



Original Article

Evaluation of the Flash-Free Adhesive System for a 6-month Period: A Split-Mouth Trial

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Main Point

- The novel APC flash-free adhesive system is effective as well as efficient.

ABSTRACT

Objective: To compare the adhesive pre-coated (APC) flash-free (FF) appliance system (3M Unitek) with an operator-coated (OC) system (Transbond XT Light Cure Adhesive Paste; 3M Unitek) in terms of bond failure, bracket survival, and chair time.

Methods: This single-center study was planned with 30 non-extraction patients, 22 females and 8 males with an average age of 17 years and 5 months. A split-mouth design was used, and bonding time, failed brackets, reasons for failure, and adhesive remnant index (ARI) scores were noted. The data were analyzed with the chi-square, Kaplan-Meier, log-rank, and Mann-Whitney U tests.

Results: OC and FF adhesive-coated brackets demonstrated bond failure rates of 0.7% and 3.0%, respectively. Failure rates and survival rates presented a statistically significant difference ($p=0.033$). Although higher bond failure for the lower arch along with higher bond failure for the incisor teeth compared with the premolar teeth were found, these findings were not statistically significant ($p=0.128$; $p=0.261$, respectively). The effect of gender on the bond failure rate ($p=0.463$) and survival rate ($p=0.473$) was not statistically significant. A significant difference was obtained for the ARI scores ($p=0.011$). The bonding time for each bracket type (64.43 seconds for FF versus 98.97 seconds for OC) demonstrated a significant difference ($p=0.174$).

Conclusion: The bond failure rate was higher for the FF APC brackets, but the chair time reduction during bonding was recorded. Therefore, it seems that FF APC brackets are promising. Trial registration: ISRCTNand ISRCTN26731749. Registered October 7, 2020-Retrospectively registered, <https://doi.org/10.1186/ISRCTN26731749>

Keywords: Orthodontics, APC flash-free adhesive, bracket failure, bracket survival, and bonding time

INTRODUCTION

Bond failure hinders the efficiency of fixed orthodontic appliance therapy. Thus, a bond failure rate as low as possible is fundamental.¹ A survey reported a median bond failure rate as 5% for labial appliances.² Furthermore, an increase in the use of ceramic and adhesive pre-coated (APC) brackets was reported.² APC brackets were introduced approximately 30 years ago.³ From then on, various APC bonding systems were developed.⁴ In 2013, an APC flash-free (FF) adhesive coated appliance system was introduced. The FF adhesive is made up of a compressible fiber mat, soaked with an adhesive resin attached to the bracket base. This innovative design eliminates the flash removal step. Furthermore, the bond failure rate has been reported to be less than 2% with this unique technology.⁴ To date, three studies evaluating the bond failure rate of the FF adhesive appliance system have been conducted,⁵⁻⁷ which were performed with a split-mouth design. The efficiency of a split-mouth design to assess bonding agents has been stated.⁸ The study by Grünheid and Larson⁵ compared the bonding

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time and bracket failure rate of ceramic brackets over 1 year between the FF adhesive and a conventional adhesive. It was reported that the bonding time was significantly shorter with the FF adhesive, resulting in a time saving of approximately 30%. The bracket failure rate was 3.7% for the FF adhesive and 0.9% for the conventional adhesive. This outcome was found to be statistically equivalent. In the second study,⁶ which was a continuation and completion of the aforementioned study,⁵ the bracket failure rate was 4.3% for the FF adhesive and 1.9% for the conventional adhesive. The bracket failure and survival rates were not significantly different between the 2 adhesives. Also, no significant differences between the adhesive remnant index (ARI) scores were obtained. Finally, Tümoğlu and Akkurt⁷ compared the bonding time and bond failure rate between the FF adhesive and a conventional adhesive using 0.018-inch-slot Clarity Advanced Ceramic brackets. The bond failure rates of the FF adhesive and the conventional adhesive were 1.21% and 1.81%, respectively. The bond failure rates were significantly different. The ARI scores did not demonstrate a significant difference. The FF bracket bonding time was significantly shorter. Bond failure rate is an acknowledged method for assessing bracket performance. Bond failure mainly occurs during the first 6 months of treatment.⁹ In addition to the simple fact of bond failure, the survival rate presents the interval before bond failure.¹⁰

