

EFFICACY OF COMPOSITE TOOTH ATTACHMENTS IN CONJUNCTION WITH  
THE INVISALIGN® SYSTEM USING THREE-DIMENSIONAL DIGITAL  
TECHNOLOGY

By

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Abstract of Thesis Presented to the Graduate School  
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Major Department: Orthodontics

Recent advances in orthodontic treatment have focused on designing new appliances that fulfill the patient's esthetic demands. In 1998, ALIGN Technology, Inc. invented the most recent esthetic orthodontic appliance system, called Invisalign®. Computer-aided scanning and imaging techniques are used to manufacture a series of custom-made clear, removable appliances to sequentially move teeth.

A prospective, randomized, controlled clinical trial involving adult patients undergoing orthodontic treatment with Invisalign® was conducted with a convenience sample of 99 patients presenting to the University of Florida Orthodontic Research clinic. All patients were treated with the Invisalign® aligners and were randomly assigned to one of six treatment protocols, consisting of five groups with tooth-colored composite-resin attachments and one control group with no attachments. Our purpose was to examine the efficacy of the attachments in producing rotation, intrusion, or extrusion. Also,

differences among the attachment groups in producing these movements were evaluated. Superimposition of digital study models from initial to final (or initial to 1st reboot) was used to determine treatment outcomes. For rotation, the experimental group with buccal and lingual attachments did not prove to be more efficient than those with buccal attachments alone. In fact, buccal and lingual attachments were less effective than the control group. Definitive results cannot be stated for efficiency of attachments with regard to extrusive movements due to the small sample sizes among the experimental groups. For intrusive movements, all groups demonstrated greater efficiency than the control.

## CHAPTER 1 INTRODUCTION

Recent advances in orthodontic therapy have focused on designing new appliances that fulfill the patient's esthetic demands. Plastic and ceramic brackets were introduced in the 1970s and late 1980s, respectively, offering improved esthetics over traditional metal brackets. However, these bonded appliances still require metal wires and clear ligatures, which tend to discolor over time (Proffit, 1993).

In 1998, Align Technology, Inc. (San Jose, CA) invented the most recent esthetic orthodontic appliance system, called Invisalign<sup>®</sup>. Boyd et al. (2000) described this system that uses computer-aided scanning and imaging techniques to manufacture a series of custom-made, clear, removable appliances to sequentially move teeth. These appliances (called aligners) are made from a 0.030" clear plastic that adapts to the anatomy of the teeth, and extends to the gingival margin. Each aligner incorporates a small amount of tooth movement to some or all of the teeth within the arch (according to the projected stages of tooth movement), allowing for a maximum displacement of 0.15 to 0.25 mm per tooth. The number of stages necessary to complete the treatment dictates the number of aligners per patient; generally, a mild malocclusion will require fewer aligners than one that is more severe. Ideally, each aligner is worn 20-22 hours per day for 2 weeks, and is removed only for eating and oral hygiene procedures.

Initially, the aligners were used successfully to treat mild malocclusions, such as anterior crowding and generalized spacing. Joffe (2003) reviewed the limitations of Invisalign<sup>®</sup> that prevent correction of moderate to severe malocclusions due to its

inability to produce controlled types of tooth movements. Closure of extraction spaces is difficult, because the aligners have limited ability to upright tipped teeth during space closure. Other limitations include achieving extrusion, root torque, and correction of severely rotated canines and premolars. To facilitate these more-complex tooth movements, bonded-composite tooth attachments were designed for use as auxiliaries during treatment with the aligners. Several attachment designs were created, to enhance delivery of controlled forces from the aligners to the teeth for the desired type of tooth movement.

Since orthodontic tooth movement is on the order of millimeters, analysis of tooth movement from study models requires an accurate measuring device. Measurement accuracy should be within tenths of a millimeter, to produce statistically significant results.

Longitudinal studies of treatment change using dental casts have been limited by the difficulty of identifying a stable anatomical reference landmark for superimposition. Suitable landmarks must be stable over the course of treatment, in order to measure tooth movement relative to the landmarks (Almeida et al. 1995). The palatal rugae in the maxillary study model may provide for a potentially stable landmark; however, the mandibular study model captures only the teeth and the surrounding alveolar bone contours that cannot be used as stable references during orthodontic treatment because of their potential for movement and remodeling, respectively.

Several studies have focused on evaluating the stability of the palatal rugae during the course of orthodontic treatment. Almeida et al. (1995) concluded that the medial rugae appear to be suitable anatomical points for superimposition during serial cast

analysis. In a comparison of extraction and nonextraction cases, Bailey et al. (1996) examined the stability of palatal rugae, and found the medial and lateral points of the third palatal rugae to be stable landmarks in both groups. Hoggan and Sadowsky (2001) concluded that superimposition of the medial ends of the third palatal rugae is as accurate as cephalometric analysis, in assessing anteroposterior molar and incisor movement.

Several linear and three-dimensional methods of analyzing dental casts (for studying treatment changes) have been reported in the literature. Linear methods include both direct measurements from the study models using digital calipers, for example and indirect measurements (through photographs, photocopies, and computer-scanned images of the study model). These two-dimensional methods are capable of measuring anteroposterior and transverse changes; however, information regarding vertical movements, tip, and torque will be lost (Hoggan and Sadowsky, 2001).

Three-dimensional methods rely on computer digitization of points from the study model to obtain x-, y-, and z-coordinates. The three-dimensional spatial coordinates for all objects digitized on a single study model can then be related, and treatment changes can be analyzed by superimposing designated reference landmarks on serial casts. Some devices used to acquire three-dimensional coordinates include laser scanners and three-dimensional digitizers (Ashmore et al. 2002).

Align Technology, Inc. developed proprietary software (Treat 3) to analyze tooth movement during treatment with Invisalign®. The software superimposes digital study models for three-dimensional analysis of tooth movement.

