Impact of Attachment Design on Efficacy of Rotational Movement with Custom Clear Aligners

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A thesis 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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Acknowledgements

To my incredible wife, Neda Perwez:

Thank you for the tremendous support and love you have given me over the last two and a half years. It always astounds me the grace with which you can love and care for your family while flourishing in your own professional endeavors. I am beyond thankful for you.

Dr. Jeffrey Nickel

Thank you for the inspiration and direction you provided in getting the ball rolling with this project. Your support has been essential in all aspects of this project.

Dr. Corey Shook

Thank you for your willingness to dive in headfirst to this project and learn with me along the way. I will always be grateful to have worked with you and learned from your experience.

Dr. Laura Iwasaki

Thank you for your incredible commitment to the research program and our education in the field of Orthodontics. You have been instrumental in moving this project along.

Dr. Jack Ferracane

Thank you for your wisdom and guidance during this study. Your vast wealth of experience in research has helped maintain our heading through the sometimes-choppy waters.

Dr. Hongzeng Liu

Thank you for your kind contribution to this project. Without you, the data in this study would not exist.

Dr. Dongseok Choi

Thank you for providing your statistical expertise to aid in the interpretation of our results. I'm very grateful for your time, especially during the holidays.

Thank you to the Dr. Bruce Fiske Resident Education and Research Fund for the financial support to get this project off the ground.

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I. Abstract

Objectives:
The aim of this pilot study was to evaluate the efficacy of rectangular beveled versus rectangular non-beveled composite attachments in facilitating rotational tooth movement during clear aligner therapy by comparing the amount of clinical rotation achieved relative to the amount prescribed in the digital treatment planning software. The null hypothesis was that there would be no significant difference in rotational efficacy between beveled and non-beveled rectangular attachments.

Methods:
This prospective split-mouth pilot study enrolled adult subjects undergoing clear aligner therapy in which one maxillary anterior tooth per side requiring rotation received either a beveled or non-beveled rectangular attachment bonded to the mid-labial crown surface. After zero-collision tolerance was achieved, subjects wore up to six aligners programmed for a maximum of 2° of rotation per tray. Pre- and post-observation intraoral scans were printed as 3D models, indexed, and analyzed using a MATLAB-based coordinate system to quantify angular rotation. Rotational efficacy was calculated as the percentage of achieved rotation relative to the prescribed value. Intrarater reliability was assessed using repeated MATLAB analyses of five independent T1–T2 model pairs.

Results:
Three adult female subjects completed the study, contributing five analyzable teeth, with two subjects providing complete antimere pairs for descriptive comparison. Intrarater reliability, as measured with intraclass correlation coefficient (ICC), demonstrated excellent agreement for translational measurements (ICC = 0.99–1.00) and high reliability for rotational measurements (ICC = 0.90). Achieved rotation ranged from 2.0° to 7.3°, with corresponding rotational efficacy ranging from 28% to 138%. Teeth with beveled rectangular attachments demonstrated higher mean rotational expression and efficiency than those with non-beveled rectangular attachments in this limited dataset; however, the sample size was insufficient to permit inferential statistical testing.

Conclusions:
This pilot study demonstrates the feasibility of a reproducible digital method for quantifying rotational tooth movement with clear aligners and suggests that attachment geometry may influence rotational performance. However, due to the very small sample size, the null hypothesis could not be formally evaluated, and no definitive conclusions can be drawn regarding the comparative efficacy of beveled versus non-beveled rectangular attachments. Larger, adequately powered randomized studies are required to confirm these findings.

II. Introduction

Orthodontic treatments have evolved significantly over the years, with a primary focus on enhancing the efficiency and effectiveness of tooth movement. Clear aligner therapy (CAT) has emerged as an alternative to traditional braces due to the discreet appearance and improved comfort.[1] CAT is an orthodontic treatment modality that utilizes a series of custom-made, removable thermoplastic appliances (RTAs) to move teeth into their desired positions through incremental force application via the fit of the trays.[2] In 1998, when clear aligners were introduced by Align Technology (Santa Clara, Calif), the product was advertised for the correction of low to moderate crowding and the closure of small spaces.[3] The Invisalign system (Align Technology, Santa Clara, Calif), like many others today, uses Computer-Aided Design/Computer-Aided Manufacturing (CAD/CAM) stereolithographic (STL) technology to plan and predict treatment outcomes digitally and fabricate RTAs, also known as trays.[4] Through ongoing research and development, the scope of CAT has increased to include more severe malocclusions.[3]

Initial reports examining the predictability of clear aligners to achieve desired tooth movements indicated success rates ranging from 41% in 2009, to an improved 50% in 2020.[1] The efficacy and accuracy of clear aligners to move teeth as planned are impacted by several factors, including the material of the aligners and the incorporation and design of attachments, which are small tooth colored composite buttons that are placed in specific locations on teeth with the intent of optimizing the forces imparted by the trays.[5] The first attachments that were introduced were ellipsoid in configuration and were largely replaced by more sharply defined and bulkier conventional attachments. These attachments include horizontal, vertical, and beveled designs, all of which aim to improve achievement of planned tooth positions.[1] The characteristics of

attachment shape, size, placement, and material may influence the biomechanics of tooth movement, treatment duration, and patient comfort with respect to difficulty or ease of removing and placing trays, emphasizing the importance of continued research on these matters.

Although it is common practice to include attachments in clear aligner therapy, there is a considerable knowledge gap regarding the impact of attachment design on overall treatment efficacy. To illustrate the variety of options and philosophies with respect to attachment design and planning, a survey study by Bates et al. found that optimized attachments were the preferred attachment design for extrusion of maxillary lateral incisors amongst general dentists (n = 36) while orthodontists (n = 90) preferred horizontal gingivally beveled attachments, but the overall average perceived efficiency was 4.7 out of 10.0.[6] When efficacy has been quantified by comparing planned versus actual tooth movements, different dental movements have exhibited varying degrees of success with clear aligners, as described in the paragraphs below.

Early prospective work evaluating the predictability of rotational tooth movement with clear aligners was reported by Kravitz et al. (2008), who examined the influence of attachments and interproximal reduction (IPR) on canine rotation.[7] The study included 53 canines (33 maxillary and 20 mandibular) and found an overall rotational accuracy of 35.8%. Notably, neither the presence of attachments nor the use of IPR significantly improved rotational accuracy, with no statistically significant differences observed among the attachment-only, IPR-only, and no-attachment/no-IPR groups. The vertical ellipsoid attachment, which was the most commonly used attachment design at the time (70.5%), did not meaningfully enhance rotational outcomes. These findings highlighted the biomechanical challenges associated with rotational control using early clear aligner systems and underscored the limitations of early attachment designs.[7]

Building on this work, Kravitz et al. (2009) conducted a broader prospective clinical study evaluating the accuracy of seven different orthodontic tooth movements achieved with Invisalign in a cohort of 37 adult subjects (n = 401 teeth, including 198 maxillary and 203 mandibular anterior teeth).[4] By comparing planned versus achieved movements after the first series of aligners using digital superimposition, the authors reported a mean accuracy of 41% across all movement types, with substantial variability between movements. Lingual constriction demonstrated the highest accuracy (47%), whereas extrusion showed the lowest (29.6%). Importantly for the present study, rotational accuracy for maxillary anterior teeth varied considerably, with mean accuracies of 54.2% for maxillary central incisors, 43.4% for lateral incisors, and only 32.2% for canines. These findings reinforced that rotational movements—particularly of cylindrical teeth—remain among the least predictable movements with clear aligner therapy.[4]

More recent clinical trials have further explored the influence of attachment design on movement accuracy. Groody et al. (2023) conducted a multicenter, single-blind randomized controlled trial investigating the effect of clear aligner attachments on extrusion of maxillary lateral incisors.[5] The study enrolled 38 subjects across 3 orthodontic centers and compared different attachment designs across 71 teeth. The attachment types observed were optimized attachments (proprietary term belonging to Align Technology), rectangular horizontal non-beveled, rectangular horizontal incisally-beveled (HIB), and rectangular horizontal gingivally-beveled (HGB) attachments. The average accuracy for the attachments was 62%, 79%, 78%, and 78% respectively with all three rectangular attachments significantly more effective than the optimized attachment.[5] Although extrusion differs biomechanically from rotation, the study

importantly demonstrates that there are differences between attachment designs in their ability to facilitate desired tooth movements, underscoring persistent limitations in aligner biomechanics.

Similarly, Karras et al. (2021) performed a retrospective clinical study evaluating the efficacy of Invisalign's optimized and conventional attachments on rotational and extrusive tooth movements across a large sample (n = 100 subjects, 382 teeth).[8] For the rotational and extrusive movements assessed, they found an overall mean accuracy of 57.2%, 63.2% for rotation and 47.6% for extrusion. Given the data, the researchers concluded that conventional attachment types may be just as effective as Invisalign's proprietary optimized attachments and that despite the attachment design, overcorrection in the software should be considered for rotational and extrusive tooth movements.[8] Collectively, these findings suggest that while attachments are integral to aligner biomechanics, their real-world impact remains inconsistent and overcorrection in the treatment planning software is recommended, as the actual movements consistently fall short of the prescribed plan.

