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# Effect of Clear Aligner Attachment Design on Extrusion of Maxillary Lateral Incisors: A Randomized Clinical Trial

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Title

Effect of Clear Aligner Attachment Design on Extrusion of Maxillary Lateral Incisors: A Randomized Clinical Trial

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Science in Dentistry at Virginia Commonwealth University.

By

Justin Groody, D.D.S.

B.S. in Biology from the University of North Carolina at Wilmington, May 2016D.D.S. from the UNC-Chapel Hill Adams School of Dentistry, May 2020

Thesis advisor: Steven J. Lindauer, D.M.D., M.D.Sc.

Department Chair, Department of Orthodontics

Virginia Commonwealth University Richmond, Virginia May, 2022

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#### Abstract

#### EFFECT OF CLEAR ALIGNER ATTACHMENT DESIGN ON EXTRUSION OF MAXILLARY LATERAL INCISORS: A RANDOMIZED CLINICAL TRIAL

By: Justin T. Groody, D. D. S.

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Science in Dentistry at Virginia Commonwealth University.

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Department Chair, Department of Orthodontics

**Introduction:** The aims of this randomized clinical trial were to compare the efficacy of extrusion of maxillary lateral incisors among "optimized", rectangular "horizontal", rectangular horizontal "incisally beveled", rectangular horizontal "gingivally beveled" attachments, and to provide a clinically relevant recommendation for attachment planning for extrusion of maxillary lateral incisors during aligner treatment.

**Methods:** 30 16-to-58 year old Invisalign patients and 56 maxillary lateral incisors requiring extrusion were randomly allocated to one of four attachment groups (optimized, horizontal, incisally beveled, and gingivally beveled). Participants were recruited from two private practice offices and the Virginia Commonwealth University School of Dentistry. The outcome assessor was blinded. Each patient was given an initial series of 20 to 25 clear aligners and iTero scans were taken initially, and at the completion of the series. The predicted posttreatment model was derived from the Invisalign ClinCheck Pro software (Align Technologies). The initial model was superimposed with the predicted posttreatment model and actual posttreatment model using Geomagic Control X software (Rock Hill, SC, USA). Extrusion was measured using the predicted posttreatment and actual posttreatment superimpositions, and the amount of extrusion achieved was compared among attachment groups.

**Results:** The mean achieved extrusion was 71% of predicted extrusion and an average of 0.22 mm less than predicted extrusion. There was no significant difference among the extrusion of the four attachment groups. However, there was a significant increase of 17% in the absolute extrusion and 29% in the relative extrusion of the conventional attachment group compared to the optimized attachment group.

**Conclusions**: Conventional, 4 mm wide, horizontal attachments (horizontal, incisally beveled, or gingivally beveled) were significantly more reliable for achieving maxillary lateral incisor extrusion than optimized attachments. Achieved extrusion of maxillary lateral incisors was 76% of the amount predicted for conventional attachments and 59% for optimized attachments. More prospective studies are needed to explore other methods to improve the predictability of extrusion of maxillary lateral incisors with clear aligners.

#### Introduction

An increasing number of adults are pursuing orthodontic treatment and many are seeking a more esthetic and comfortable option over conventional fixed appliances.<sup>1</sup> Advancements in intraoral scanning, digital treatment planning, and three-dimensional technology in general have contributed to the increase in clear aligner therapy. Invisalign was released as a clear aligner system with direct advertising in 1998 as an esthetic, no wire, no bracket, alternative to traditional fixed appliances.<sup>2</sup> Software is used to formulate a treatment plan and CAD/CAM stereolithographic technology to manufacture a series of clear aligners from a single digital impression.<sup>3</sup> The clear aligners are designed to be changed every 7-14 days and the Align Technology software programs each successive aligner to move teeth up to a limit of 0.25 to 0.33 mm.<sup>4</sup>

Since their introduction, ongoing improvements to the Invisalign system have increased the complexity of cases that can be treated with clear aligners. Clear aligners have grown in popularity and demand over the past two decades.<sup>5</sup> According to Align Technology, their aligners have been used to treat over 9 million patients worldwide in patients ranging from adolescents to children and adults.<sup>6</sup> Align Technology also reports that only 20% to 30% of aligner patients require a mid-treatment intervention or refinement series to address the full scope of the orthodontic problem list and treatment plan and accomplish all goals of treatment.

Orthodontists have claimed otherwise, however, reporting that 70% to 80% of their patients require some level of mid-treatment intervention or refinement series to accomplish the goals of the treatment plan.<sup>7</sup>

