Original Article

Assessment of preparation time and 1-year Invisalign aligner attachment survival using flowable and packable composites: *A split-mouth clinical study*

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ABSTRACT

Objectives: To compare preparation time and 1-year Invisalign aligner attachment survival between a flowable composite (FC) and a packable composite (PC).

Materials and Methods: Fifty-five participants (13 men and 42 women, mean age $\pm$ SD: 24.2 $\pm$ 5.9 years) were included in the study. Ipsilateral quadrants (ie, maxillary and mandibular right, or vice versa) of attachments were randomly assigned to the FC group (Filtek Z350XT Flowable Restorative) and the PC group (Filtek Z350XT Universal Restorative) by tossing a coin. The primary outcome was preparation time. The secondary outcome was time to the first damage of an attachment. Preparation times were compared using the paired *t*-test, and the survival data were analyzed by the Cox proportional hazards model with a shared frailty term, with $\alpha = .05$.

Results: The preparation times were significantly shorter with the FC (6.22 $\pm$ 0.22 seconds per attachment) than with the PC (32.83 $\pm$ 2.16 seconds per attachment; $P < .001$). The attachment damage rates were 14.79% for the FC and 9.70% for the PC. According to the Cox models, attachment damage was not significantly affected by the attachment material, sex, arch, tooth location, attachment type, presence of overbite, or occurrence of tooth extraction.

Conclusions: The use of a FC may save time as compared with the use of a PC. With regard to attachment survival, there was no significant difference between the two composites. None of the covariates of attachment materials (sex, arch, tooth location, attachment type, presence of overbite, oir occurrence of tooth extraction) affected attachment damage. (*Angle Orthod.* 2021;91:583–589.)

KEY WORDS: Clear aligner; Attachment; Damage; Flowable composite; Packable composite

INTRODUCTION

Clear aligners (CAs) are removable transparent thermoplastic appliances that are fabricated with stereolithographic technology. With advantages in esthetics, CAs have received much attention and have been improved rapidly, but they also have limitations in efficacy[1] and efficiency,[2] especially in complicated cases. To improve control of tooth movement, attachments with specific geometrical shapes are bonded to the tooth surfaces in strategic positions. The preservation and geometries influence tooth movement, especially with rotations and root control.[3,4] Because attachments are crucial mechanical components, attachment damage may sometimes cause the tooth to not track properly, which may affect treatment results.

Because of the occlusion, the need to chew food and the removal and placement of aligners, attachments made of composite resins cannot be physically preserved with abrasion, fracture or detachment occurring. Although many studies have investigated

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the risks of bracket bonding failure in conventional orthodontic treatment, few studies have reported attachment damage during CA treatment. The reported risk factors of bracket bonding failure include bonding procedure, tooth type, arch, bracket type, initial occlusion, age, sex, and bonding material.[5–8] Some of these risks might also be related to attachment damage.

For the attachment material, flowable composites (FCs) and packable composites (PCs) are commonly used in the clinic in accordance with the Align company's instruction manual. Some of the mechanical properties of flowable nanocomposites are similar to those of PCs, but flowable nanocomposites with the injector design are more convenient to use in the clinic. It has been reported that FCs have a higher bond strength than PCs do.[9] In previous studies, precision of the attachment fit in vitro[10] and surface wear[11] of different composites in the clinic were investigated. However, few studies reported the operating time and attachment damage rate of different materials in CA treatment.

The objectives of this clinical study were to evaluate the performance of an FC and PC on the preparation time of attachments and attachment damage and to investigate the possible risks related to attachment damage in CA treatment.

MATERIALS AND METHODS

Ethical Approval

Ethical approval was granted by the Ethics Committee of the Nanjing Stomatological Hospital (approval number 2017NL-061), and written informed consent was received from all patients. All methods were performed in accordance with the approved guidelines and regulations.

Trial Design and Any Changes After Trial Commencement

The study was a split-mouth randomized controlled trial with a 1:1 allocation ratio of individuals recruited from a single center. No changes were reported after study commencement.