Four systematic reviews examining the efficacy and accuracy of tooth movements with clear aligners further contextualize the previously described clinical observations. Galan-Lopez et al. (2019) reviewed 20 clinical studies that met a high level of evidence as graded by the Swedish Council on Technology Assessment in Health Care system in combination with the Cochrane tool for risk bias assessment, and reported overall tooth movement accuracy ranging from 55–72%, with vertical movements and rotation consistently falling within the lowest-performing categories.[3] With respect to rotation, the study recommended that interproximal reduction (IPR) be incorporated in addition to limiting the amount of rotation per tray to 1.5°.[3] Rossini et al. (2015) analyzed 11 studies and reported accuracies ranging from 30% for extrusion to 88% for molar distalization, again confirming that movements requiring complex force

systems, especially rotation, are the least predictable with aligners.[9] Although the two previous reviews did not specifically evaluate attachment effects, they do provide data to support the need for further research on the efficacy of CAT. Additionally, meta-analyses were not possible in these systematic reviews due to heterogeneity of the studies and the lack of consistency in measuring techniques, legitimizing the need for further research on CAT.

In contrast, two more recent systematic reviews did evaluate the impacts of attachments, though both noted a lack of quantitative synthesis. Jedliński et al. (2023) included 26 papers and reviewed attachment types, shapes, and placements.[10] Four of the papers evaluated the protocols for attachment bonding while 22 comprised the influence of composite attachments on movement efficacy. Due to heterogeneity in study designs, imaging methods, and defined outcomes, the authors could only report qualitative findings, concluding that the use of attachments significantly improves the expression of orthodontic movements and aligner retention and that conventional attachments with at least one beveled edge are beneficial for both tooth movement and anchorage, however evidence supporting specific attachment designs remains weak.[10] Similarly, Nucera et al. (2022) analyzed five studies and found limited, heterogeneous data, describing the effects of composite attachments on movement accuracy.[11] No meta-analysis could be performed, and the review concluded that while attachments appear to enhance aligner retention and force delivery, there is insufficient evidence to determine which attachment designs are most effective, particularly for complex movements. With respect to rotational movements, the study concluded that there are conflicting results on the influence of attachments on the ability to influence tooth rotational control. Most studies demonstrated a positive influence of attachments, although not statistically significant.[11]

Because clinical evidence remains inconsistent and often low in quality, researchers have increasingly relied on finite element analysis (FEA) studies to explore how attachment geometry affects force systems during planned tooth movement.

Gomez et al. (2015) conducted one of the early comprehensive FEA analyses examining the initial force systems generated during bodily movement of maxillary canines with clear aligners with and without composite attachments.[12] Their simulations demonstrated that the presence of composite attachments, in contrast to no attachments, increased the uniform compression and tension on the root surfaces of canines, improving the ability of aligners to generate controlled translation. Although not focused exclusively on rotation, their findings established the foundational concept that attachment shape and placement can substantially alter moment-to-force ratios, improving the efficacy of CAT.[12]

Kim et al. (2020) evaluated how different attachment shapes and positions influence the biomechanics of planned movements, including rotation, on a mandibular canine.[13] Their simulations demonstrated that attachment placement meaningfully altered the stress distribution and the direction of force application between the aligner and the tooth. Notably, attachments placed on the lingual surface generated more favorable stress patterns for rotational control compared to several labial configurations. While the study did not model real-world factors such as incomplete seating or occlusal interference, the authors concluded that attachment geometry and placement significantly influence the effectiveness of rotational force systems, supporting the broader concept that modifying attachment design, such as altering bevel orientation or surface area, can impact the predictability of rotational tooth movement.[13]

Additionally, one notable in vitro study by Costa et al. (2020) compared the extrusive forces generated by three different attachment designs on maxillary central incisors.[14] The

authors found that the three designs all produced sufficient force for extrusion but significant differences in the resultant forces in three dimensions were detected, suggesting the attachment design can have a significant impact on the desired tooth movements.[14]

These FEA studies demonstrate that attachment geometry, including shape, beveling, and placement, can influence predicted force systems. However, FEA models inherently rely on idealized assumptions such as perfect aligner seating, uniform material properties, and absence of occlusal interference, limiting their direct translation to clinical outcomes.

Together, these clinical, systematic, and FEA studies clearly illustrate the limitations of current attachment designs research and provide justification for investigating whether differences in attachment geometry, such as beveling, meaningfully affect not only rotational efficacy but any desired tooth movement when utilizing RTAs. They also highlight the need for controlled, well-designed clinical studies to better isolate and quantify the specific effects of attachment design on rotational tooth movement.

Understanding the impacts of different attachment designs is critical to the advancement of clear aligner therapy. These differences in attachment preferences should be based on measured effectiveness. However, the challenges associated with specific tooth movements highlight the need for more comprehensive research to determine the optimal attachment designs and aligner configurations for improving treatment outcomes across a broader range of clinical scenarios.

The primary objective of this pilot study was to assess the effectiveness of beveled versus non-beveled rectangular attachments in facilitating tooth rotation using custom clear aligners. Specifically, the objective was to compare the actual tooth rotation achieved, measured in

degrees, relative to the amount prescribed in the treatment planning software. Attachments were used to facilitate tooth movement predictability during CAT by creating a greater surface area for the plastic aligner to contact and by providing improved aligner retention, thus, allowing the incremental tooth movements, planned via the custom series of aligners, to be realized.[1] A better understanding of the impact of attachment design on tooth movement effectiveness could potentially provide benefits to both provider and patient in the form of improved tooth movement outcomes, and therefore, reduced treatment time. This study evaluated one tooth on each side of the maxillary arch in the anterior dentition, from canine to canine. The null hypothesis was that there was no significant difference in tooth rotational movement between rectangular beveled versus rectangular non-beveled attachments. The independent variables in this study were the attachment design and the side of the mouth. The two attachment designs were rectangular and rectangular beveled (Figure 1A, B). The dependent variables in this study were the efficacy of tooth movement, more specifically, the rotation achieved relative to the amount of rotation prescribed.

III. Methods and Materials

The protocol for this study was approved by the Oregon Health & Science University (OHSU) Institutional Review Board (Appendix A). This study utilized a split-mouth design, with subjects serving as their own control, receiving each of the two attachment designs, one per side.

Subject recruitment:

All subjects were recruited at the OHSU School of Dentistry in Portland, OR. 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 determined to be 18 years or older and not actively growing, with a Cervical Vertebral Maturation (CVM) stage four or higher.[15] Exclusion criteria included treatment plans that involved tooth extraction or inter-arch elastic wear during the course of the study period; self-reported habits such as nail-biting or digit sucking; relatively short clinical crowns that could compromise retention of aligners; pregnancy, which could increase the 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 study personnel evaluating the initial records of each subject. If the subjects met all the study requirements and did not meet any exclusion criteria, they were recruited for the study during the clear aligner treatment consultation appointment. The subject recruitment script (Appendix B) was used to ask all potential subjects about their interest in volunteering for the study. If the subject agreed to be a part of the study, informed consent (Appendix C) was collected. If the subject declined to participate, they proceeded with standard orthodontic treatment after consultation, and any other data collected for the study were immediately destroyed if not part of routine care. Baseline demographic and clinical characteristics collected included pre-treatment age, sex, Angle's Classification of malocclusion (Class I, II, or III), and relevant medical history.[16]

Tooth selection:

Only teeth in the anterior maxillary arch, from canine to canine, were considered for inclusion in the study, and only one tooth on each side of the arch was rotated and observed, for a total of two teeth per subject. For each subject, the teeth under observation were the same in each quadrant, also known as antimere teeth. To determine which teeth were to be observed, providers evaluated the treatment needs of the subjects and determined where rotations were appropriate for their respective treatment plans. Direction of rotation was not critical, as the anatomy of the roots of teeth in the anterior dentition is generally conical and the crowns exhibit symmetrical properties on either side of the midline.

Attachment design:

The teeth of interest underwent orthodontic rotations using custom clear aligners (Align, Santa Clara, Calif)(Solventum, St. Paul, Minn), with two different attachment designs, rectangular non-beveled (Figure 1A) and rectangular beveled (Figure 1B). Each participant received both attachment designs, one on each side of the arch. Participants were enrolled into one of two groups based on the order in which they consented to participate. Group one included the rectangular non-beveled attachment on the selected tooth in the upper right quadrant and the beveled rectangular attachment on the antimere tooth in the upper left quadrant. Group two included the rectangular beveled attachment on the selected tooth in the upper right quadrant and the rectangular non-beveled attachment on the antimere tooth in the upper left quadrant.

Figure 1A: Rectangular non-beveled attachments (red) as shown on the treatment planning software. The attachment displayed is in the center of the clinical crown on the upper left central incisor, where the incisal view (right) shows the attachment bevel which is the same labio-palatal dimension going from mesial-to-distal.