The first studies surrounding clear aligners primarily included case reports, surveys, material studies, expert opinions, and few clinical trials.<sup>4</sup> The body of evidence continues to grow, but few clinical trials assessing interventions with clear aligners have been published. A prospective clinical study in 2009 by Kravitz et al,<sup>2</sup> investigated the efficacy of tooth movement with Invisalign. They evaluated the movements of each tooth individually and concluded that the mean accuracy of tooth movement with Invisalign was 41%. The most accurate movement observed was lingual constriction at 47.1% accuracy. The least accurate movement was extrusion at 29.6%. Krieger et al<sup>8</sup> specifically evaluated anterior tooth position with Invisalign and investigated interarch parameters such as overjet, overbite, and midlines. They concluded that Invisalign successfully corrected anterior crowding, including severe crowding via incisor proclination. Similar to the study by Kravitz et al,<sup>2</sup> Simon et al<sup>9</sup> investigated the effect of attachments and power ridges with Invisalign on tooth movements. They found that premolar rotations were the least accurate movement at 40%. In 2017, Grünheid et al<sup>5</sup> evaluated the efficacy of Invisalign. Utilizing a superimposition protocol using a best-fit algorithm to compare predicted and achieved digital models (versMaxiion 8.1; GeoDigm, Falcon Heights, Minn); and finding that the least accurate movements were molar torque, mandibular incisor intrusion, and mandibular lateral, canine, and first premolar rotation. Haouili et al<sup>6</sup> in 2020 re-evaluated the efficacy of the Invisalign appliance and found that the mean accuracy improved to 50% and the maxillary incisor extrusion improved to 53.7%.

In the Kravitz et al<sup>2</sup> study, maxillary lateral incisors were the most common teeth needing extrusion. This was a particularly inaccurate movement with Invisalign clear aligners due to the difficulty of the aligners grasping the teeth and pulling them vertically. Boyd et al<sup>10</sup> described absolute extrusion being particularly challenging and advocated the use of mid-treatment correction such as elastics attached to a button bonded to the facial aspect, or combining extrusion with more predictable movements such as lingual constriction or retroclination. A recent systematic review found that some limitations of the Invisalign appliance could benefit from the use of attachments, such as bodily expansion of the maxillary posterior teeth, canine and premolar rotations, overbite control, and extrusion of maxillary incisors.<sup>11</sup>

Clear aligners utilize attachments composed of composite resin of various shapes and sizes to increase the efficacy of tooth movement. Clinicians can choose any attachment design based on their preference, whether it be the optimized attachments Invisalign provides, a horizontal attachment, or a beveled horizontal attachment, to name a few. It is up to the clinician's expertise to determine which attachment design best suits the goals of their treatment plan. Composite attachments aid in tooth movement and increase retentiveness of the aligners. Conventional attachments were the first attachments utilized with the Invisalign appliance, including both rectangular and ellipsoid designs. The rectangular attachments include vertical, horizontal, incisally beveled, and gingivally beveled attachment designs. Optimized attachments, a type of SmartForce® attachment introduced in 2009 by Align Technology, vary in shape, are customized for the particular tooth and movement, and are placed automatically within the ClinCheck Pro software (Align Technology). The clinician, on the other hand, designs their own conventional attachments. The size, bevel, angle of the bevel, and position on the tooth can be modified to the clinicians' preferences in the ClinCheck software.<sup>12</sup>

Expert opinions offer advice to achieve the challenging movement of extruding maxillary lateral incisors. Dr. Barry Glaser describes in his "10 commandments of attachment design", that 4 mm wide gingivally beveled attachments on the maxillary lateral incisors aid in more accurate extrusive movement.<sup>13</sup> Gomez et al<sup>14</sup> described the initial force systems generated by plastic aligners with and without attachments. They found that attachments applied the necessary force systems more effectively to achieve bodily tooth movement. Additionally, Dr. Naphtali Brezniak described that attachments add retentiveness and that extrusion is a difficult movement without attachments due to the clear aligners' tendency to concentrate force in the incisal portion of the teeth.<sup>15</sup> No studies to date have evaluated the challenging movement of maxillary lateral extrusion prospectively, comparing differences in the effectiveness between optimized and conventional attachments. Designing a prospective study to evaluate specific individual tooth movements with aligners is challenging and accounts for a limited number of prospective clinical studies published to date in the literature.

The aims of this randomized clinical trial were: 1) to determine whether there were differences in the efficacy of extrusion of maxillary lateral incisors between optimized extrusion attachments and three conventional attachment designs: horizontal, incisally beveled, and gingivally beveled attachments, and 2) to provide a clinically relevant recommendation for attachment planning for extrusion of maxillary lateral incisors during aligner treatment.

#### Methods

The study design was a multicenter randomized clinical trial. The institutional review board at Virginia Commonwealth University granted permission to conduct this study (VCU IRB HM20021396). This randomized clinical trial was registered at *clinicaltrials.gov* (NIH) and there were no changes to the protocol after the trial commenced.

#### Participants, eligibility criteria, and setting

Patients were recruited from the Department of Orthodontics at Virginia Commonwealth University as well as two private practice offices (Richmond and Chantilly) in Virginia. Both private practice orthodontists were Invisalign VIP Diamond Plus Providers. Two orthodontists and VCU orthodontic residents, treated all patients in the study. Patients were recruited at the time of their consultation if they met the study criteria.