Currently, no studies exist that examine the effect of composite tooth attachments on facilitating the controlled tooth movements necessary for effective orthodontic

movement with Invisalign<sup>®</sup> aligners. Therefore, the first goal of our study was to examine the efficacy of composite tooth attachments in facilitating the following tooth movements: (1) rotation of canines and premolars; (2) intrusion of incisors, canines and premolars; and (3) extrusion of incisors, canines and premolars. Our second goal was to determine whether significant differences exist in actual versus planned tooth movement among the different attachment designs. Assessment of three-dimensional tooth displacement was accomplished through computer-aided superimposition techniques with the Treat 3 software.

## CHAPTER 2 MATERIALS AND METHODS

### **Experimental Design**

A prospective, randomized, controlled clinical trial involving adult patients undergoing orthodontic treatment with Invisalign<sup>®</sup> was conducted with a convenience sample of 99 patients presenting to the University of Florida Orthodontic Research clinic. Two faculty orthodontists were involved in selection and treatment of the patients. Those who met the following inclusion criteria were eligible to participate in the study.

- Patients were at least 18 years of age or older.
- Patients had a minimum of 3 teeth with the following necessary tooth movements: intrusion or extrusion of canines, premolars, and/or incisors; or rotation of premolars and/or canines.
- Patients had any type of malocclusion not requiring orthognathic surgery.
- Patients were available for a minimum treatment period of 2 years.
- Patients were free of active dental caries and periodontal disease.
- Patients were willing to sign an informed consent.

All patients were treated with the Invisalign<sup>®</sup> aligners, and were randomly assigned to one of six treatment protocols, consisting of five tooth-colored composite resin attachment groups (each having a different shape) and one control group with no attachments (Figure 2-1). The efficacy of the different attachment groups in producing the desired tooth movement was investigated. These movements included (1) intrusion of canines, premolars and incisors; (2) extrusion of canines, premolars and incisors; and (3) rotation of canines and premolars. Randomization for subjects requiring extractions was separate from the nonextraction subjects. However, the same type of randomization scheme was applied for both groups.

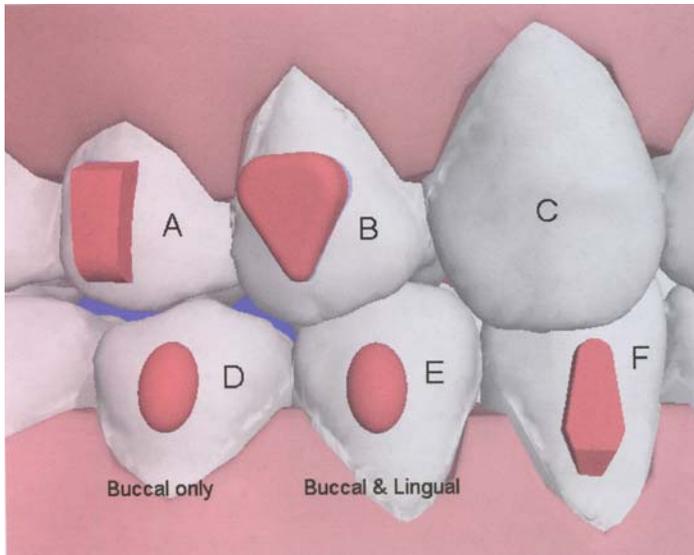


Figure 2-1. Six treatment groups. Attachments A, B, D, and F are bonded to the buccal surface only. Attachment E is bonded to both buccal and lingual surfaces. C represents the control group with no attachments present on any of the teeth.

#### **Data Collection and Treatment**

At baseline (DC 0), two sets of polyvinylsiloxane (PVS) impressions were taken: one for study models, and the other for fabrication of the aligners by Align Technology, Inc. Examiners provided complete instructions to Align Technology, Inc. regarding whether or not extractions were necessary; the specific teeth to be intruded, extruded, and/or rotated; and any other specific treatment objectives. To monitor the progress of tooth movement, PVS study model impressions were taken after 3 months (DC 1), after 6 months (DC 2), and every 6 months thereafter until completion of treatment (DC F).

Once the aligners had been fabricated, patients presented for the initial treatment appointment. This appointment involved bonding of composite tooth attachments (if required), interproximal reduction for space creation, and delivery of three sets of maxillary and mandibular aligners (one set for each 2 weeks). Patients were instructed to wear each aligner full-time for 2 weeks except for eating, drinking, and performing oral hygiene procedures. Unless an emergency arose, patients were scheduled to visit every 6

weeks so that we could observe changes in occlusion, condition of the attachments, and fit of the current aligners. Treatment consisted of rebonding broken or missing attachments and any additional interproximal reduction. Previous aligners were collected, and patients were given the next three sets of aligners.

Teeth that do not move the prescribed amount for each stage will interfere with the proper fit of subsequent aligners. At any time during treatment, if the examiner observed that a patient's aligners were not properly fitting, and tooth movement was not progressing as planned, the patient was "rebooted" for midcourse correction. A "reboot" consists of modifications to the original treatment plan and new maxillary and mandibular PVS impressions for fabrication of a new series of aligners and study models (DCB 0). Patients were placed in retention until delivery of the new aligners. Any patient subjected to more than 2 reboots was randomized into a different treatment group.