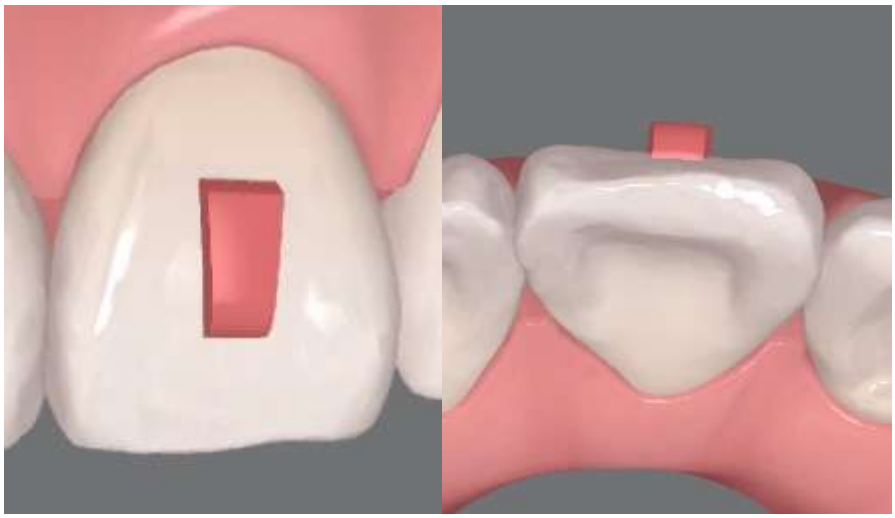
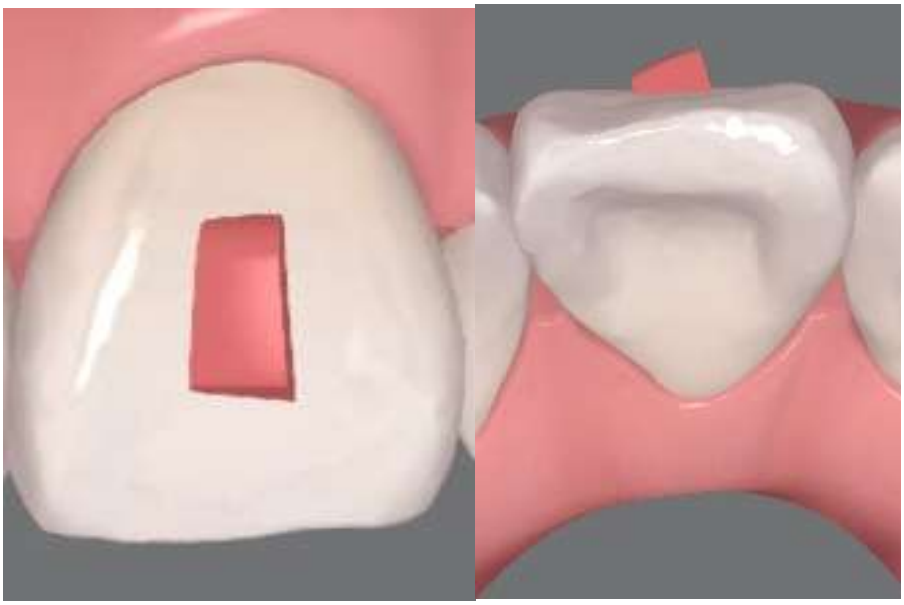


Figure 1B: Rectangular beveled attachments (red) as shown on the treatment planning software. The attachment displayed is in the center of the clinical crown on the upper left central incisor, where the incisal view (right) shows the attachment bevel which is smallest-to-largest in labio-palatal dimension going from mesial-to-distal.



Study phases:

For clarity and consistency, the study timeline was divided into three phases and referenced throughout the Methods.

The pre-observation period encompassed digital impression of the subject's dentition, digital treatment planning, attachment placement, and preparatory tooth movements performed to eliminate interproximal contacts and permit unobstructed rotational movement of the selected teeth, a process known as creating zero-collision tolerance. Tooth movements occurring during this phase were not included in the outcome analysis.

The observation period represented the defined interval during which rotational tooth movement of the selected teeth was carried out using the prescribed sequence of clear aligners.

The post-observation period occurred after completion of the final study scan. Subjects then resumed routine orthodontic treatment, and any remaining planned tooth movements were completed outside the study framework.

Subject Activities:

At the initial visit (V1), comprehensive records were obtained to facilitate elective clear aligner treatment planning per standard treatment protocols. These included demographic information, medical history, radiographs, clinical photographs, and intraoral scans of the teeth and soft tissues using an intraoral scanner (iTero, Align Technology, San Jose, CA, USA, or Trios 4, 3Shape, Copenhagen, Denmark). Treatment plans and digital models were reviewed by study personnel in consultation with the subjects' orthodontic providers to determine eligibility.

At the consultation visit (V2), eligible subjects were invited to participate. A standardized recruitment script (Appendix B) was used, and written informed consent was obtained using the IRB-approved consent form (Appendix C).

Visit V3 was scheduled once zero-collision tolerance was achieved in the maxillary anterior dentition. At this appointment, a pre-observation intraoral scan was obtained to register baseline tooth position. Subjects received written and verbal instructions regarding study responsibilities and were provided a QR code linking to the OHSU-approved survey platform (Qualtrics, Provo, UT) (Appendix D). Subjects were reimbursed for participation via a secure debit card system (ClinCard, Greenphire, King of Prussia, PA).

Between V3 and V4, subjects wore the prescribed sequence of up to six aligners, each for one week. During this observation period, they completed a brief daily compliance survey accessed through the QR code, reporting the number of hours per day aligners were worn.

At V4, following completion of the final study aligner, a post-observation intraoral scan was obtained. Subjects also completed the overall wear-time survey. Routine orthodontic treatment then resumed under provider direction.

Table 1 summarizes subject activities and estimated time commitments.

Table 1: Subject Activities with estimated times for treatment and study participation

Visit	Description
V1: Records	Collect demographics, medical history, x-rays, photos, and intraoral scans (STL files); for treatment planning of regular CAT and to evaluate for study eligibility. *Time: 90 minutes (treatment)*
V2: Consultation	Conduct clear aligner consultation; invite eligible subjects to participate; obtain informed consent; confirm baseline medical data. *Time: 1 hour (45 minutes for treatment, 15 minutes for study)*
Between V2 – V3	Delivery of attachments using the provided attachment template and delivery of initial trays for space opening in the maxillary anterior. *Time: 90 minutes for delivery*
V3: Pre-observation Scan	Confirm zero collision tolerance in the maxillary anterior dentition. Take intraoral scan after 4 trays, or as many needed to achieve zero-collision tolerance, to register baseline tooth positions; review study instructions and QR code for daily compliance surveys. *Time: 20 minutes for study*
Between V3 – V4	Instruct subjects to wear trays (1/week) during duration of observation period, up to 6 weeks; complete daily compliance surveys via QR code. *Time: ~5 minutes/day for 6 weeks for study*
V4: Post-observation Scan	Take final intraoral scan; confirm completion of overall compliance survey. *Time: 20 minutes for study*
Post-V4: Treatment Continues	Resume aligner treatment per provider plan; unlock previously restricted teeth; assess compliance data. *Time: Ongoing treatment*

Provider activities:

Records were reviewed to confirm eligibility based on the study inclusion and exclusion criteria. Digital treatment plans were created using the aligner-planning software with the goal of achieving zero-collision tolerance through incremental proclination of anterior teeth performed

prior to the observation period. In cases where more than four aligners were required to create sufficient spacing, the observation period began only after visible space was present.

To enhance measurement accuracy, all teeth not involved in the observation phase were digitally locked, meaning no programmed movements were assigned to them during the observation period. Aligners were fabricated once the treatment plan was finalized, and all required attachments, including those on the study teeth, were bonded using manufacturer-provided templates. Attachments on observed teeth were placed at the center of the clinical crown in both the inciso-gingival and mesio-distal dimensions. Clear aligner therapy was delivered using commercially available aligner systems, mentioned previously, and selected according to routine clinical provider preference at the OHSU orthodontic clinic.

Composite attachments were bonded using a standardized multi-step adhesive protocol. Enamel surfaces were etched with 35% phosphoric acid gel (Ultradent Products, South Jordan, Utah), followed by application of a bonding resin (Reliance Orthodontic Products, Itasca, Ill). Attachments were fabricated using light-cured orthodontic composite resin (3M Unitek, Monrovia, Calif) and positioned using manufacturer-provided attachment templates corresponding to each aligner system.

Following completion of the observation period (V4), providers resumed routine clinical follow-up visits. Refinement scans were obtained as needed, and providers retained flexibility to modify or reposition attachments based on clinical judgement.

Table 2 summarizes provider responsibilities across the study timeline.

Table 2: Provider Activities

Visits	Description
Between V1 and V2	Evaluate records for study eligibility; confirm presence of two antimere maxillary anterior teeth requiring rotation.
Between V2 and V3	Create digital treatment plan; procline anterior teeth to achieve zero collision tolerance; lock non-observed teeth; deliver trays and apply attachments.
After V4	Continue treatment per provider's plan; take refinement scans if needed; modify attachments as clinically indicated.

Tooth Movement Analysis:

To evaluate the effectiveness of the tooth movement, actual tooth rotation achieved during the observation period was compared to the total amount of rotation prescribed for the series of trays worn by each subject. A maximum of 2° of rotation, per the clear aligner software parameters, was planned per tray, for a possible total of 12° of rotation given the maximum number of trays in the observation period was six. The effectiveness percentage was calculated using the formula:

$$\textbf{(Actual rotation °} \div \textbf{Prescribed rotation °)} \times \textbf{100}$$

The number of aligners included in the observation period was determined by the total amount of rotational correction prescribed for each selected tooth. When the prescribed rotation could be completed within six aligners, the observation period included only the number of aligners required to complete the planned rotation. When the prescribed rotation exceeded this

limit, the observation period was capped at six aligners, and any remaining rotational correction was completed after the observation period as part of routine treatment.