Inclusion criteria were:

- Patients 16 years or older to be treated with either Comprehensive Invisalign<sup>™</sup> or Invisalign Teen<sup>™</sup>
- (2) At least one maxillary lateral incisor requiring 0.3 mm or more extrusion
- (3) Maxillary arch with less than 6 mm of crowding or spacing
- (4) All teeth present and fully erupted (excluding third molars)

Exclusion criteria were:

(1) Treatment plan requiring surgery or extractions of any maxillary teeth

- (2) Maxillary lateral incisors with pathology or large restorations (crowns, veneers, etc.)
- (3) Severely rotated maxillary anterior teeth ( $\geq 15$  degrees)
- (4) Presence of anterior crossbite
- (5) Poor compliance
- (6) Poor tracking requiring midcourse intervention (Bootstrap, refinement, etc.)
- (7) Failure to complete the aligners prescribed

#### Interventions

All patients received the same treatment they would have received were they not in the study, except that the designs of those attachments prescribed for maxillary lateral incisor extrusion during the first 20-25 aligners were assigned randomly. A random number generator was used to assign each lateral incisor requiring extrusion to one of four different attachment groups: "optimized" (O), rectangular "horizontal" (H), rectangular horizontal "incisally beveled" (HIB), and rectangular horizontal "gingivally beveled" (HGB). (Figure 1) All participants signed informed consent to participate in the study and received a \$50 gift card at completion to compensate for their participation.

Figure 1. Attachment Types



Optimized

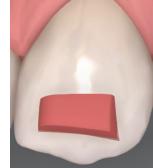


Horizontal



Incisally Beveled

Rectangular



Gingivally Beveled

Invisalign's software program, ClinCheck (Align Technology), was used to design each patients' treatment sequence. Invisalign technicians were instructed to place optimized attachments. The orthodontist prescribed the conventional (horizontal and beveled attachments) and removed optimized attachments if an optimized attachment was originally designated on a tooth randomly assigned for the other conventional attachments. The movement limit was set to 0.25 mm maximum per aligner. Clinicians were permitted to change interproximal reduction (IPR) prescriptions, tooth angulation, attachments on teeth not included in this study, and overcorrections as preferred.

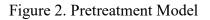
Patients were instructed to wear each aligner for a minimum of 22 hours a day, 7 days a week each before moving to the next aligner, which is the standard aligner protocol. Proper demonstration of aligner wear to ensure proper fit was instructed. Participants verbally confirmed compliance at each appointment and compliance was recorded in hours per day.

Conventional attachments (horizontal, incisally beveled, gingivally beveled attachments) were designed to be 4 mm wide mesiodistally; the incisogingival dimension and the angulation were unaltered. Each attachment was placed in the incisal third and centered mesiodistally and incisogingivally. The protocol for attachment bonding was standardized with standard bonding procedures.

Midcourse interventions to improve tracking, such as rescanning or introduction of a "bootstrap" were recorded and reported, but teeth involved were not analyzed as part of the corresponding group. Maxillary lateral incisors not tracking, as noted by a minimum of 1mm of aligner material incisally when the aligner was fully seated, were also recorded and reported but not analyzed within the group assigned.

Patients were evaluated only after the first series of aligners (20-25 aligners). Thereafter, treatment proceeded as necessary as determined by patients and individual practitioners. Only maxillary arches were used in this study. Pretreatment scans were taken with iTero scanners and sent to Align Technology for initiation of the ClinCheck (Figure 2). The predicted posttreatment ClinCheck STL file was downloaded from Align Technology (Figure 3). An actual posttreatment iTero scan was taken at the completion of the series of aligners (Figure 4). STL files of the pretreatment, actual posttreatment, and the predicted posttreatment were transferred to GeoMagic Control X by 3D Systems (Rock Hill, SC, USA). All models were standardized to a global XYZ coordinate system with the Z-axis representing the vertical axis. The pretreatment models were used as the reference data model. The actual posttreatment and predicted posttreatment were used as the measured data models. The reference data model was divided into regions: posterior teeth, lateral incisors, and central incisors and gingiva. The posterior teeth region was used for the superimpositions. According to the method described by Grünheid et al,<sup>4</sup> a best-fit algorithm was used to superimpose two models (pretreatment to predicted posttreatment and pretreatment to actual posttreatment) to compare individual tooth movements planned and achieved in 3dimensions with 50 iteration counts (Figure 5, Figure 6). The Initial Alignment algorithm was used prior to the best-fit algorithm for superimposition. Following superimposition, the 3D Compare tool was used to measure the vertical distance of each maxillary lateral incisor between both the pretreatment and predicted posttreatment models, and the pretreatment and actual posttreatment models (Figure 7, Figure 8). Measurements were made at three distributed points in the middle third of the incisal edge of the lateral incisor for the predicted extrusion and actual extrusion measurements. After 2 weeks, the measurements for 14 models (25 teeth) were repeated and intra-examiner reliability was evaluated.

A subsample of 10 teeth were measured for extrusion by superimposing with and without the palatal rugae as stable landmarks to quantify the potential measurement bias introduced by superimposing models on the posterior teeth. The differences in the extrusion with and without the rugae were compared with two one-sided t-test (TOST) method. Equivalence bounds were preset at 0.1 mm and evaluated at the 0.05 level to generate 90% equivalence bounds.