Participants, Eligibility Criteria, and Setting

The recruitment period was from July 2017 to December 2019. The inclusion criteria were (1) no craniofacial anomalies, (2) permanent dentition, and (3) no previous orthodontic treatment with fixed appliances or aligners. The exclusion criteria included (1) crown restorations, (2) congenital enamel defects, (3) active periodontal disease, (4) poor oral hygiene, (5) absence from regular visits, and (6) completion of the first stage of treatment within 1 year.

Interventions

All attachments were bonded by a single senior orthodontist (Dr Li). The materials used included a FC (Filtek Z350XT Flowable Restorative) and a PC (Filtek Z350 XT Universal Restorative). The materials were selected for their physical properties, with the major difference being in the percentage of filler (by weight and volume; Appendix 1).

The clinician bonded the attachments with the instrument reported previously,[11] working one quadrant at a time. All teeth were cleaned with water and pumice slurry for 30 seconds and then dried with an oil-free air syringe. The enamel was then etched for 30 seconds with 35% orthophosphoric acid (Gluma Etch 35 Gel, Heraeus Kulzer, Hanau, Germany), washed with water until clear, and air-dried with oil-free compressed air. The adhesive (Adper Easy One, 3M-ESPE, St Paul, Minn) was applied with a small brush and spread with oil-free compressed air. When the operator worked with each tooth, an experienced assistant cleaned the template, dried it with oil-free compressed air, began the timer, injected the FC or dispensed and pressed the PC into the attachment well of the template, and ended the timer. Then, the operator replaced the prepared template to the teeth, light cured it with an LED lamp (Elipar TM S10, 3M-ESPE) at 1200 mW/cm^2 for 20 seconds per attachment, and removed the flash.

After the appliances were initially placed, the attachments were checked when the patients attended their regular appointments approximately every 8 weeks. A data sheet was used for each patient to record the date of attachment damage and the teeth involved for each patient. Damage was defined as the absence or the presence of residual composite with an irregularly shaped attachment. All patients were observed for 1 year at their regular orthodontic appointments.

Outcomes and Any Changes After Trial Commencement

The primary outcome was the preparation time per tooth for each patient. The secondary outcome was time to the first damage of an attachment. The outcomes were not changed after trial commencement.

Sample Size and Power of the Study

Calculations were based on the primary outcomes. With a sample size of 55 patients, a paired t test was calculated to 83% power to detect an effect size of 0.40 at a level of significance of $\alpha = .05$.

Randomization

The randomization process was as follows: after a coin was tossed, if the character side of the coin was facing upward, the assistant applied the FC to the maxillary and mandibular right regions. If that side of the coin was facing downward, PC was applied. With this method, two quadrants for each patient were randomly assigned to the FC group, and the other quadrants were assigned to the PC group.

Blinding

Although the assistant who put the material into the template could not be blinded to the group assignments, the clinician was not told which attachment material was being used. Patients and evaluators were completely blinded to the group assignments. Incidents of attachment damage were noted in the patient records by other coauthors who were blinded to the study group assignments and did not perform any orthodontic treatment in this study. The grouping situation was coded and kept by the assistant, so both the outcome assessors and the statisticians were blinded to the subjects' allocation. The coding of the data was broken at the end of the analysis, and no breaches of blinding were identified.

Statistical Analysis

SAS 9.4 software and SPSS 25.0 were used for statistical analysis. A paired *t* test was used to compare the preparation time between the two materials after the normality of the data was assessed by the Shapiro-Wilk test. Descriptive statistics were used to summarize the data with means and standard deviations. The clustering effect that occurs within a patient was evaluated using the chi-square test. Kaplan-Meier estimates of the attachment survival curves were plotted. The Cox proportional hazards model with a shared frailty (for within-patient correlations) was used to compare the survival times for several variables simultaneously. The statistical significance was set at the .05 probability level.