Measurement of tooth movement:

STL data files from both the pre-observation and post-observation period intraoral scans of the maxillary dentition were printed in-lab (Excel Orthodontics, Tigard, Oregon) for evaluation and analysis. STL files were securely stored on an OHSU-approved encrypted server prior to 3D model fabrication and analysis. Using dental loupes with 2.5 times magnification, two unique and identifiable anatomical landmarks per tooth, from second premolar to second premolar, were marked with the same fineliner pen (Sakura of America, Hayward, Calif) on both the pre- and post-observation models (Figure 2A).

The first landmark served as the origin of a two-dimensional orthogonal coordinate system. For premolars, this landmark could be placed anywhere on the occlusal surface, marked by an observable anatomical feature, while for anterior teeth it could be placed anywhere on the lingual surface, also selecting for a unique and repeatable feature of the tooth. Once the landmark position was established on the T1 model, the identical anatomic location was identified and marked on the corresponding T2 model for the same tooth, using the tooth's unique morphological features to ensure consistent landmark placement between time points.

The location of the first landmark was therefore anatomically indexed to each individual tooth and not arbitrarily reselected on the T2 model. Its placement was constrained only by the requirement that a second landmark could subsequently be placed within the appropriate quadrant of the defined coordinate system.

Once the first landmark was placed, it defined the origin of the X–Y axis system for that tooth, where the X-axis represented the transverse dimension and the Y-axis represented the anteroposterior dimension (Figure 2B). Quadrant I was located in the upper left of the axis system, with the remaining quadrants assigned in clockwise fashion.

The second landmark was then placed relative to the position of the first landmark and constrained to a specific quadrant to standardize angular orientation. For teeth on the right side of the maxillary arch, the second landmark was placed within Quadrant I. For teeth on the left side of the arch, the second landmark was placed within Quadrant II. If the first landmark position did not allow unambiguous placement of the second landmark within the required quadrant, the first landmark was adjusted.

To facilitate accurate transverse measurements, a single reference point was placed on each first molar at a reproducible anatomic landmark, such as the central pit. These points served as intermolar reference landmarks and, together with a millimeter ruler included in each image, established scale for converting digital measurements into millimeters. If a subject was missing a premolar on each side of the arch, the first molars were marked at two unique anatomical positions and the second molars were marked at a single point each to maintain transverse reference and scale calibration.

Once the models from both time points were marked, they were placed on a document scanner with a millimeter ruler in the field of view. Images were captured in JPEG format and downloaded for analysis.

Using MATLAB software (MathWorks, Natick, Mass), positional changes were calculated in two dimensions with three degrees of freedom: transverse (X), antero-posterior (Y),

and rotational change (A) around the center of the tooth (origin). The quadrant system facilitated consistent angular measurement relative to the defined origin and standardized landmark placement across subjects and time points. Appendix E details the MATLAB tooth-tracking program.

Figure 2A: Image of the occlusal view of a maxillary model with reference marks and ruler for scale.

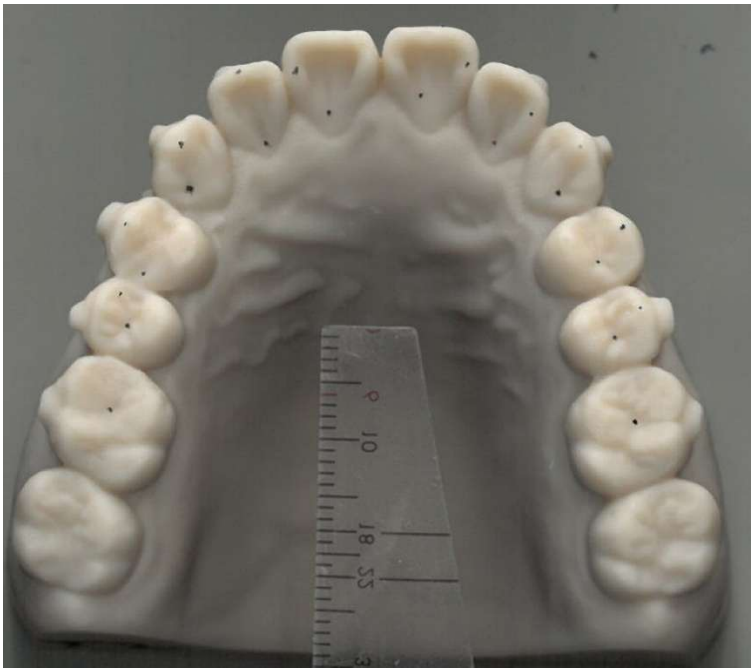
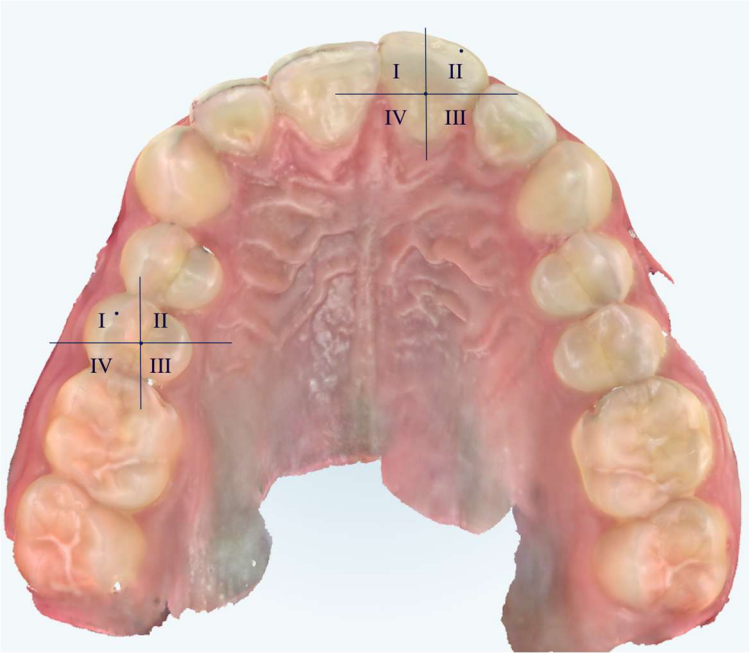


Figure 2B: Representation of the quadrant system demonstrated on the upper right second premolar and the upper left central incisor.



Reliability of Measurement:

Intrarater reliability testing was performed to confirm that the measurement protocol used to assess rotational movement was consistent and repeatable when applied by the same examiner. Intrarater reliability was assessed using five independent sets of time-point 1 (T1) and time-point 2 (T2) dental models obtained from initial records (T1) and corresponding refinement scans (T2) of five individuals undergoing standard clear aligner therapy. These models were not part of the primary study sample and were selected specifically for reliability testing.

All T1 and T2 models were prepared using the same standardized indexing protocol employed in the primary analysis. Reproducible anatomical landmarks were identified on the printed models under magnification, and index markings were placed to establish the axis for

measurement. Importantly, once the index markings were placed, they were not altered between repeated measurements.

Tooth movements for premolars and anterior teeth were quantified using the MATLAB-based coordinate analysis system. For each indexed T1–T2 model pair, the same digital measurement workflow was applied to calculate translational displacement in the x- and y-directions as well as angular change (ΔA), representing the degree of tooth rotation achieved. To evaluate intrarater reliability, the MATLAB analysis was performed twice for each T1–T2 model pair using the identical indexed models and unchanged reference markings. Thus, the repeated measurements isolated the reliability of the digital measurement and analysis process rather than variability introduced by landmark placement or physical indexing.

Statistical Analysis:

All statistical analyses were conducted at the tooth level using the split-mouth design in which each subject contributed one maxillary anterior tooth treated with a rectangular non-beveled attachment and the antimere tooth treated with a rectangular beveled attachment. For each attachment type and each outcome variable, descriptive statistics were calculated, including mean, standard deviation, minimum, and maximum values. Descriptive summaries were also generated for the within-subject beveled–non-beveled differences.

In addition, power and sample-size estimates for a paired-sample study design were generated using the observed within-subject differences from Subjects 2 and 3 as preliminary pilot data. For each outcome variable, the mean paired difference (δ_1) and the standard deviation of the paired differences (σ) were calculated and used to estimate the number of subjects required to achieve 80% statistical power at $\alpha = 0.05$ (two-sided) using a paired-samples t-test framework.

These estimates assume that each subject contributes paired beveled and non-beveled tooth measurements.

No additional inferential hypothesis-testing procedures were performed. Power analysis was conducted using PASS 2022 (NCSS, LLC, Kaysville, UT).

Because this study was designed as a pilot investigation, the available sample size was insufficient to support formal hypothesis testing. However, the following inferential statistical analysis plan was prespecified and would have been implemented if an adequately powered sample had been obtained.

Prior to inferential testing, normality of paired differences was to be evaluated using visual inspection of histograms and the Shapiro–Wilk test. If paired differences were normally distributed, a paired-samples *t*-test would have been used to compare achieved rotation and rotational efficiency between attachment types. If normality assumptions were violated, the Wilcoxon signed-rank test would have been used to determine whether within-subject differences in achieved rotation or rotational efficiency differed significantly from zero.

Group differences in reported compliance were to be evaluated using the Kruskal–Wallis test due to the ordinal and non-normally distributed nature of self-reported wear-time data.