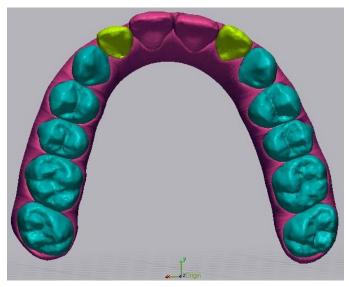


Figure 3. Predicted Posttreatment Model

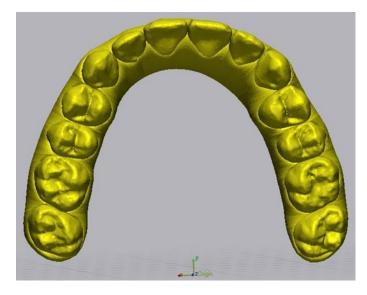


Figure 4. Actual Posttreatment Model

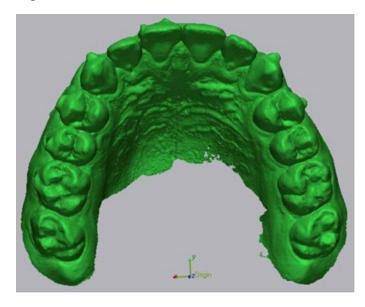


Figure 5. Pretreatment and Predicted Posttreatment Model Superimposition

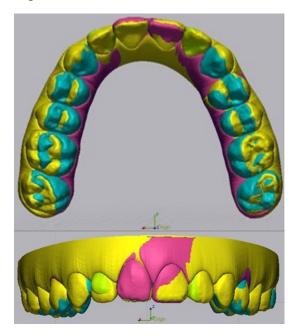


Figure 6. Pretreatment and Actual Posttreatment Model Superimposition

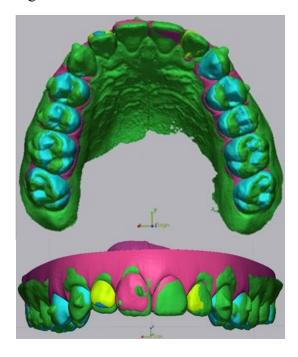
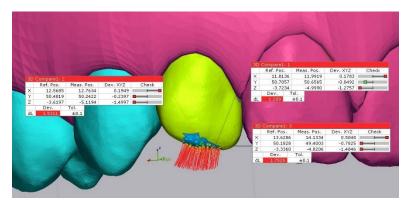
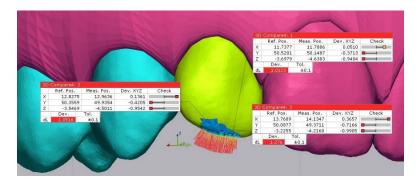


Figure 7. Predicted Extrusion Measurement



#### Figure 8. Achieved Extrusion Measurement



#### Outcomes

The primary outcome was achieved extrusion of the maxillary lateral incisors for each conventional attachment group (H, HIB, HGB) compared to that achieved using the optimized extrusion attachment group (O). Secondary outcomes included the analysis of compliance, sex, age, and number of trays related to accuracy of extrusion.

#### Sample size calculation

Power analysis determined that 20 teeth per attachment would have 80% power to detect clinically meaningful differences among attachments. Each maxillary lateral incisor was considered as independent, even when two teeth were used in the same patient. Based on data from prior publications, the common standard deviation for extrusion was assumed to be 1.25.<sup>16,17</sup> A sample size of 20 per group had the power to detect an effect size of 0.146 and variance of means of 0.114. These estimates reflect small effect sizes and therefore would be able to detect clinically meaningful differences in the extrusion ability among the four attachments.<sup>18</sup> Sample size calculations were estimated with nQuery v8.5.2 (Statistical Solutions Ltd 2020).

#### Randomization

Four different attachment designs were randomly assigned based on results of a previous study which identified those attachments as the ones chosen most often by practitioners for the purpose of extruding maxillary lateral incisors during treatment with clear aligners.<sup>19</sup> The operators utilized a randomization list to assign each lateral incisor to one of the four attachment groups.

#### Blinding

A single evaluator completed the measurements and was blinded to the attachment used for each tooth. Blinding of the treatment providers and patients was not possible. Digital pretreatment models, prediction models and post-treatment models were de-identified for each tooth involved. Attachments were removed from the maxillary lateral incisors for the final scan to ensure blinding during the superimposition and comparison process. After a two-week washout period, 14 models (25 teeth) (pretreatment to prescribed posttreatment and pretreatment to posttreatment) were superimposed again and re-analyzed for intra-examiner reliability evaluation.

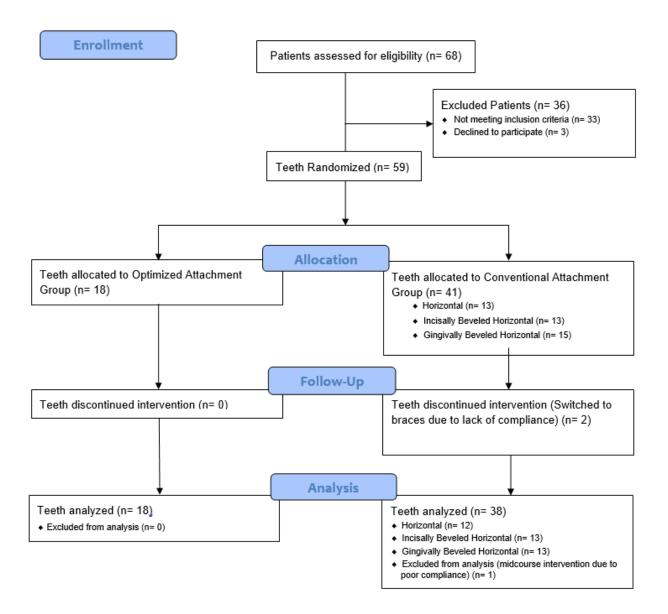
#### **Statistical Analysis**

Intra-rater reliability of the measurements were calculated using the intraclass correlation coefficient (ICC) and the repeated measurements for the predicted and actual extrusion by the single rater. Bivariate analyses were conducted to determine if the four treatment groups were equally balanced in terms of patient sex, predicted extrusion, patient age, and self-reported compliance. These analyses were conducted using Fisher's Exact test and ANOVA methods based on the variable type. The difference between actual extrusion and predicted extrusion was compared for each tooth using a paired t-test. Linear models were used to determine the

difference in achieved extrusion which was calculated as achieved extrusion divided by predicted extrusion. Other covariates of interest included were patient age, sex, number of trays, and self-reported compliance (average hours of aligner wear per day). SAS EG v.8.2 was used for all analyses (SAS Institute, Cary, NC). The significance level was set at 0.05.