RESULTS

Participant Flow

From the patients who were referred to Nanjing Stomatology Hospital, Medical School of Nanjing University, 55 patients who met the inclusion criteria and agreed to participate were selected for this study. Three patients who were initially enrolled were later excluded from further analysis because one patient visited irregularly and two restarted treatment during the first year (Figure 1).

Table 1. Sample Characteristics

	Number	%
Number of patients	55	—
Distribution of patients by gender		
Male	13	23.6
Female	42	76.4
Distribution of patients by age, y		
11–18	16	29.1
19–26	20	36.4
27–34	19	34.5
Mean age, y	24.2 ± 5.9	

Baseline Data

The demographics of the study population are shown in Table 1. The average age of the participants at baseline was 24.2 ± 5.9 years.

Numbers Analyzed for Each Outcome, Estimation and Precision, Subgroup Analyses

The data from 55 patients were used to assess the preparation time (Table 2). The preparation times were significantly shorter with the FC than with the PC ($P <$ .001). When the FC was used, the average prepararion time per attachment was 6.2 ± 0.2 seconds, and when the PCV was used, it was 32.8 ± 2.2 seconds per attachment. The total time saved with FC amounted to 7.3 minutes per patient, with an average of 16.5 attachments.

The data from 52 patients were used to assess the outcomes of attachment damage. The number of attachments per patient was 16.5 ± 0.4 and ranged from 9 to 26 (Figure 2). Nine of 52 patients did not exhibit damage during the first year. Twelve patients had one damage. Fifteen patients had two damages. Nine patients had three damages. Three patients had four damages. Four patients had six damages. The damage rate per person ranged from 0% to 35.3% (12.5% ± 1.3%). The intraclass correlation coefficient (ICC) was .01.

During the first 4-month observation period, 66 attachments were damaged: 41 (9.62%) in the FC group and 25 (5.77%) in the PC group. During the second 4-month observation period, 29 attachments were damaged: 15 (3.90%) in the FC group and 14 (3.43%) were in the PC group. During the last 4-month observation period, 13 attachments were damaged: 7

Table 2. Preparation Time per Attachment by Material Type

Attachment Type	Time, Mean ± SD, s
FC	6.2 ± 0.2*
PC	32.8 ± 2.2*

* Statistically significant differences between adhesives (paired *t*-test, $P <$ .001).