To further investigate the independent effect of attachment design on rotational efficacy, a multiple linear regression model was planned. The dependent variable would have been the amount of rotation achieved (degrees), and independent variables would have included attachment type (beveled vs non-beveled), compliance score, age, sex, and Angle's classification. This model would have allowed estimation of the effect of attachment geometry while adjusting for potential confounding variables.

Intrarater reliability of the digital measurement protocol was assessed by repeating the MATLAB-based measurement workflow on indexed T1–T2 model pairs. Reliability was evaluated for translational displacement in the x-direction (ΔX, mm), translational displacement in the y-direction (ΔY, mm), and angular change representing tooth rotation (ΔA, °).

Statistical significance for all planned inferential analyses was defined as $p < 0.05$.

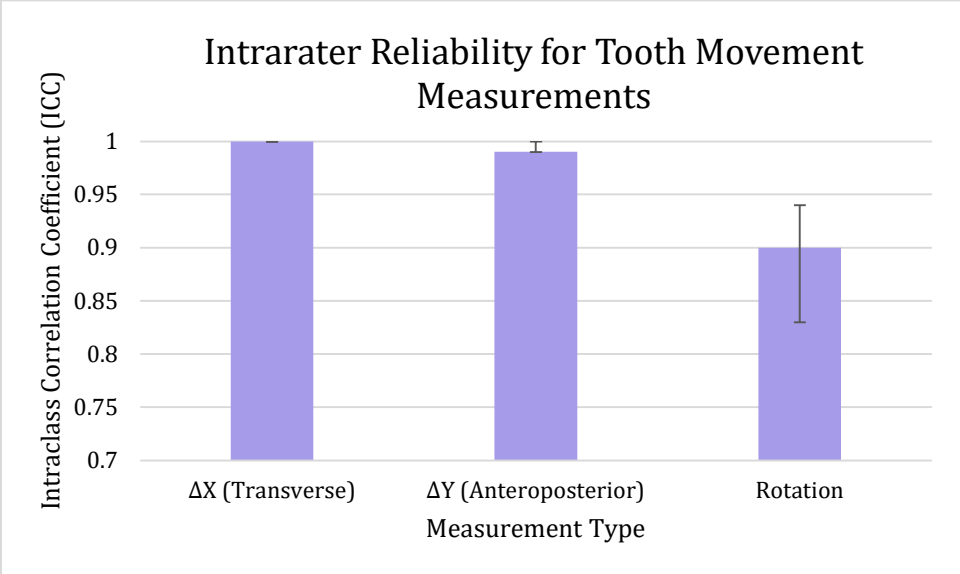
IV: Results

For ΔX, intraclass correlation coefficients demonstrated perfect agreement between repeated measurements. The single-rater fixed-effects model yielded an ICC of 1.00, with a 95% confidence interval of 1.00–1.00 and a highly significant F-statistic ($p < 0.001$), indicating no measurable variability between repeated measurements. Similarly, average-measure ICC values were 1.00, confirming complete repeatability of the ΔX measurements.

For ΔY, intrarater reliability was likewise excellent. The single-rater fixed-effects ICC was 0.99, with a 95% confidence interval ranging from 0.99 to 1.00 ($p < 0.001$). Average-measure ICC values also reached 1.00, indicating minimal measurement error and near-perfect agreement between repeated analyses for vertical displacement measurements.

For rotational measurements (ΔA), intrarater reliability remained high, though slightly lower than for translational measures. The single-rater fixed-effects ICC for rotation was 0.90, with a 95% confidence interval of 0.83–0.94 ($p < 0.001$), indicating excellent agreement. Average-measure ICC values for rotation increased to 0.95 (95% CI: 0.91–0.97), reflecting improved reliability when considering the mean of repeated measures and confirming the robustness of the rotational measurement protocol.

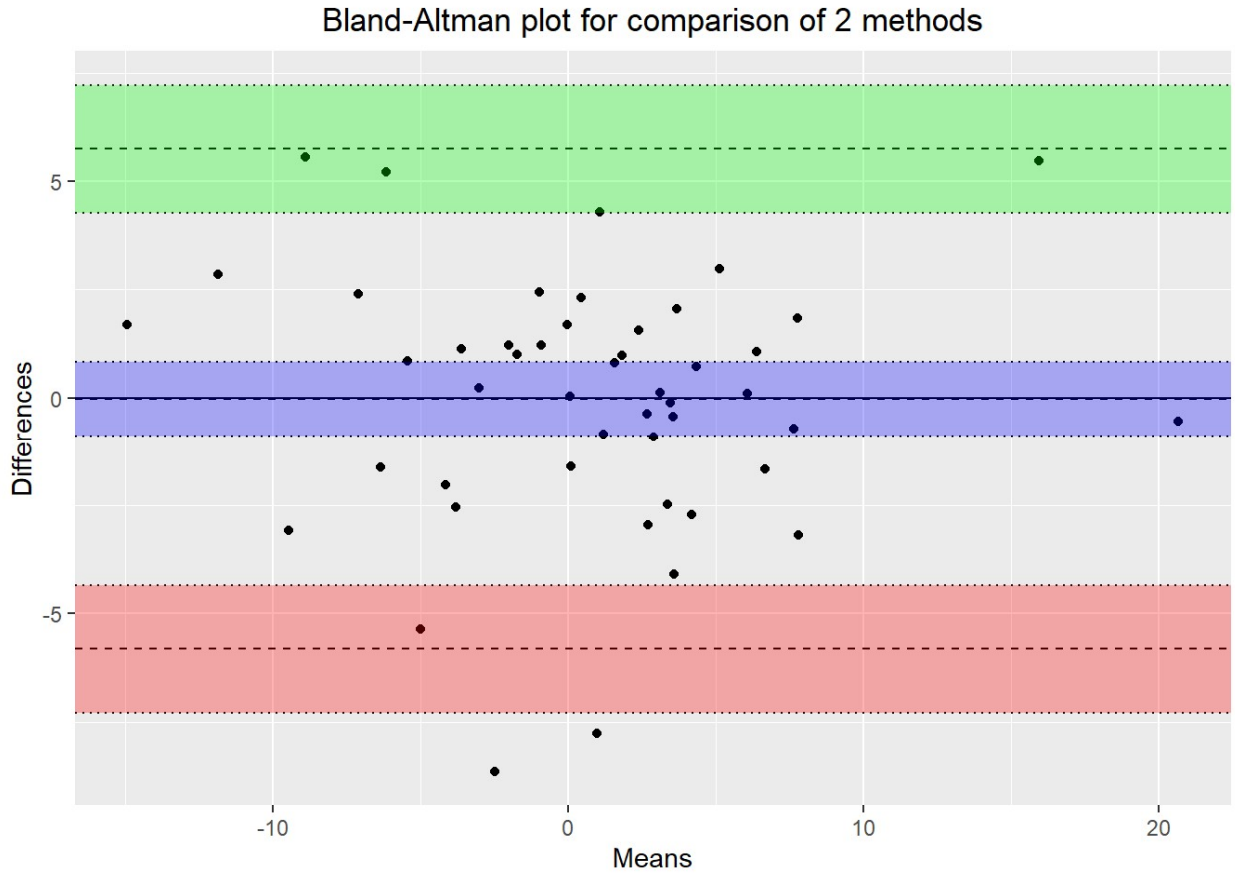
Figure 3: Intraclass correlation coefficients (ICC) for intrarater reliability across translational and rotational measurements.



Agreement between repeated rotational measurements was further evaluated using Bland–Altman analysis. The mean difference (bias) between repeated rotational measurements was −0.04°, indicating negligible systematic error between measurement sessions. The 95% confidence interval for the bias ranged from −0.89° to 0.82°, demonstrating that the average difference between repeated measurements did not differ significantly from zero.

The limits of agreement were calculated as −5.82° to 5.75°, with a total agreement span of 11.56°. Inspection of the Bland–Altman plot revealed no evident trend toward increasing measurement differences with increasing magnitude of rotation, suggesting an absence of proportional bias. The narrow bias and symmetrical limits of agreement support strong consistency between repeated measurements across the observed range of rotational values.

Figure 4: Bland–Altman plot assessing intrarater agreement for rotational measurements.



The solid line represents the mean difference between repeated measurements, and the dashed lines indicate the 95% limits of agreement.

Subject characteristics:

Three adult female subjects met the eligibility criteria and completed the observation period (Table 1). A total of three patients were screened for eligibility, and all three met inclusion criteria, consented to participate, and were enrolled, resulting in a final study sample of three subjects. The mean age at enrollment was 35.7 ± 15.3 years (range 24–53 years). Each subject contributed two maxillary anterior teeth planned for rotational movement; however, one antimere tooth in Subject 1 did not receive the intended rectangular non-beveled attachment due

to a bonding error. Therefore, that tooth contributed only to descriptive analyses and not to the paired within-subject attachment-type comparison.

Table 3: Demographic characteristics of enrolled subjects

Characteristic	Value
Total subjects (n)	3
Sex	
Male	0
Female	3
Age at enrollment (years)	
Mean ± SD	35.7 ± 15.3
Range	24-53

Tooth level rotational outcomes:

Tooth-level translational and rotational movement outcomes for each observed tooth are summarized in Table 4. Achieved rotation ranged from 2.0° to 7.3°, and corresponding rotational efficiency ranged from 28.2% to 137.7%, reflecting variability in expression of planned rotational movement across subjects and attachment types.