### **Outcomes Assessment**

Study models from baseline (DC 0) and final records (DC F) or first reboot (DCB 0) were scanned to create three-dimensional digital images of tooth position (Figure 2-2). Treat 3, proprietary software created by Align Technology, utilized the digital study models for three-dimensional computer analysis of tooth movement through superimposition techniques. Prior to superimposition of timepoints DC 0 to DC F (or DC 0 to DCB 0), the patient's surface anatomy for individual teeth from the two timepoints was matched (Figure 2-3). The software only permitted one arch (maxillary or mandibular) at a time to be matched. Matching deviation for each tooth in the arch was expressed as an average deviation (mm), maximum deviation (mm) and coverage percentage. Since tooth anatomy is stable, any deviation between the two timepoints would indicate some degree of impression inaccuracy or improper placement of the tooth

axis for one of the timepoints. In Figure 2-3, matching timepoints DC 0 with DCB 0 indicated excellent tooth matching in the mandibular arch except for tooth #21 with only a 58% tooth surface match. Identification of the axis for tooth #21 revealed improper placement of the x-axis (Figure 2-4, A) that was subsequently corrected manually to improve surface match (Figure 2-4, B).



Figure 2-2. Digital images of initial malocclusion (DC 0)

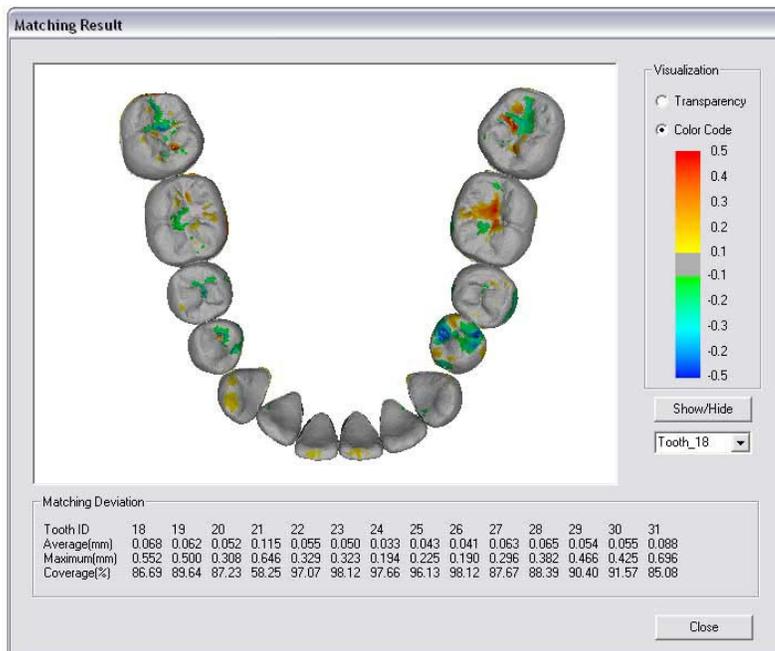
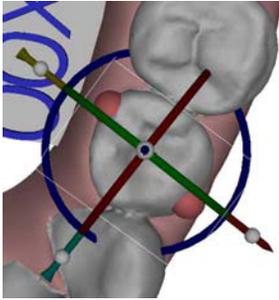
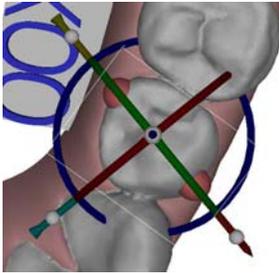


Figure 2-3. Result of matching DC 0 with DCB 0 digital models indicates a poor match of tooth #21.



A



B

Figure 2-4. Placement of x-axis through buccal and lingual cusp tips. A) Improper. B) Proper.

If matching deviation was negligible, best-fit superimposition of digital study models between DC 0 to DCF (or DC 0 to DCB 0) was performed using reference teeth and a reference stage. The software automatically selected the stable reference teeth by a statistical filtering process. The reference stage corresponds to the aligner number that the patient was wearing at the time of study model impressions (DC F or DCB 0). This allows the software to compare the amount of tooth movement achieved to the amount attempted relative to the reference stage. Raw data of tooth movement obtained from the superimposition were exported into a spreadsheet. Quantitative treatment changes for each tooth were described as changes in x, y, and z coordinates for translation (mm) and rotation (degrees). The coordinates were then exported into another spreadsheet for separate analyses of vertical displacement and rotation. The spreadsheet for rotational analysis listed several variables, including initial degrees of rotation for each tooth,

amount of rotation attempted from initial to current and final stages, actual degrees of rotation achieved, and percentage of rotation achieved. The same variables were listed for vertical analysis using displacement in millimeters.

For each patient, only those teeth under investigation for rotation, intrusion, and/or extrusion were used in the statistical analyses. Finally, a comparison of the efficacy of the six treatment groups was made with respect to (1) intrusion of canines, premolars and incisors; (2) extrusion of canines, premolars and incisors; and (3) rotation of canines and premolars

### **Statistical Analyses**

One-way analysis of variance was calculated and, if significant, was followed by student's t-tests to establish statistically significant differences for amount of rotation attempted and amount of rotation achieved among the different experimental groups from baseline (DC 0) to first reboot (DCB 0) or final records (DC F). One-way ANOVA was also used to compare amount of rotation achieved among the experimental groups for both maxillary and mandibular arches. Linear regression was performed to determine the efficiency of the attachments and to correlate amount of rotation attempted from baseline to first reboot or final records to the actual rotation achieved for each of the experimental treatment groups. The same analyses were performed to evaluate statistically significant differences among groups during intrusion and extrusion.

## CHAPTER 3 RESULTS

Of the 99 patients enrolled in the study, 74 were rebooted, 11 completed treatment without reboot, one patient had the maxillary arch rebooted but not the mandibular, seven were missing DC 0, DCB 0 or DC F digital study models for superimposition and another six patients dropped out of the study prior to any reboot or completion of treatment.

Therefore, only 86 patients remained for analysis of tooth movement.

### Rotational Analysis

Table 3-1 summarizes the number of teeth (canines and premolars) per experimental attachment group that were available for rotational analysis. In total, 284 teeth were analyzed among the rebooted patients and only 35 teeth for those completing treatment without reboot. Group A had the most total teeth. The treatment groups included more mandibular than maxillary teeth, with maxillary groups B, D, and E having the fewest number of teeth. All patients treated with attachments B or E were rebooted at some time during treatment. Of the patients that completed treatment without reboot, only groups C and F were available for comparison due to the small sample of groups A and D.

