trays.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
It was easy to remove my aligner trays.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I am confident my aligner trays were tracking.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>