Table 4: Tooth-level rotational and translational movement outcomes by attachment design

Subject #	Tooth	Tx Group	Diff X mm(Tx)	Diff Y mm (Tx)	Diff ^{o} ΔA (Tx)	Planned^{o} ΔA (Rx)	^{o}Efficiency (%)
1	Right Lateral	*	0.97	1.82	2.8	5.8	48.3
1	Left Lateral	B	0.75	1.59	7.3	5.3	137.7
2	Right Canine	B	0.60	1.35	5.6	8.0	70.0
2	Left Canine	A	0.36	0.72	2.0	6.7	29.9
3	Right Central	A	1.75	3.27	2.8	8.9	31.5
3	Left Central	B	1.54	3.57	2.4	8.5	28.2

Tx = A, rectangular non-beveled attachment; Tx = B, rectangular beveled attachment.
ΔX and ΔY represent transverse and anteroposterior displacement, respectively.
* Attachment was not placed on this tooth; therefore, this tooth did not contribute to paired attachment-type comparison.

Rotational outcomes by attachment design:

Descriptive statistics organized by attachment type are presented in Table 5. Two teeth received rectangular non-beveled attachments, and three teeth received rectangular beveled attachments. Mean achieved rotation was 2.4 ± 0.6° for the non-beveled group and 5.1 ± 2.5° for the beveled group. Mean rotational efficiency was 30.7 ± 1.1% for the non-beveled group and 78.6 ± 55.3% for the beveled group. These descriptive trends suggest a greater magnitude of rotational expression among teeth with beveled attachments; however, no inferential hypothesis-testing was performed due to the small pilot sample size.

Table 5: Descriptive statistics of tooth movement outcomes by attachment design

Outcome	Non-beveled (A) Mean ± SD	Median (Range)	n	Beveled (B) Mean ± SD	Median (Range)	n
Achieved rotation (ΔA)°	2.4 ± 0.6	2.4 (2.0–2.8)	2	5.1 ± 2.5	5.6 (2.4–7.3)	3
Rotational efficiency (%)	30.7 ± 1.1	30.7 (29.9–31.5)	2	78.6 ± 55.3	70.0 (28.2–137.7)	3

A = non-beveled rectangular attachment; B = beveled rectangular attachment.
SD = standard deviation; n = number of teeth receiving each attachment type.
One beveled lateral incisor in Subject 1 did not have a corresponding non-beveled antimere tooth and therefore contributed only to descriptive statistics (Table 3) and not to paired analysis (Table 4)

Within subject paired comparison:

Two subjects had complete beveled and non-beveled antimere tooth pairs and were therefore eligible for paired analysis. Within-subject beveled–non-beveled differences are summarized in Table 4. The mean difference in achieved rotation (B − A) was 1.6 ± 2.8°, and the mean difference in rotational efficiency was 18.4 ± 30.7%, indicating that beveled attachments demonstrated higher rotational expression on average in this small pilot sample. The direction of the effect was not consistent across both subjects, reflecting individual variability.

Table 6: Descriptive statistics of within-subject beveled and non-beveled differences

Outcome	Mean ± SD	Median (range)	n
Achieved rotation (ΔA)°	1.6 ± 2.8	1.6 (−0.4 to 3.6)	2
Rotational efficiency (%)	18.4 ± 30.7	18.4 (−3.3 to 40.1)	2

Paired differences were calculated as beveled minus non-beveled (B − A), such that positive values indicate greater rotational movement or efficiency with beveled attachments.
Only subjects with complete beveled and non-beveled antimere tooth pairs were included (n = 2).
Subject 1 was excluded from paired analysis due to missing attachment placement on one antimere tooth

Power and sample size estimates:

Observed paired differences from subjects 2 and 3 were used to generate preliminary effect size estimates for a future paired-sample study. Because the primary outcome of interest in this trial was rotational tooth movement, power and sample size interpretation focused on rotational difference (ΔA) and rotational efficiency rather than translational displacements (ΔX, ΔY), which were recorded only as secondary descriptive measures.

Table 7: Preliminary power and sample-size estimates for paired comparisons of rotational outcomes between beveled and non-beveled attachments

Measure	Power	n	δ_1	σ	Effect size	alpha	beta
Diff X mm	0.80001	636	-0.04	0.36	0.11111	0.05	0.19999
Diff Y mm	0.88605	5	-0.46	0.24	1.91667	0.05	0.11395
Diff (ΔA)º	0.80869	27	-1.62	2.86	0.56643	0.05	0.19131
ºEfficiency (%)	0.81037	14	21.57	26.27	0.82109	0.05	0.18963

n = required number of subjects. δ_1 = mean paired difference (B − A). σ = standard deviation of the paired differences. Effect size = δ_1 / σ.

For the primary outcome of rotational movement, the observed paired effect size for achieved rotation (ΔA) corresponded to a required sample size of approximately 27 subjects to detect a beveled–non-beveled difference with 80% power at α = 0.05. For rotational efficiency, the estimated required sample size was approximately 14 subjects. Translational measurements

(ΔX and ΔY) are shown in Table 7 for completeness but were not considered clinically meaningful primary outcomes for this study.

Compliance:

Daily wear-time compliance was monitored using an online survey platform during the observation period. Subjects were asked to report the number of hours they wore their aligners each day. A total of 54 daily survey responses were submitted across all subjects, 50 of which included a reported wear-time value (Table 8). Reported daily wear time ranged from 19 to 23 hours, with a mean of 22 hours per day (SD = 1). Survey completion was inconsistent across subjects, and four submitted entries did not include a wear-time value. At the conclusion of the observation period, subjects were also invited to complete a brief overall compliance survey. Two subjects submitted responses, reporting an average daily wear time of 20–21 hours per day and seven days of aligner wear per week (Table 9). Because these data were self-reported and survey completion was incomplete, compliance information was used only to provide descriptive context and was not incorporated into inferential analyses.

Table 8: Daily survey response and reported wear time summary

Subject ID	Total daily surveys submitted	Surveys with wear time entered	Surveys missing wear time	Mean reported daily hours	SD	Range
1	47	43	4	22	0	21-23
2	1	1	0	22	--	22-22
3	6	6	0	21	5	19-23
Total	**54**	**50**	**4**	**21**	**1**	**19-23**

Wear-time values were self-reported by subjects using a daily online survey. Surveys were not completed consistently by all subjects, and some entries did not include a wear-time value. Results are descriptive only and were not used for inferential analysis.

Table 9: Overall compliance survey responses

Measure	Mean ± SD	Range	Number of respondents
Self-reported daily wear time (hrs/day)	20 ± 1	20-21	2
Self-reported wear frequency (days/week)	7 ± 0	7-7	2

Only two subjects completed the overall compliance survey. Responses reflect self-reported behavior and were not independently verified.

V: Discussion

Clear aligner therapy continues to grow in popularity due to its esthetic appeal, removability, and perceived comfort advantages compared with fixed appliances. However, despite these benefits, variability in the predictability of specific tooth movements remains an important clinical consideration. Previous investigations have demonstrated that certain orthodontic movements, including rotations of maxillary anterior teeth, may be less predictable with clear aligners, with achieved movement often falling short of the prescribed amount.[3,4,7] Reported accuracy values for rotational movement vary widely across the literature, reflecting differences in methodology, tooth type, aligner systems, and clinical protocols.[1,3,9] Among the many factors believed to influence rotational performance are aligner deformation, tooth morphology, the presence and design of composite attachments, and the interaction between attachments and the aligner material.[2,5,7,8]

Because attachment geometry is a clinician-controlled variable, the present pilot study sought to evaluate differences in rotational performance between beveled rectangular and non-beveled rectangular attachments during a defined observation period. A split-mouth design was used so that each subject could serve as their own control. Rotational outcomes were assessed

both as absolute degrees of clinical rotation and as rotational efficiency, defined as the percentage of planned rotation that was expressed clinically.

Across all observed teeth, achieved rotation ranged from approximately 2.0° to 7.3°, and rotational efficiency ranged from roughly 28% to 138%, highlighting the variability in rotational response. When data were grouped by attachment design, beveled rectangular attachments demonstrated higher mean rotational expression and rotational efficiency than non-beveled rectangular attachments. In the two subjects who contributed complete antimere pairs, within-subject differences generally favored beveled attachments, although the magnitude and direction of the effect varied by individual tooth and subject. These results suggest that beveled rectangular attachments may provide some rotational advantage compared with non-beveled rectangular attachments; however, the sample size in this study was too small to allow formal hypothesis testing or statistical inference. Therefore, these findings should be interpreted as preliminary and exploratory only.

Several biomechanical principles described in the literature help explain why attachment geometry may influence rotational expression. Clear aligners rely on the generation of effective force couples to control rotational movement, and this depends on aligner engagement and sufficient contact area between the aligner and the tooth surface.[2,7,9] Upadhyay et al. describe how attachments increase the surface area available for aligner contact and enhance the ability of the appliance to transmit controlled moments rather than simply sliding over the crown surface.[17] They further note that the geometry, size, and orientation of attachments affect the magnitude and direction of force systems generated during tooth movement. A beveled attachment may therefore modify the contact interface in a way that enhances aligner retention and stabilizes the force couple acting on the tooth, potentially improving rotational control. Although the current

study was not designed to evaluate these mechanisms directly, the observed differences are consistent with the principle that attachment shape influences the biomechanics of aligner-mediated rotation.[2,7,12,13,17]

This pilot investigation developed and successfully tested a novel protocol to address the specific aim in a future study with a larger sample size. Additionally, the pilot data from the current study allowed a projection of sample size via a power analysis. A methodological strength of this investigation was the structured and repeatable approach used to quantify rotational movement. A standardized coordinate-based system and MATLAB-driven analytical workflow was applied consistently across all cases. Intrarater reliability testing demonstrated excellent consistency of repeated measurements, indicating that once the models and landmarks were prepared, the analytical program itself introduced minimal variability.