#### Results

Sixty-eight patients were assessed for eligibility for the present study. Thirty-two patients (59 maxillary lateral incisors) were enrolled in this clinical trial. A total of 56 maxillary lateral incisors from 30 patients were included in the final analysis. One patient (2 maxillary lateral incisors: H, HGB) was excluded due to poor compliance and switched to braces. One patient (1 maxillary lateral incisor: HGB) had poor compliance and tracking requiring midcourse correction. The last data collection was in April 2022 (Figure 9).



#### Figure 9. CONSORT Flow Diagram.

Of the 56 teeth, 18 (32%) were treated with optimized (O) attachments, 12 (21%) with horizontal attachments (H), 13 (23%) with incisally beveled horizontal attachments (HIB), and 13 (23%) with gingivally beveled horizontal attachments (HGB). The predicted extrusion did not differ significantly among the four groups (P = 0.1492). The average predicted extrusion ranged from 0.31 mm to 2.46 mm. The distribution of patient sex (P = 0.1243), age (P = 0.8560), number of trays (P = 0.9249), and self-reported compliance (P = 0.8269) did not differ significantly among the four attachment groups. The characteristics of the four attachment groups are presented in Table 1.

	Optimized n=18	Horizontal n=12	Incisally Beveled <i>n</i> =13	Gingivally Beveled <i>n</i> =13	P Value
Predicted Extrusion (mm)	$0.7 \pm 0.32$	$0.7 \pm 0.29$	$0.9\pm0.49$	$1.0 \pm 0.58$	0.1834
Age	$31.4 \pm 13.6$	$30.8 \pm 14.83$	$35.4\pm15.34$	$32.8\pm15.28$	0.8560
Number of Trays	$21.9 \pm 2.37$	$22.0 \pm 2.37$	$22.5 \pm 2.37$	$22.1 \pm 2.33$	0.9249
Compliance (hrs/day)	21.8 ± 0.6	$18.6 \pm 2.84$	$19.4 \pm 2.1$	$18.8 \pm 1.77$	0.8269
Sex (n, % Female)	5, 45%	3, 60%	4, 67%	2, 50%	0.1243

Table 1. Comparison of attachment groups (Mean, SD)

Intra-rater reliability was calculated and found to be very high (ICC = 0.985). Extrusion measurements were on average 0.03mm larger (SD=0.12) without the presence of the palatal rugae for reference. Results from the equivalence testing determined the two measures were equivalent within 0.1mm. The 90% equivalence bounds were (-0.09, 0.03).

Patients verbally reported their compliance at each visit with the clinician and the average compliance for optimized (O), horizontal (H), incisally beveled (HIB), and gingivally beveled (HGB) attachments was:  $21.8 \pm 0.6$ ,  $18.6 \pm 2.84$ ,  $19.4 \pm 2.1$ ,  $18.8 \pm 1.77$  (hrs/day), respectively (P = 0.8269).

The amount of predicted extrusion was significantly greater than the achieved extrusion (P < 0.0001). On average, the achieved extrusion was 71% of the predicted extrusion (95% CI: [74%-86%]). The achieved extrusion was significantly less than the predicted extrusion by an

average of 0.22 mm (95% CI: [0.17-0.27 mm]; P < 0.0001). The association between achieved and predicted extrusion is presented in Table 2, Figure 10 and Figure 11.

	Achieved Extrusion (Percent of Predicted)
	(Mean, SD)
Optimized	0.59, 0.21
Conventional	0.76, 0.19
Horizontal	0.74, 0.23
Incisally Beveled	0.78, 0.20
Gingivally Beveled	0.77, 0.15
Overall	0.71, 0.21

Table 2. Summary of Achieved Extrusion (Percent of Predicted) by Group (Mean, SD)

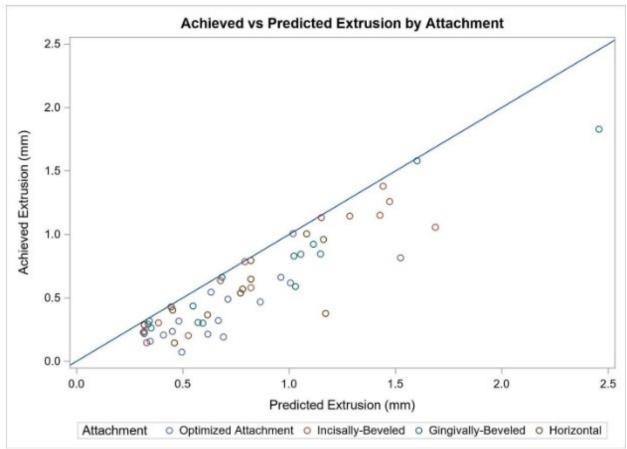


Figure 10. Association between Actual Extrusion and Predicted Extrusion by Attachment Type

Note: Line represents where actual and predicted are equal. Data points below the line reflect cases where the achieved extrusion is less than predicted and those above it are those where actual extrusion was more than predicted.