Table 3-1. Total number of teeth for rotational analysis per attachment group

Group	Reboots (Total)			No Reboot (Total)		
	Teeth	Mandibular	Maxillary	Teeth	Mandibular	Maxillary
A	67	35	32	2	2	0
B	37	24	13	0	0	0
C	59	35	24	19	13	6
D	38	24	14	4	3	1
E	46	33	13	0	0	0
F	37	18	19	10	8	2
Total	284	169	115	35	26	9

When the amount of rotation attempted or achieved for those that underwent reboot was examined, no statistical differences were found among the experimental groups. For those patients that were rebooted, the mean rotation attempted and achieved from timepoint DC 0 to DCB 0 is shown in Figure 3-1. The attempted rotation ranged from  $8.33^\circ (\pm 1.49^\circ)$  to  $13.75^\circ (\pm 1.64^\circ)$  for groups E and D, respectively. The rotation achieved ranged from  $2.97^\circ (\pm 0.8^\circ)$  to  $5.6^\circ (\pm 0.66^\circ)$  for groups E and A, respectively. Percentage of rotation achieved ranged from 49.7% (group F) to 34.2% (group C, Table 3-1).

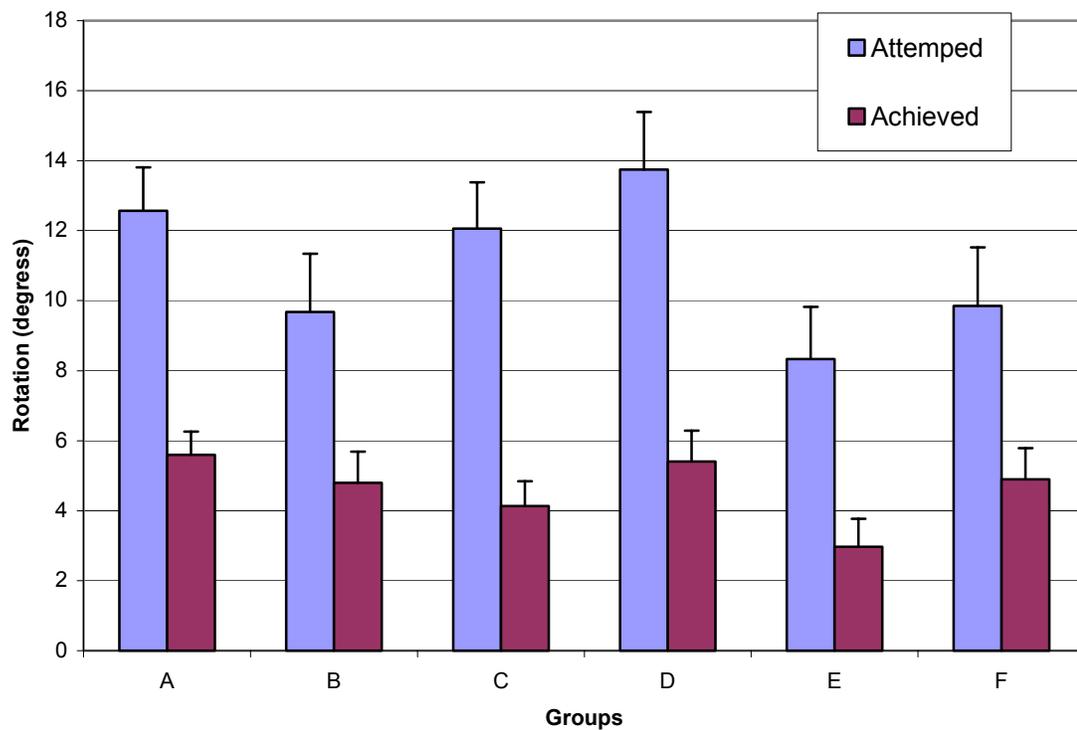


Figure 3-1. Comparison of mean rotation attempted and achieved from DC 0 to DCB 0 among the 6 attachment groups for patients whose treatment was rebooted.

Table 3-2. Rotational data summary of rebooted patients

Grp	n	Mean Rotation Attempted (degrees)	Mean Rotation Achieved (degrees)	% Achieved	Correlation (R)	Efficiency (m)	p
A	69	12.57	5.60	44.5	0.72	0.43	<0.001
B	37	9.68	4.80	49.6	0.70	0.38	<0.001
C	78	12.06	4.13	34.2	0.50	0.26	<0.001
D	42	13.75	5.41	39.3	0.70	0.37	<0.001
E	46	8.33	2.97	35.7	0.46	0.16	<0.001
F	47	9.85	4.90	49.7	0.62	0.40	<0.001

Using linear regression, the efficiency of the attachments from timepoints DC 0 to DCB 0 was determined by the relationship between rotation attempted and rotation achieved (slope of the line, Figure 3-2). Also, correlations were calculated to examine the predictability of rotation attempted with rotation achieved. For the rebooted patients, group A (m= 0.43) had the greatest rotational efficiency whereas group E (m= 0.16) had the least. Correlations were highest for groups A (R= 0.72), B (R= 0.70), and D (R= 0.70). Lower correlations were found with groups F (R= 0.62), C (R=0.50), and E (R= 0.46). Table 3-2 summarizes the rotational data for rebooted patients. Patients that were not rebooted show higher correlations of achieved versus attempted rotation; however, very few teeth were available for investigation in each of the experimental attachment groups.