However, it is important to distinguish the reliability of the analytical software from the potential for error across the entire measurement chain. Before measurements could be performed, intraoral scans were converted to printed models, anatomical landmarks were manually applied to those models, and the models were then rescanned to create digital images for processing. Each of these steps may contribute small but meaningful sources of variability, including printer tolerance, human landmark identification error, and variation in scan positioning or resolution. Because the intrarater reliability assessment repeated only the MATLAB analysis step using the same indexed models, it reflects primarily the repeatability of the digital measurement component rather than the cumulative variability of the full workflow. Future research incorporating direct digital landmarking or fully digital superimposition may help further reduce these upstream sources of error.

One promising alternative is to register serial digital models on a stable anatomic structure such as the palate rather than relying on the dentition for alignment. A recent protocol described digitally superimposing maxillary models using the palatal rugae and adjacent palatal surface as reference regions to calculate three-dimensional changes in tooth position.[18] The palate is considered a relatively stable structure during orthodontic treatment, and prior evidence supports the use of palatal rugae as a reliable reference for superimposition because their morphology demonstrates minimal change over time.[19] Using the palate as the registration base may also offer an advantage over tooth-based alignment in clear aligner research, because even teeth that are "locked" in the digital treatment plan are still in intimate contact with the appliance and may be exposed to secondary forces. As a result, they may not remain completely static and therefore may not serve as ideal reference points. Palatal-based superimposition techniques have shown good reproducibility and may reduce the cumulative error introduced by model printing, manual landmark placement, and rescanning in workflows such as the one used in this study. Future work incorporating palatal or other stable intraoral reference structures may further improve the precision and validity of three-dimensional assessments of tooth movement in aligner studies.

Compliance with aligner wear represents another potential source of variability. In this study, compliance data were collected using self-reported daily and overall surveys. Although mean reported daily wear time was high, suggesting general adherence to recommended wear schedules, survey completion was inconsistent across subjects and some entries lacked recorded wear-time values. Because these data were self-reported and incomplete, they were interpreted descriptively and were not incorporated into inferential analyses. Nevertheless, it is possible that variations in actual day-to-day wear time, even when small, may have contributed to differences

in rotational expression observed between teeth and between subjects. Future studies may benefit from integrating objective compliance monitoring technologies to better characterize the relationship between aligner wear behavior and rotational predictability.

The findings of this study should also be interpreted within the context of several additional limitations. Most notably, only three subjects were enrolled, and only two contributed complete paired tooth observations. As a result, the sample size was insufficient to support formal statistical comparison or to answer the study hypothesis. All analyses were descriptive in nature, intended to explore potential patterns rather than establish treatment effects. The study sample consisted entirely of adult female subjects, which limits generalizability. Although zero-collision tolerance was achieved prior to the observation period to reduce interproximal contact resistance, biological variability, occlusal loading differences, and compliance variation may also have influenced rotational outcomes. In addition, one antimere tooth did not receive the intended non-beveled attachment, further reducing the number of paired comparisons available for analysis.

Despite these limitations, this pilot study provides useful feasibility information for future research. Power calculations based on paired rotational outcomes suggest that approximately 14 subjects may be required to detect differences in rotational efficiency and approximately 27 subjects may be needed to detect differences in absolute degrees of rotation using a split-mouth design with 80% power. Although these estimates should be interpreted cautiously due to the small dataset from which they were derived, they indicate that a modestly larger sample should be sufficient to rigorously evaluate the effect of attachment geometry in a future randomized study.

Future investigations should aim to enroll a larger and more diverse study population, ensure complete antimere pairing where possible, and consider stratifying analyses by tooth type given known differences in crown morphology and expected force systems. Incorporating digital automation into the measurement workflow and objective compliance monitoring through clinical photographs of the attachments from multiple angles may further reduce variability. Finally, including clinically meaningful outcomes such as refinement burden, number of additional aligners, or total treatment time may help translate biomechanical findings into practical clinical recommendations.

Within the limitations of this small pilot study, beveled rectangular attachments demonstrated a trend toward greater rotational expression and higher rotational efficiency than non-beveled rectangular attachments during maxillary anterior clear aligner treatment. However, the results were not sufficiently powered to determine whether these apparent differences are statistically or clinically significant, and no definitive conclusions regarding the study hypothesis can be drawn at this stage. These findings support continued investigation into the role of attachment geometry in optimizing the predictability of rotational tooth movement with clear aligners.

VI: Conclusions

This pilot study explored whether beveled rectangular attachments improve rotational expression during clear aligner treatment compared with rectangular non-beveled attachments. Beveled attachments demonstrated a trend toward greater rotational expression and higher rotational efficiency; however, the very small sample size and incomplete antimere pairing

prevented statistical evaluation of the study hypothesis, and the findings should be interpreted as preliminary.

The measurement protocol demonstrated high intrarater reliability, supporting the repeatability of the digital analysis workflow. At the same time, the study highlighted potential sources of cumulative measurement error and the influence of real-world clinical variables such as compliance and individual biological response.

Power analysis suggests that a modestly larger split-mouth sample would be sufficient to evaluate the effect of attachment geometry on rotational predictability. Future research incorporating objective compliance monitoring and digitally based model superimposition methods may further strengthen the study design.

Within the limitations of this pilot investigation, these results support continued examination of attachment design as a clinically modifiable factor that may influence the predictability of rotational tooth movement with clear aligners.

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VIII: Appendices

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

OREGON HEALTH & SCIENCE UNIVERSITY

IRB MEMO

Research Integrity Office
3181 SW Sam Jackson Park Road - L106RI
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APPROVAL OF SUBMISSION

May 5, 2025

Dear Investigator:

On 3/13/2025, the IRB reviewed the following submission:

Type of Review:	Initial Study
Title of Study:	Impact of Attachment Design on Efficacy of Rotational Movement with Custom Clear Aligners
Principal Investigator:	Corey Shook
IRB ID:	STUDY00027935
Funding:	Name: OHSU Foundation, PPQ #: Fiske Fund
IND, IDE, or HDE:	None
Documents Reviewed:	• HIPAA- Prep to Research Form_Efficacy of Orthodontic Aligner Attachments_CS_032125.docx • Consent and Authorization Form • Data and Safety Monitoring Plan_SpencerIRB_CS_JCN_1-14-25.docx • Protocol • Recruitment Script

Additional minor modification(s) were approved on 5/5/2025. The IRB granted final approval on 5/5/2025. The study is approved until 3/12/2026.

Review Category: Full Board. **The IRB determined and documented at a convened meeting that the study involves no greater than minimal risk to subjects. If no new risks are identified, future continuing reviews may be conducted using expedited review procedures under Expedited Category 9.**

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 must be submitted 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 that are outlined in the "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.

Impact of Attachment Design on Efficacy of Rotational Movement with Custom Clear Aligners

Participant Recruitment Script

My name is _____ and I want to speak to you about the opportunity to volunteer in this study. The 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 take place during the duration of 6 trays after the initial stages of tooth alignment have occurred. If you choose to participate, we ask that you wear your trays for the prescribed 22 hours per day as instructed by your provider. Additionally we ask that you complete a daily compliance survey and an overall compliance survey at the end of the observation period. At the start of the observation period and following the 6-tray progression, we will take additional intraoral scans that will help us track the changes that have occurred. Does this sound like something you may be interested in?

If yes Here is a consent form here that we can go through together.

If no Thank you for your time.

Appendix C. Subject consent form

OHSU

Medical Record Number_____
Name_____
Date of Birth_____

CO1450

OHSU Clinical Consent and Authorization Form

SUMMARY OF KEY INFORMATION ABOUT THIS STUDY

STUDY TITLE: Impact of Attachment Design on Efficacy of Rotational Movement with Custom Clear Aligners

OHSU eIRB STUDY NUMBER: 00027935

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 whether two different tooth attachment shapes used to attach the clear aligners can improve results 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 your questions have been answered to your satisfaction.

DURATION:
Your participation in the study will generally consist of 4 visits over 6 weeks. Study visits will be scheduled with your regular visits for orthodontic treatment and add about 20 minutes to each visit.

CO1450

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 be asked to complete daily surveys and one additional overall survey at the end of the study and will undergo two scans of your teeth using a handheld device, one scan today and the other during your regularly scheduled visit after 6 weeks of appliance wear.

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
- 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 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

INTRODUCTION & PURPOSE

STUDY TITLE: Impact of Attachment Design on Efficacy of Rotational Movement with Custom Clear Aligners

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

CO-INVESTIGATORS:	Jeff Nickel, DMD, MSc, PhD (503-494-8223)
	Spencer Gibbons, DDS (503-494-8801)

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

WHO IS PROVIDING OTHER SUPPORT FOR THE STUDY? *The study is supported by the OHSU Graduate Orthodontic Clinic*

WHY IS THIS STUDY BEING DONE:
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 orthodontic 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 measure the difference in tooth movement between two different shapes of clear aligner tooth attachments.