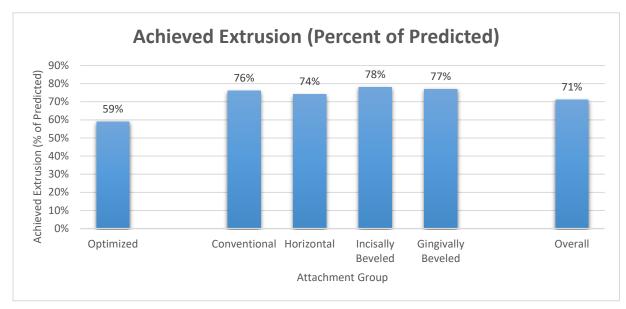


Figure 11. Achieved Extrusion by Attachment Group

The achieved extrusion was significantly associated with the attachment type (P = 0.0322). Although the overall test was significant, the pairwise comparisons did not show a significant difference in achieved extrusion by attachment type, after adjusting for multiple comparisons. Model results are presented in Table 3. Although not significantly different, teeth with the H, HIB, or HGB attachments extruded an average of 0.60 to 0.66 mm and optimized attachments extruded an average of 0.51 mm.

	Estimate	SE	95% CI	P value
Intercept	0.59	0.05	0.49, 0.68	< 0.0001
Attachment Type				0.0322
Horizontal	0.16	0.07	0.01, 0.30	
Incisally Beveled	0.19	0.07	0.04, 0.33	
Gingivally Beveled	0.18	0.07	0.03, 0.32	
Optimized	Reference			

Table 3. Model for Association between Attachment Type and Achieved Extrusion

The full model, which adjusted for attachment type, number of trays, age, sex, and selfreported compliance, is presented in Table 4. There was a significant association between achieved extrusion and attachment type (P = 0.0470). Again, after adjusting for multiple

comparisons, the pairwise comparisons were not significant.

	Estimate	SE	95% CI	P value
Intercept	0.18	0.34	-0.51, 0.86	0.6121
Attachment Type				0.0470
Horizontal	0.16	0.08	0.01, 0.32	
Incisally Beveled	0.18	0.08	0.03, 0.33	
Gingivally Beveled	0.18	0.08	0.02, 0.33	
Optimized	Refei	rence		
Sex				0.5991
Female	0.04	0.07	-0.1, 0.17	
Male	Reference			
Age	0.00	0.00	-0.01, 0	0.2938
Number of Trays	0.01	0.01	-0.02, 0.03	0.5922
Self-Reported	0.02	0.01	0, 0.04	0.1530
Compliance				

Table 4. Full Model Predicting Achieved Extrusion Adjusting for Attachment, Age, Sex, Number of Trays, and Self-Reported Compliance

Based on the preliminary models, the conventional attachments had an estimated average extrusion of 76%, and 59% the optimized attachments had an estimated average extrusion of 59%. Due to this trend, the three conventional attachments were combined into one group and the model was refit. The full model, which adjusted for attachment type, number of trays, age, sex, and self-reported compliance, is presented in Table 5. This model again adjusted for number of trays, age, sex, self-reported compliance, and a variable to indicate conventional attachment (H, HIB, HGB) or optimized attachment (O). In this model, the attachment type (conventional vs. optimized) was significantly associated with achieved extrusion (P = 0.0045). When conventional attachments were combined into one group, the average extrusion for conventional attachments was 76% of the predicted extrusion. The average extrusion for optimized attachments to

optimized attachments, conventional attachments had an estimated absolute average increase in achieved extrusion of 17% (95% CI: [6%-29%]) and 0.14 mm more than optimized attachments, holding all other variables equal. The relative increase in extrusion of conventional attachments versus optimized attachments is 29%. There was no significant association with patient sex, age, number of aligners worn by patients, or self-reported compliance and the amount of achieved extrusion.

	Estimate	SE	95% CI	P value
Intercept	0.17	0.33	-0.5, 0.84	0.6178
Attachment Type				0.0045
Conventional	0.17	0.06	0.06, 0.29	
Optimized	Refe	rence		
Sex				0.5486
Female	0.040	0.060	-0.09, 0.17	
Male	Reference			
Number of Trays	0.01	0.01	-0.02, 0.03	0.5727
Age	-2.26E-03	2.08E-03	-0.01, 0	0.2814
Self-Reported Compliance	0.02	0.01	-0.01, 0.04	0.1396

Table 5. Full Model Predicting Achieved Extrusion Adjusting for Conventional or Optimized Attachment, Age, Sex, Number of Trays, and Self-Reported Compliance

#### Discussion

Designing a study to evaluate the effect of attachment design on the extrusion of maxillary lateral incisors with clear aligners requires a well thought out standardized protocol. A well-designed prospective clinical trial is necessary to control the clinical environment to evaluate specific outcomes with treatment, while still providing patients with efficient and effective treatment. A retrospective design fails to control for variables such as attachment design and placement, compliance, use of auxiliaries, and tooth movements. The design of this study was to balance the control for all variables that would affect maxillary lateral extrusion meticulously and provide an efficient clinical outcome for the patients involved.