Figure 3-3 illustrates the mean rotation attempted and achieved between groups C and F for the patients who completed treatment without reboot. The mean rotation attempted for group C was 23.65° ( $\pm$  2.44°) whereas the mean for group F was 13.07° ( $\pm$  3.37°). The mean rotation achieved was 14.54° ( $\pm$  1.70°) and 6.98° ( $\pm$  2.34°) for groups C and F, respectively. Percentage rotation achieved was 61.5% for group C and 53.4% for group F.

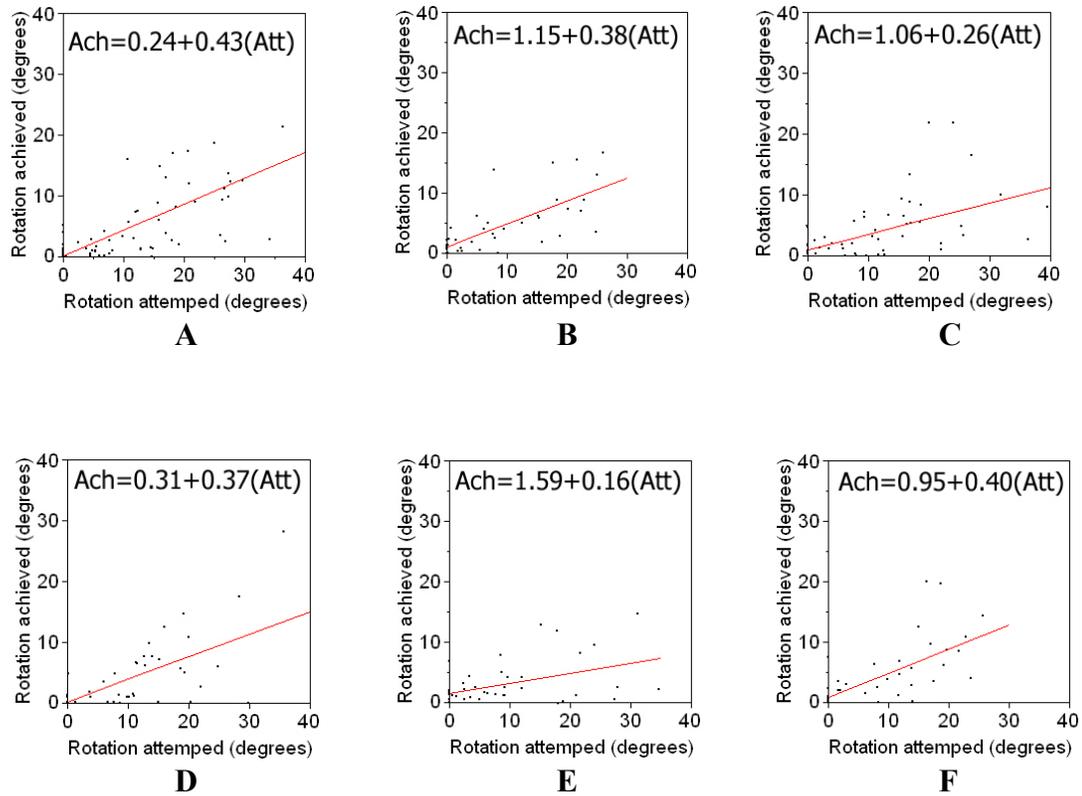


Figure 3-2. Plots of attempted vs. achieved rotation within the rebooted patients to obtain the slope for the six attachment groups. The equation of the line is given at the top of each graph.

In addition, no statistical differences were found for the amount of rotation achieved among experimental groups within the maxillary arch. The mean rotation achieved among the treatment groups in the maxillary arch was  $5.0^{\circ}$  for reboot patients and  $6.0^{\circ}$  for patients that were not rebooted. In the mandibular arch, however, statistical differences were found between those patients that completed treatment but not within the patients whose treatment was rebooted. In the mandible, attachment group C with a mean achieved rotation of  $16.05^{\circ} (\pm 2.14^{\circ})$  was statistically different from group F with a mean rotation of  $5.63^{\circ} (\pm 2.73^{\circ}, p < 0.05)$ .

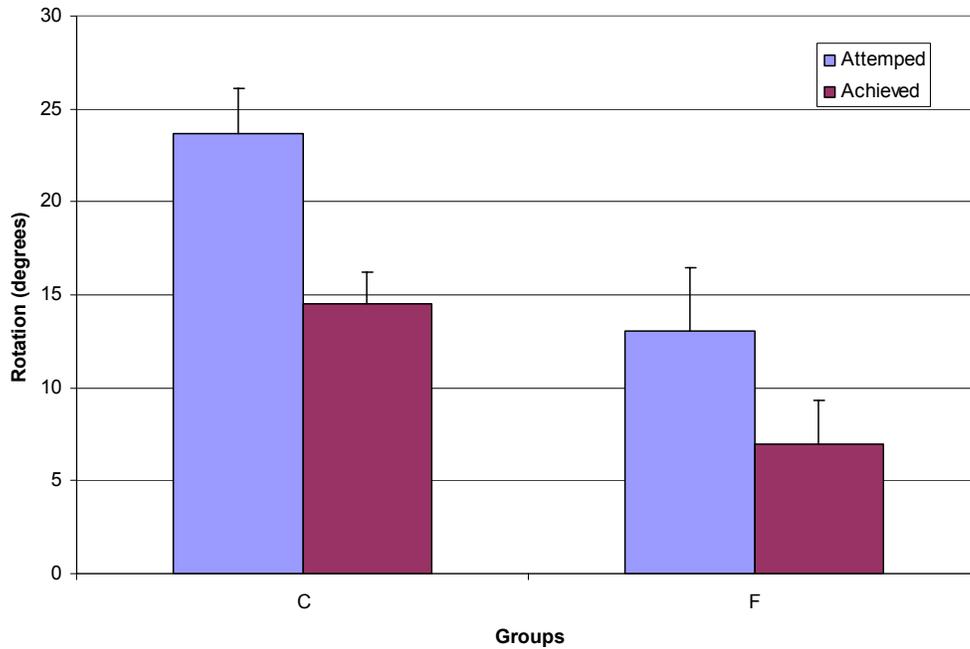


Figure 3-3. Comparison of mean rotation attempted and achieved from DC 0 to DC F among patients who completed treatment without reboot.