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 30 people will take part in this study which will be conducted at Oregon Health & Science University. Of these participants, we expect 40 will be screened and 30 will participate in the study at OHSU.

PROCEDURES

WHAT ARE THE STUDY GROUPS?

This study has one study group, with equal numbers of participants assigned female or male at birth. In each individual, on one side of the top jaw, a rectangular tooth attachment will be used to help the clear aligner trays straighten your teeth. On the other side of the top jaw, a rectangular beveled tooth attachment will be placed on your teeth. Each attachment will help the aligner tray move your tooth to the desired location.

A random number generator will assign which side of your top jaw will receive the designed tooth attachments, in no particular order. This is called randomization. You will not know which type of tooth attachment is placed on your right and left sides. The study is done this way because it is not known whether a particular design of attachment is better in aligning teeth.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to be in this study, you will participate for an extra 20 minutes during 4 visits over the 6 weeks. Participation in the study will occur during regularly scheduled orthodontic treatment visits. 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?

If you agree to be in this study, you will have two digital scans taken of your upper teeth using a small handheld device, one during today's visit and the other during your regular orthodontic treatment appointment 6 weeks after you start your clear aligner treatment. You will also complete daily surveys and one overall survey at the end of the study period.

STUDY PROCEDURES

Visit 1: CONSULTATION VISIT FOR TREATMENT (+20 minutes for study)

This visit will occur today if you agree to participate in the study. Prior to reviewing this consent form, the plans for your clear aligner treatment should have been presented to you and discussed. If you are willing to participate in this study, we will ask you to sign this consent form. Additionally, for the study, we will perform 1 scan of your upper teeth using a small hand-held scanning device that creates a 3D image of your teeth. These procedures will add 20 minutes to your consultation visit.

Visit 2: 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 regular clear aligner treatment. Additionally, for purposes of this study, you will be instructed on how to complete daily research survey questionnaires which take approximately 1 minute to complete and will be completed during the 6 weeks of observation for a total of 40-45 minutes.

Visit 3: Six weeks (6 Trays) Later Visit (+20 minutes)
At this visit, a scan of your upper teeth will be performed for the study to assess your treatment progress. This procedure will add 20 minutes to your regular treatment visit.

Visit 4: End of Study and Continuation with Regular Treatment (+20 minutes)
At this visit, you will complete an end-of-study participation survey and will continue your clear aligner treatment as normal with your treating doctor

RISKS

WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?
Risks of study tests and procedures:

- **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.
- **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 may affect tooth movement.

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.

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.

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.

Information privacy and security:
You can choose to receive text messages as part of this study. These messages will include information related to OHSU's Clincard service to reimburse you for your participation. If you agree to receive text messages, we will send them to the personal phone number you give us. You do not have to agree to receive text messages to be part of this study.
Text messages may contain information that you wish to keep confidential. Text messages travel over unencrypted networks that OHSU does not own or control. There is a risk that these text messages could be

viewed and read by someone else. By agreeing to receive text messages you agree that OHSU may send your information across those unencrypted networks. OHSU is not responsible for cell phone carrier charges. Your cell phone provider may bill you for the cost of any text messages used for this study. Please check with your cell phone provider for more information.
We cannot promise that no one else will see a text message from OHSU. For example, if you lose your cell phone or you let someone else use your phone, that person might see text messages from OHSU containing your health information. You should not agree to receive text messages if you share your cell phone with someone else.
You may choose to stop receiving text message at any time by replying STOP to a study text message, sending an email to shookco@ohsu.edu, or calling this number 503-346-4709.

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:

- 3Shape, Inc. This is the scanning device that will be used to scan your teeth at visits 1 and 3. Information sent to 3Shape may include your name, date of birth, email, and facial photos or characteristics.
- 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):

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:

- 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 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/gui/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. Your orthodontic treatment will be billed to you/your insurance as usual.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

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

We 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 the use the card.

You will be reimbursed $30.00 at the end of Visit 2 (CLEAR ALIGNER DELIVERY VISIT) and $20.00 at the end of Visit 4 (End of participation survey), for a total of $50.00 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, Spencer Gibbons, DDS (503) 494-8801, or Jeff Nickel, DMD, MSc, PhD (503) 494-8223.

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

SIGNATURE

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.

Participant Printed Name	Participant Signature	Date
Person Obtaining Consent Printed Name	**Person Obtaining Consent Signature**	**Date**

	Yes, I agree	*No, I decline*
I agree to receive text messages for this study and understand that OHSU cannot guarantee they will be confidential.	_____ *Participant initials*	_____ *Participant initials*

Appendix D1. Daily compliance survey

Compliance Survey (daily)

Date? _____

How many hours did you wear your aligners? _____

Additional Comments:

Appendix D2. 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? ____

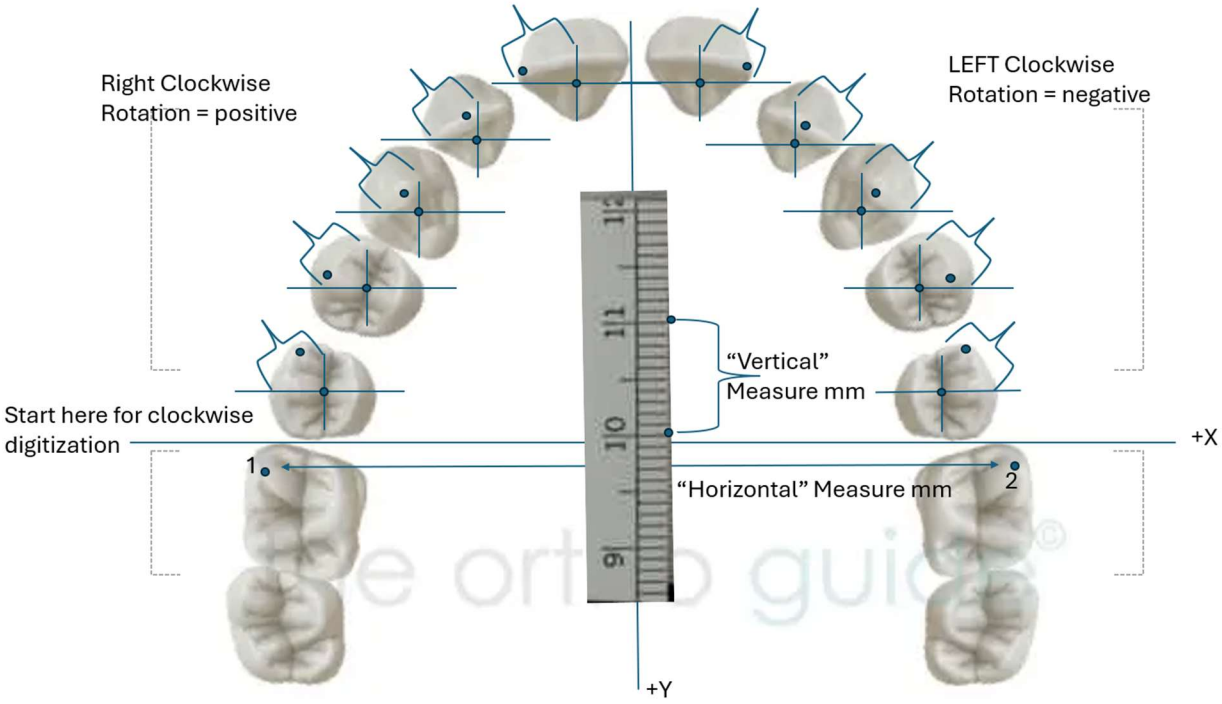
Additional Comments:

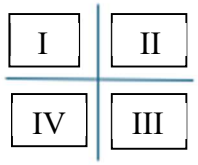
Appendix E: MATLAB tooth tracker program instructions

Tooth Tracking Program

D:\TeethMTrackingM02

1. On either printed models or stone, place marks on the T1 (initial) and T2 (progress) models according to the blueprint. Note that on the right, marks must be within quadrant 4, while on the left marks must be within quadrant 1.





2. Scan the occlusal surfaces of the models in the photocopier to make a .pdf file. Store the .pdf file in the subjects folder. From the .pdf file, make .jpg files of each image using **Paint** or another program. Be sure to label them (ie T1, T2) and store the .jpgs in the subject's folder.

3. Go to D:\Tooth Tracking and open the MATLAB program titled **TeethMTrackingM02**

4. Double click, and wait for the Green Arrow to appear on the top of the user interface

5. Follow the instructions. First instruction will be to create an output file. Second instruction will be to click on the subject's T1 .jpg file. Once it comes up, move it to the screen on the right, and enlarge it.

6. Follow the instructions: i) Horizontal measurements, ii) vertical measurements, iii) clockwise digitization of points 1-4.

7. Now follow the instructions for digitizing the teeth, sequentially, starting at the right second bicuspid.

8. Once completed, follow the prompt to access the subject's T2 .jpg file. Move the image to the right screen and maximize the size.

9. Follow the program prompts.

10. The output file is in .csv format. Open excel, then use excel to open the .csv file. A dialog box will open indicating that the file is in a delimited format. Click on next, and click on the radio button next to "comma", then click on "FINISH"

11. The data are values for: i) X (labio-lingual, where + is to the right), ii) Y (mesio-distal, where + is to the distal), and iii) rotation (on the right, positive is clockwise; on the left, negative = clockwise).