The current study concentrated on intra-arch movement of maxillary lateral incisors, specifically extrusion. Extrusion of these teeth has been reported as the least accurate tooth movement with clear aligners and Invisalign specifically. Charalampakis et al,<sup>20</sup> in a retrospective study evaluating the accuracy of clear aligners, found no significant difference between predicted and achieved movement values in the horizontal dimension. They did find significant differences in the vertical dimension for all teeth, and specifically with maxillary incisor intrusion as being the least accurate. There have been numerous expert opinions that explain strategies to efficiently extrude maxillary lateral incisors. There is limited study evaluating these strategies. In the 2009 study by Kravitz et al,<sup>2</sup> they found maxillary incisor

extrusion to be the least accurate (29.6%). They proposed that combining more predictable and accurate movements such as retroclination, can increase the accuracy of achieving extrusion through resultant extrusion. This movement would relatively extrude the lateral incisors after proclination, thus causing a result of extrusion. Other strategies noted have been to slow the velocity of tooth movement per aligner and create space mesiodistally to allow more coverage of the tooth by the aligners. Al-Nadawi et al,<sup>21</sup> in a randomized clinical trial, evaluated the effect of a 7-day and 14-day wear protocol for Invisalign. The 14-day protocol was significantly more effective in posterior maxillary intrusion, distal-crown tip, mandibular incisor intrusion and extrusion, and buccal crown torque. Maxillary anterior tooth extrusion was not significantly different, however.

Maxillary lateral incisors are particularly difficult to move predictably without attachments due to their relatively flat anatomy with minimal undercuts on the buccal and lingual surfaces. Due to the lack of surface area and undercuts, attachments can be used to increase the retentiveness of aligners and the overall surface area of the teeth. The first attachments were ellipsoid and rectangular conventional attachments. Ellipsoid attachments have been deemed the least effective compared to other attachments due to their small size and undefined pushing surface. <sup>12</sup> In a laboratory study of aligner shape and material on retention by Dasy et al,<sup>22</sup> they observed the effect of ellipsoid and conventional rectangular beveled attachments on aligner retentiveness. They found that a greater amount of force was necessary to remove aligners from conventional attachments and suggested that beveled rectangular attachments increase the retentiveness of aligners on the teeth while ellipsoid attachments do not. The present study demonstrated that conventional attachments compared to optimized attachments, had an average extrusion of 76% of the predicted extrusion. Optimized attachments achieved 59% of the

predicted extrusion. The results using conventional attachments exhibited an increase in absolute extrusion of 17%, or an average of 0.14 mm. A previous study determined that a discrepancy between two points of 0.2 mm was a clinically relevant difference that the human eye can detect.<sup>23</sup> Therefore, on average, the absolute improvement of extrusion between aligner attachment designs was statistically significant but may not be clinically significant. The relative improvement in extrusion of conventional attachment design versus optimized attachment design for extrusion is 29%. This may be clinically relevant depending on various patient factors, such as duration of treatment, compliance, and amount of prescribed extrusion. Clear aligners can be used for many more trays than the 20-25 used in the present study. If teeth with optimized attachments fail to track, this may cause a loss of tracking to the point where mid-course intervention is necessary. A prospective study with a larger sample size could explore this. A comparison between predicted and achieved extrusion of these four attachments in groups divided based on extrusion amount could determine the effect of attachment type in a continuous manor.

A trade-off of using a larger conventional attachment versus a smaller optimized attachment is esthetics. Thai et al<sup>24</sup> compared esthetic perceptions of clear aligner therapy with attachments and esthetic brackets using eye-tracking technology. The participants preferred the group with no attachments to anterior, posterior, and ceramic brackets. When larger anterior attachments were evaluated, the preference significantly decreased. Nevertheless, nearly all respondents desire minimal attachments, but 88.4% of the participants said they would compromise esthetics during treatment for a more efficient outcome.

Another finding of this study was the difference between predicted and achieved extrusion of all attachment groups at an average of 71% (0.22 mm). It has been shown in many

studies that achieved values of extrusion are significantly less than the predicted outcomes. The majority of these studies used the Invisalign aligner appliance, as in the current study. Kravitz et al<sup>2</sup> in 2009 noted the overall mean accuracy of tooth movement was 41% with extrusion being the least accurate at 29.6%. In a 2020 study by Haouili et al,<sup>6</sup> they found that Invisalign overall mean accuracy was 50% with maxillary lateral incisor extrusion increasing to 53.7% from the 2009 study. The results of this current study showed greater efficacy of maxillary lateral incisor extrusion compared to previous studies and this may be attributed to a number of factors. Invisalign has undergone numerous modifications to their technology including the G7 Protocol in 2016 and SmartTrack. Our strict study design included patients with strong compliance for aligner wear, standardized placement of the attachment in the incisal third, and was restricted to only mild to moderate cases. This contributed to the success seen in the present study. The results may not be generalizable to all orthodontic patients. Actual differences between optimized and conventional attachments may vary in less compliant and more complex patients.