### Vertical Analysis

Table 3-3 shows the combined number of teeth (incisors, canines, and premolars) available for vertical analysis of extrusion and intrusion (in millimeters). Among the rebooted patients, only 31 teeth were available for analysis of extrusion; none were randomized into attachment group C or F. For intrusion, 150 teeth from the six attachment groups were analyzed. The vertical data from no-reboot patients was not analyzed due to the small sample sizes for all attachment groups.

Table 3-3. Total number of teeth for vertical analysis per experimental attachment group

Group	Reboot	
	Intrusion	Extrusion
A	25	9
B	17	11
C	22	0
D	35	8
E	23	3
F	28	0
Total	150	31

For extrusion (Figure 3-4), no statistically significant differences were found for the amount attempted or the amount achieved from DC 0 to DCB 0 among groups A, B, D, and E. The mean attempted extrusion ranged from 0.47 mm ( $\pm 0.14$  mm, group A) to 0.90 mm ( $\pm 0.15$  mm, group D). Amount of extrusion achieved ranged from 0.14 mm ( $\pm 0.10$  mm, group A) to 0.47 mm ( $\pm 0.09$  mm, group B).

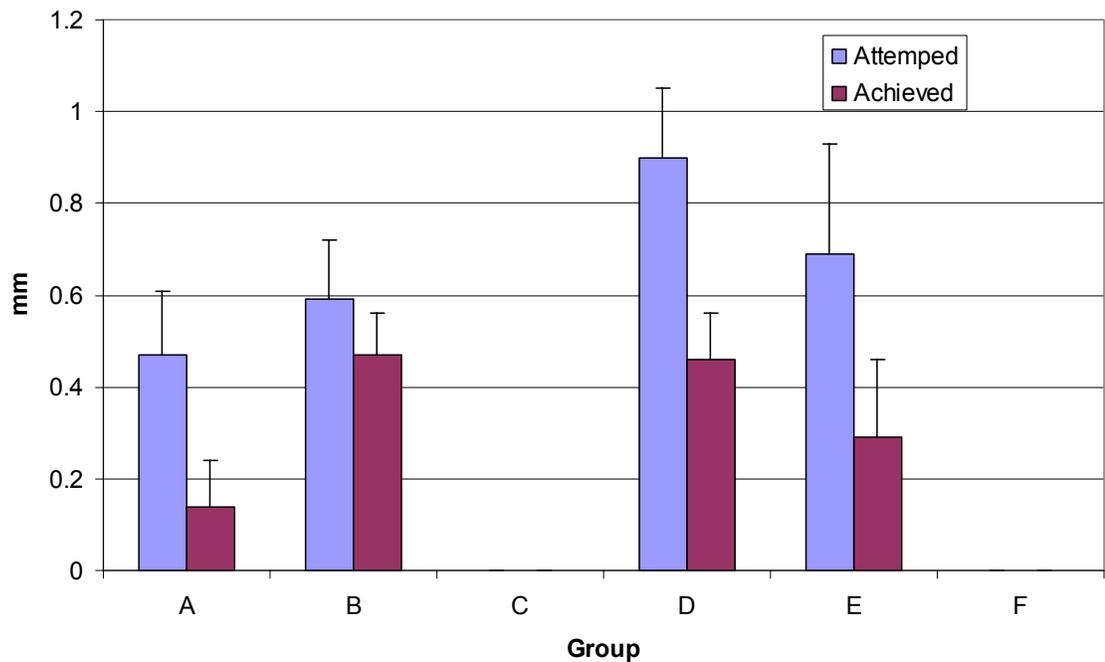


Figure 3-4. Comparison of mean extrusion attempted and achieved among the 4 attachment groups for patients whose treatment was rebooted

For extrusion, Table 3-4 summarizes the data for the rebooted patients from DC 0 to DCB 0. The efficiency ( $m= 0.81$ ) and correlation ( $R= 0.77$ ) was highest for group D. Group B had moderate efficiency ( $m= 0.43$ ) with a high correlation ( $R= 0.62$ ). The efficiency of groups A and E ( $m= -0.40$  for both) was poor; likewise, negative correlations were found between amounts of extrusion attempted versus achieved for attachment groups A ( $R= -0.16$ ) and E ( $R=-0.74$ ).

Table 3-4. Data summary for extrusion among rebooted patients

Grp	n	Mean Extrusion Attempted (mm)	Mean Extrusion Achieved (mm)	% Achieved	Correlation (R)	Efficiency (m)	p
A	9	0.47	0.14	21.3	-0.16	-0.04	ns
B	11	0.59	0.47	79.7	0.62	0.43	0.04
C	0	0	0	0	0	0	0
D	8	0.90	0.46	51.1	0.77	0.81	0.02
E	3	0.69	0.29	42.0	-0.74	-0.40	ns
F	0	0	0	0	0	0	0

Figure 3-5 illustrates the mean attempted and achieved intrusion from DC 0 to DCB 0 among the six attachment groups. No statistical differences were found for amount of attempted intrusion among the six attachment groups. The range of attempted intrusion was 0.81 mm ( $\pm 0.13$ mm, group B) to 1.18 mm ( $\pm 0.12$  mm, group C). There were, however, statistically significant differences ( $p < 0.05$ ) for amount of intrusion achieved. Group A was significantly different from all other groups except group B. Group A achieved the lowest mean intrusion (0.48 mm $\pm$  0.08 mm). All other groups were not statistically different.