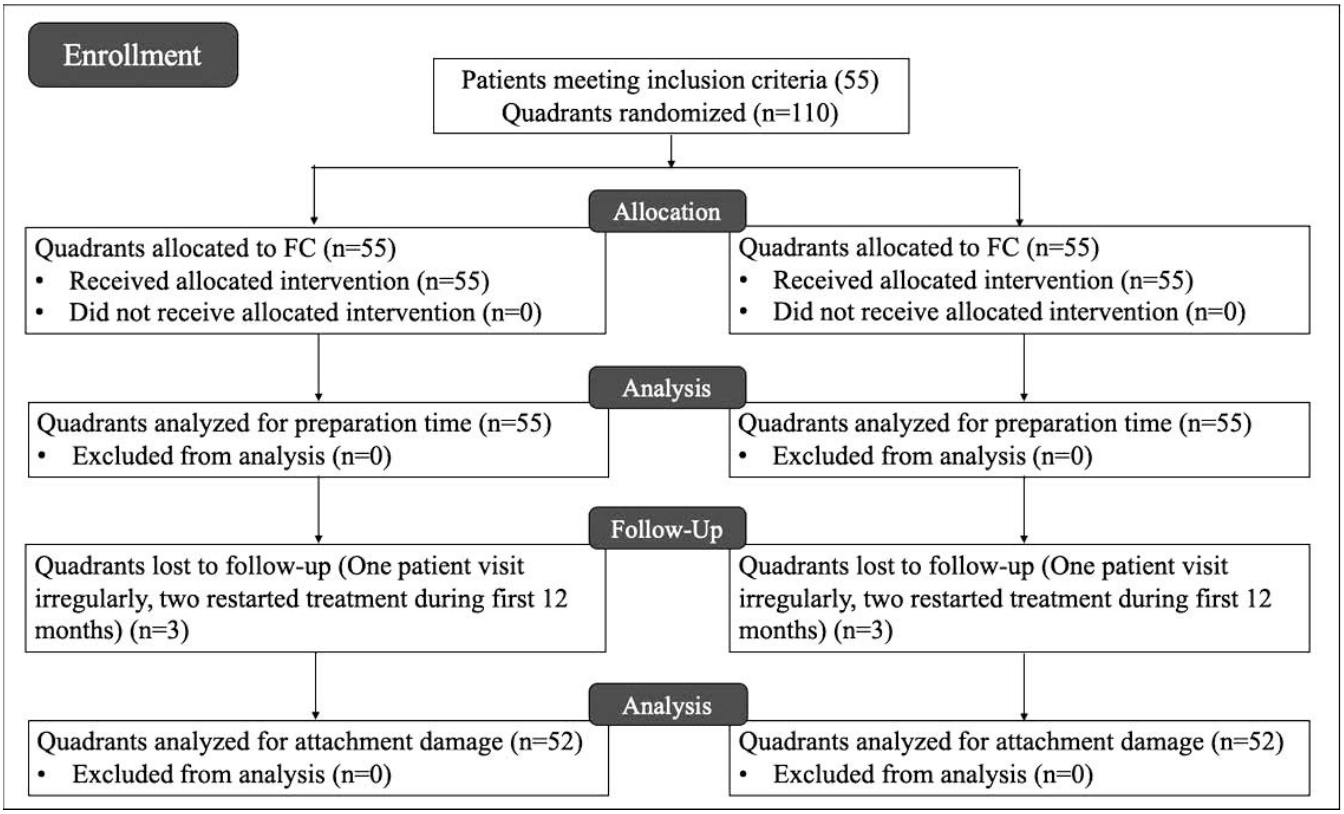

Figure 1. CONSORT participant flow diagram.

(1.89%) in the FC group and 3 (0.76%) in the PC group. At the end of 1 year, the overall damage rate was 14.79% (63 attachments) for the FC group and 9.70% (42 attachments) for the PC group (Table 3).

The attachment survival data were tested by the Cox proportional hazards model with a shared frailty (for within-patient correlations) with the attachment materials, sex, arch, tooth type, attachment type, presence