A recent retrospective study by Karras et al<sup>25</sup> evaluating the efficacy of Invisalign attachments found the overall mean accuracy to be 57.2% and 47.6% for extrusion. They found the extrusion of maxillary lateral incisors to be 46.3%. They compared optimized and conventional attachments and did not find a significant difference for extrusion, with the mean difference being 0.14 mm or 4.33%. They attributed this to most of the conventional attachments utilized being 3 mm wide rectangular attachments, larger than the typical optimized attachment. They postulated that optimized attachments may still be better though, due to the intentional gap between the aligner and attachment, allowing the tooth to extrude unobstructed. That study was retrospective, however. In the present, prospective study, we utilized 4 mm wide attachments and

were able to control several other variables. Many clinicians believe that the beveled attachments resemble the shape of optimized attachments, allowing a force to be perpendicular to the beveled surface. Optimized attachments are designed to have a slight space between the aligner and attachment and this allows the tooth to move progressively into the aligner during movements. Additionally, Align Technology places optimized attachments as part of the SmartForce® feature and they claim that they allow the aligners to deliver more precise forces and eliminate interferences during movement.<sup>26</sup> Conversely, conventional attachments are completely retentive and rely on the flexion of the aligner material to deliver force to the attachment<sup>15</sup>. Conventional attachments may be considered in cases requiring more prescribed extrusion and optimized attachments can be used in cases with a smaller amount of prescribed extrusion. The maxillary lateral incisors may not track with the clear aligners as well if an optimized attachment is used for a large prescribed extrusive movement and could require mid-treatment intervention. Our data demonstrate that conventional attachments are more effective in achieving this challenging movement in comparison to optimized attachments, but more prospective studies are needed to evaluate other factors and strategies to improve this challenging movement and to further compare which conventional attachment, if any, is more effective at maxillary lateral incisor extrusion.

The superimposition method used in this study utilized a best-fit analysis to superimpose the initial models with the predicted and achieved models on the maxillary posterior teeth. The predicted model was derived from the Invisalign ClinCheck with all palatal gingiva removed and does not have skeletal references. Superimposition on the palatal rugae may provide a more stable landmark to measure the movement of teeth in three dimensions to derive movement data. The palatal rugae area has been shown to be relatively stable for reproducible superimposition of

maxillary models.<sup>27–29</sup> In the subsample of teeth that were measured by superimposing with and without the palatal rugae, equivalence testing determined the two measures were equivalent within 0.1 mm with no significant difference in the superimposition methods. The palatal rugae may be stable for superimposing, but the rugae can remodel when anterior teeth move.<sup>30</sup> Other studies have utilized posterior teeth, even portions of only the second molar, to superimpose models.<sup>2,5,6</sup> Utilizing all posterior teeth for superimposition and a protocol of 20-25 aligners was based on the assumption that there would be only slight posterior tooth movement, if any, during this time, thus resulting in a reliable superimposition method. The superimposition method in this study was reliable and accurate as it compared the predicted and achieved models through a standardized and reproducible method. Future studies may consider superimposition of stable structures with the assistance of Align Technology providing access to root and bony structures in their ClinCheck, or the use of 3D cone-beam computed tomography rather than posterior teeth, which move during orthodontic treatment.

A limitation of this study was the small sample size of 56 teeth. Having a larger sample size in fulfillment of the power analysis (20 teeth per attachment group) would have 80% power to detect clinically meaningful differences among the four attachment groups. Additionally, patients in this study self-reported their compliance and that could have been inaccurate. The strict selection of eligible patients for the study may not be representative of orthodontic patients. Three enrolled teeth were excluded due to poor compliance of aligner wear by the patient. All three of these teeth were in the conventional attachment group; one horizontal, and two gingivally beveled. The horizontal and one gingivally beveled attachment were from one patient and that patient wore aligners five hours per day, which is significantly less than the required wear time for the aligners to apply force necessary for efficient tooth movement. <sup>21</sup> This patient

discontinued aligner treatment and was then treated with braces. The other tooth had a gingivally beveled attachment. This patient had low compliance of 16 hours per day, did not abide by the clinical protocol by skipping an aligner, causing the tooth not to track with the aligners. A refinement scan was performed. This lack of tracking with the aligner was attributed to the lack of compliance, rather than the attachment design.

Future studies evaluating the effect of attachment design on tooth movement with clear aligners should be prospective and utilize a superimposition method involving either 2-D cephalometric or 3-D cone-beam computed technology and stable anatomical landmarks. In addition to evaluating attachment shape and type, other methods such as creating space mesially and distally to the incisor and extruding teeth indirectly by using predictable tooth movement sequencing should be studied. Other attachment designs such as the "sash" attachment should be studied. This study utilized Invisalign clear aligners and with recent advances in technology and popularity, other clear aligner appliances have become increasingly utilized by clinicians. These should be studied as the material, clinical setup, and attachments may differ.

#### Conclusion

- Conventional, 4 mm wide, horizontal attachments (horizontal, incisally beveled, or gingivally beveled) were significantly more reliable for achieving maxillary lateral incisor extrusion than optimized attachments.
- 2. Achieved extrusion of maxillary lateral incisors was 76% of the amount predicted for conventional attachments and 59% for optimized attachments.
- 3. More prospective studies are needed to explore other methods to improve the predictability of extrusion of maxillary lateral incisors with clear aligners.

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