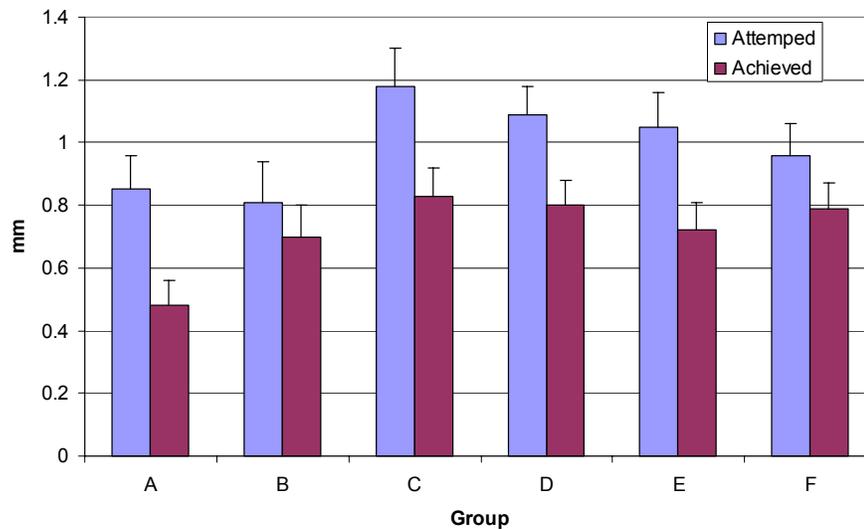


Figure 3-5. Comparison of mean intrusion attempted and achieved among the 6 attachment groups for patients whose treatment was rebooted

For intrusion, outcomes are summarized in Table 3-5. All groups showed moderately high efficiency with a range from 0.46 to 0.71 for groups C and F, respectively. There were good correlations between amounts of intrusion attempted versus achieved for all attachment groups. Group F showed the highest correlation ( $R=0.86$ ) whereas group C showed the lowest correlation ( $R=0.53$ ). The percent intrusion achieved ranged from 56.5% in group A to 87.5% in group B.

Table 3-5. Data summary for intrusion among rebooted patients

Grp	n	Mean Intrusion Attempted (mm)	Mean Intrusion Achieved (mm)	% Achieved	Correlation (R)	Efficiency (m)	p
A	16	0.85	0.48	56.5	0.71	0.53	0.001
B	8	0.81	0.70	86.4	0.68	0.63	0.003
C	17	1.18	0.83	70.3	0.53	0.46	0.01
D	25	1.09	0.80	73.4	0.73	0.52	<0.001
E	23	1.05	0.72	68.6	0.79	0.53	<0.001
F	23	0.96	0.79	82.3	0.86	0.71	<0.001

## CHAPTER 4 DISCUSSION

The purpose of this prospective, randomized clinical trial was to evaluate the efficacy of different attachments on various types of tooth movement during treatment with Invisalign<sup>®</sup>. Specifically, our aim was to determine whether one type of attachment was more effective than another in achieving rotation, intrusion, and extrusion. The attachment efficacy was studied without the use of other auxiliaries, which are commonly employed today.

Scanned digital images of study models were used for superimposition between timepoints. Superimposition of the digital models was performed using the Treat 3 software designed by Align Technology, Inc.

For a variety of reasons, a majority of the patients were rebooted. As a result, the groups were analyzed as reboot and no-reboot, with the reboot group having a greater number of teeth. More teeth in the mandibular arch required rotation than in the maxillary arch (Table 3-1). For vertical displacement (Table 3-3), more teeth underwent intrusion than extrusion resulting in small sample sizes for analysis of extrusive movements.

In the rebooted patients, group C (with no attachment) achieved approximately 1/3 of the rotation attempted. A higher percentage of rotation was achieved with attachment groups A, B and F that could be attributed to their size and shape. Specifically, these attachments were larger and possessed sharper edges that could have improved adaptation of the aligner over the attachments throughout all stages of tooth movement.

Surprisingly, despite group E having buccal and lingual attachments, it was similar to the control group with regard to percentage rotation achieved (Table 3-2).

Linear regression analysis was used to describe rotation achieved with respect to rotation attempted, with the slope of the line representing the efficiency of a given attachment. In general, the attachment groups with a higher percentage rotation achieved, also had the highest efficiency (Table 3-2).

It is interesting to note that, in the no-reboot group, the percentage achieved was 61.5% in group C and 53.4% in group F. These patients were never rebooted despite the incomplete rotation of the teeth. One explanation may be that the rotation achieved may have appeared clinically acceptable.

Regarding extrusion, the attempted mean was less than 1mm with a mean achievement of less than 50% for the four attachment groups (Table 3-4). Group D was highly efficient for extrusion; however, groups A and E had very poor correlations and little efficiency. It is interesting to note the dramatic difference between the efficiency of groups D and E. Both of these experimental groups had the same attachment shape on the buccal, but the latter had an additional attachment on the lingual. It should be noted that the four attachment groups used during extrusion had small sample sizes.

For intrusion (Table 3-5), group F was the most efficient attachment and had the greatest correlation between attempted and achieved intrusion. All other experimental groups, except the control group, were moderately efficient and demonstrated high correlations. The results confirm the importance of using an attachment for intrusion, but similar results may be achieved with any shape of bonded attachment.

In the present study, there are several possible limitations that could have affected the treatment outcomes. These include deficiencies in the treatment software, superimposition software, treatment provided, and patient-related factors.

The software used by Align Technology, Inc. to formulate treatment plans could have some deficiencies. Proper sequencing, or staging, of specific tooth movements is essential to obtain successful treatment outcomes with the aligners. For example, space may need to be created prior to rotating a tooth, but if attempts are made to rotate the tooth without space creation, movement will be prevented. Also, the programmed velocity may be too great despite a maximum of 0.25 mm movement per tooth within a given stage. When comparing crown versus root movement, the later will experience greater resistance to tooth movement and, as a result, may require a slower velocity per stage. Similarly, rotation of a tooth off its long axis may require a slower velocity than a tooth undergoing pure rotation along its long axis.