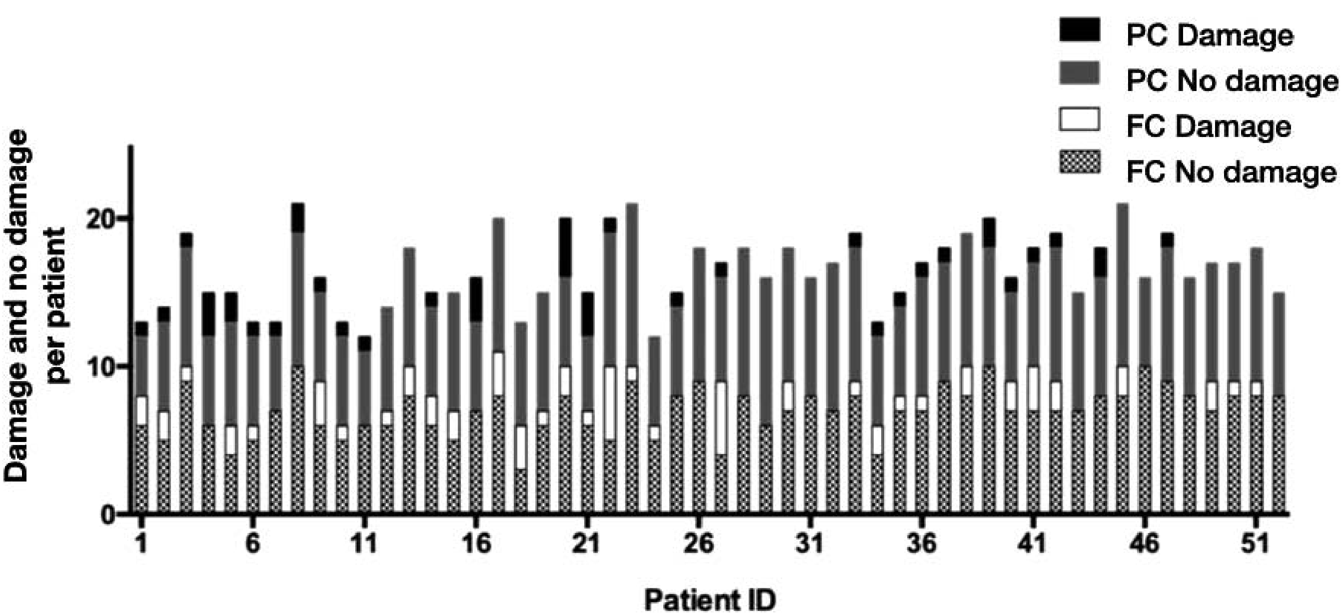

Figure 2. Histogram showing clustering of damages within patients. The *x*-axis shows the patient ID, and the *y*-axis indicates the damage and no damage number per patient.

Table 3. Attachment Damage by Attachment Material Type at 1 Year

Material	FC			PC		
	Damage	No Damage	Damage Rate, %	Damage	No Damage	Damage Rate, %
First 4 mo	41	385	9.62	25	408	5.77
Middle 4 mo	15	370	3.90	14	394	3.43
Last 4 mo	7	363	1.89	3	391	0.76
Total 12 mo	63	363	14.79	42	391	9.70

of overbite, and occurrence of tooth extraction as covariates. The results showed insignificant differences between the variates (Table 4). A Kaplan-Meier survival graph for the material types is shown in Figure 3.

DISCUSSION

Study Design

A split-mouth design was used in this study, in which two quadrants were considered as a cluster within each patient. In this study, the ICC was .01, which was similar to that reported previously regarding bracket bonding failures. In the current study, an attachment damage as an observation within a cluster was not independent. Thus, clustered trials often require larger sample sizes and specific analyses.[12]

Because the patients acted as their own controls, this design minimized bias and the influence of interindividual differences on the results. This design also ensured that the number of attachments was balanced within the groups and subgroups regarding factors such as the material, tooth type, and attachment type. Therefore, the split-mouth design for comparing two composites was considered appropriate, as it led to a higher statistical power than did conventional parallel designs.[13,14]

Main Findings

This study showed that the preparation time of the FC was significantly shorter (one-fifth) than that of the PC. This result was in accordance with expectations, because the dosage of composite for each attachment can be better controlled through an injector-like design, and the FC had good fluidity. In contrast, the dosage of the PC should be estimated and adjusted after it is placed into the mold and pressed flat.

The 1-year attachment damage rate was 14.79% for the FC and 9.70% for the PC (overall, 12.22%). The damage rates were higher than the first-year damage rate for orthodontic brackets, which has been reported to range from 2.67% to 2.8% in previous studies.[7,8] The causes of the higher damage rate for attachments than with fixed appliances may due to the repeated removal of aligners and less attention being paid to diet during CA treatment. In addition, most attachment damages occurred in the early stage of treatment, which was in agreement with results reported for brackets.[15] This finding may be explained by deficiencies in bond strength caused by the bonding operation, acclimatization of the patients to putting on and removing aligners, and the types of food the patients ate.

Because the clustering effect should be taken into consideration when attachment damages are observed, a Cox proportional hazards model with a shared frailty was used to analyze the survival data. Although the first-year damage rate of the FC seemed higher than that of the PC, the results of survival data considering the clustering effect showed no significant difference between the two composites. Although an FC was reported to have higher bond strength than a PC in an in vitro study,[9] it showed similar clinic performances from a 1-year clinical evaluation of an FC and a PC used as an occlusal restorative material.[16] In addition, the bond damage rate and survival time were affected not only by the bond strength but also by patients' habits and diets. The two composites were considered similar in terms of performance and the use of the FC saved more time, which may suggest that the FC should be used more often for attachments in CA treatment.