Validity of the Treat 3 software designed by Align Technology, Inc. for superimposition of digital models to evaluate treatment outcomes has not been studied. The software uses a statistical filtering technique to select reference teeth for superimposition from two digital models; no external reference points are used. The reference stage corresponding to the aligner number at the time of study model impression is used to match the teeth with equal weight to obtain an average match between the two digital models. The error is calculated for all matched teeth within a given arch to obtain the average and standard deviation of the error. Teeth with a standard deviation larger than 68% in normal distribution are not used as stable reference teeth. New developments in the Treat 3 software which permit the use of palatal rugae as

an external stable reference structure may improve the validity of the software superimposition technique. In 2003, Miller et al. tested its validity and concluded that digital superimposition using the palatal rugae was reproducible.

Another limitation of the software is the potential error in the placement of tooth axis by the operator. The x-axis should traverse buccolingually through the cusp tips near the cemento-enamel junction. The y-axis points mesio-distally and the z-axis points occluso-gingivally in the center of the crown. Incorrect placement of any of the axes would lead to matching errors or treatment outcome errors.

Matching errors may also occur if surface irregularities are present on the teeth in the study model. Voids or bubbles on the surface of the impression and distortion of the impression material will be captured in the scanned digital study model. In this study, polyvinylsiloxane impression material was used instead of alginate to provide a more accurate and dimensionally stable impression of the teeth. However, it is not possible to completely eliminate surface irregularities.

In addition, the software uses the given reference stage to superimpose two digital models while assuming that all projected movement up through that stage should have been achieved. It was not feasible, however, to obtain records on patients as they were transitioning from one aligner to the next. The reference stage used was always the current aligner number at the time of study model impression regardless of how many days the aligner had been worn. Therefore, the aligner may not have had enough time to express the projected tooth movement, thus negatively influencing the outcome for that patient.

Several treatment variables could have further affected the results of this study. If treatment was not progressing as planned, attempts were made to avoid rebooting the patient's treatment. Some patients were instructed to wear the aligners for more than two weeks to allow more time for the expression of tooth movement by the aligner. In addition, several patients were backtracked to a previous aligner.

Bonding failure of composite resin attachments or fracture of a portion of the attachment occurred in some patients. Bonding failures resulted from the inability to maintain isolation on the tooth for a dry field during bonding, especially when bonding attachments near the gingiva. Some failures were subsequent to excessive retention of the aligners by the attachment. If removal of the aligners debonded the attachments, attempts were made to rebond the attachment. If multiple attempts to rebond the attachment failed, the profile of the attachment was reduced to decrease the retention of the aligner. Some attachments were left off of for a period of time if bonding failures continued.

Specific amounts of interproximal tooth reduction, if necessary, were prescribed at different stages during treatment. Measuring the amount of interproximal reduction achieved is difficult. Inadequate reduction can lead to collisions between adjacent teeth that would inhibit the projected tooth movement by the attachment.

Poor patient compliance can negatively affect the treatment outcome. The aligners are removable appliances that must be worn 20-22 hours per day. Patients are instructed only to remove the aligners when eating, drinking and performing oral hygiene procedures. At each treatment appointment, examiners asked patients to estimate the

number of hours per day that the aligners were worn. However, this study did not evaluate the effect of compliance on treatment outcome.

Differences among individual patients in treatment outcome were not analyzed. Some patients may have had greater success for all types of planned movement with the specific attachment. Several contributing factors could have played a role in the success or failure of the attachments within a given individual. First, differences in baseline malocclusion such as amount of crowding and/or spacing and underlying skeletal pattern may exist. Second, inherent biologic differences in tissue remodeling could also account for some variation in the treatment outcomes between individuals. In addition, some patients may have longer clinical crowns that increase the surface area for aligner adaptation. Therefore, patients with longer clinical crowns could experience greater movement as compared to teeth with short clinical crowns. Variations in root length could affect the ease of tooth movement, with greater difficulty moving teeth with longer roots. The density of the bone through which the roots are moved is likely to impact tooth movement. Finally, differences may exist between sexes, and among different races and age groups.

It is important to point out that patients may have been rebooted for teeth other than those under investigation. Also, the length of time between timepoints (DC 0 and DCB 0 or DC F) differs dramatically among the patients treated in the study.

Since the commencement of this study, Align Technology, Inc. has developed other methods to facilitate tooth movement with the aligners. Specifically, plastic buttons can be bonded to the tooth and/or aligner for which elastics are attached to produce a rotational or extrusive force. Also, the use of dimples similar to Sheridan and colleagues'

(1997) concept of divots and windows with Essix retainers has helped with producing rotations, but this is better suited for incisor tooth rotations. These methods are generally implemented to recapture planned movements once a problem is apparent. Therefore, in order to prevent the need for reboot, early identification and correction of problems is critical. Rebooting treatment results in increased cost to the orthodontist and increased treatment time for the patient. Future studies are indicated to evaluate the efficiency of tooth movements with the aligners in conjunction with attachments.

## CHAPTER 5 CONCLUSIONS

Surprisingly, the use of buccal and lingual attachments was less efficient for tooth rotation than the control group. The other four attachments produced similar results to each other with regard to rotational efficiency. Definitive results cannot be stated for extrusive movements; however, intrusive movements demonstrate greater efficiency when a composite attachment was placed versus no attachment. Further developments by Align Technology, Inc are indicated to increase the efficiency of the Invisalign® system in order to reduce treatment time of the patient and cost to the orthodontist.

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## BIOGRAPHICAL SKETCH

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