Table 4. Results of Cox Proportional Hazards Model With a Shared Frailty

Parameter	Parameter Estimate	Standard Error	Chi-Square	*P*	Hazard Ratio	95% Hazard Ratio Confidence Limits	
Materials	0.01	0.07	0.02	0.88	1.01	0.88	1.17
Arch	−0.01	0.07	0.01	0.93	0.99	0.86	1.15
Tooth type	0.00	0.04	0.00	0.99	1.00	0.92	1.09
Sex	−0.00	0.09	0.00	1.00	0.10	0.84	1.18
Attachment type	−0.01	0.10	0.00	0.95	0.99	0.82	1.20
Overbite	−0.00	0.08	0.00	0.97	1.00	0.85	1.17
Extraction	−0.01	0.08	0.01	0.92	0.99	0.85	1.16

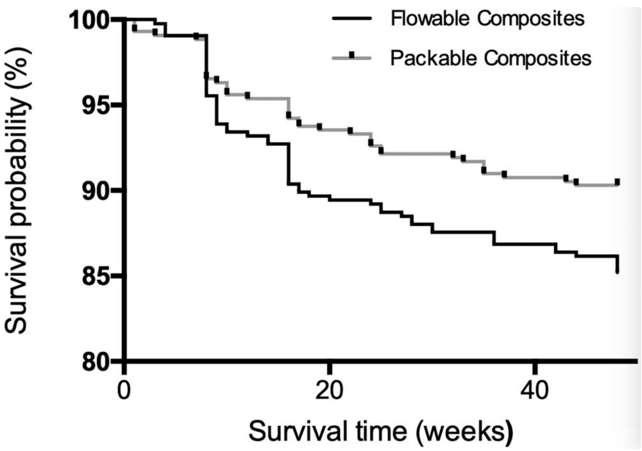

Figure 3. Kaplan-Meier survival curves for the flowable composite group and the packable composite group for the 1-year observation period. The *y*-axis indicates survival percentage of the attachments. The *x*-axis indicates the follow-up period in weeks.

In addition to attachment materials, attachment damage was not affected by other potential risk factors, including arch, tooth type, sex, attachment type, presence of overbite, and occurrence of extraction. Some previous studies on bracket bonding failure reported similar findings, showing that sex, arch, and the occurrence of tooth extraction did not affect bracket failure.[17–19] However, some studies showed that bracket failure was significantly affected by the presence of deep bite and tooth type.[19,20] Attachment damage in the current study was not affected by the presence of deep bite, which might have been due to the advantage of using computer-aided design for avoiding occlusal interference. The damage rate of molars (17.7%) was higher than those of incisors (9.6%), canines (11.1%), and premolars (9.3%), but there was no significant difference when the clustering effect was taken into account (Appendix 2). More studies with larger sample sizes are needed in the future. However, it is suggested that clinicians weigh this potential factor and pay attention to moisture isolation in the posterior part of the arch.

Limitations

The results found in this study might be limited by the fact that this study was performed in a single center by a single clinician. Although the operator-dependent parameters were controlled, the results may not be widely applicable to other operators.

Only the Filtek Z350XT Flowable Restorative and Filtek Z350 XT Universal Restorative composites were tested. The results cannot be generalized to all FCs and PCs.

Although a prospective study was conducted and the clustering effect was taken into consideration when investigating possible risk factors related to attachment damage, more studies with larger sample sizes are needed in the future.

CONCLUSIONS

- The use of an FC may reduce the preparation time for clear aligner attachments to one-fifth of that required for a PC.
- Attachment damage was not affected by differences between the two composites, tooth location, tooth type, sex, attachment type, presence of deep bite, or occurrence of tooth extraction.

ACKNOWLEDGMENTS

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SUPPLEMENTAL DATA

Appendix 1 and 2 are available online.

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