The objectives of this single center trial were as follows:

1. To compare the bond failure and survival rates of the APC FF Adhesive Coated Appliance System (3M Unitek) with an operator-coated (OC) system (Transbond XT Light Cure Adhesive Paste; 3M Unitek) for 6 months.
2. To compare the bond failure and survival rates of the upper and lower arches.
3. To compare the bond failure and survival rates of incisor, canine, and premolar teeth.
4. To compare the bracket failure and survival rates with respect to gender.
5. To compare the ARI scores.
6. To compare the chair time for each bonding procedure.

The null hypothesis was that there would be no difference in these parameters.

METHODS

Ethics approval was obtained from the Ondokuz Mayıs University Clinical Research Ethics Committee (OMÜ KAEK 2018/416). To determine the sample size for this trial, a power analysis using the G*Power software version 3.1.9.2 (University of Düsseldorf, Germany) was conducted, based on a previous trial.^{11,12} It was found that a minimum of 27 patients were needed to observe a 4.2% difference in failure rates, with a power of 90% at a

confidence rate of 95%. To account for potential dropouts, a total of 30 patients were enrolled. Patients included in the study had fully erupted maxillary and mandibular teeth with intact buccal enamel and were treated with a non-extraction protocol. They had Angle Class I or mild Class II malocclusion with normal overbite and teeth alignment without severe dental rotations. They had not undergone pretreatment of the enamel with any chemical agents and had good oral hygiene. Patients with skeletal problems, missing teeth, systematic disease and a previous history of orthodontic treatment were not included. Every patient and legal guardian (if the patient was under the age of 18) signed the informed consent. Table 1 presents the characteristics of the patient samples. Before the start of the trial, study models, X-rays, and photographs were obtained. 0.022 inch slot MBT prescription Clarity Advanced Ceramic Brackets (3M Unitek) were used. These brackets, designated as Interventions A and B (Figure 1), were bonded using OC and FF systems with the split-mouth method. The OC brackets were bonded with a conventional light cure adhesive (Transbond XT, 3M Unitek).

Light curing was carried out on the facial surface for 5 seconds using a new LED curing light (Elipar™ DeepCure-L, 3M Unitek) with an output power of 1470 mW/cm² (milliwatts/square

Table 1. Sample characteristics

	Number	%
Number of total patients	30	-
Distribution of patients by gender		
Female	22	73.3
Male	8	26.7
Age range of patients		
13-22 years		
Distribution of patients by age		
<18	24	80
>18	6	20
Average age		
17 years 5 months		
Number of total brackets	600	
Distribution of brackets by gender		
Female	440	73.3
Male	160	26.7
Distribution of brackets by dental arch		
Upper	300	50
Lower	300	50
Distribution of brackets by tooth type		
Incisor	240	40
Canine	120	20
Premolar	240	40
Distribution of brackets by adhesive type		
Flash-free adhesive	300	50
Operator-coated adhesive	300	50

centimeter) and a wavelength range of 430-480 nanometers for both interventions. The distance between the light guide tip and the bracket base was approximated at 5 millimeters (mm) for optimum polymerization.^{5,13}

The time required to bond each adhesive system was recorded. For FF, timing was started with the opening of each blister packaging and removal of the bracket until the completion of light curing for ten brackets (i.e., for both quadrants). For OC, timing was started from bracket removal until the completion of light curing. The maxillary and mandibular molar tubes, which were not evaluated in this study, were bonded with Transbond XT. Following the bonding procedure, patients received either a 0.014 or a 0.016 inch heat-activated nickel-titanium (HANT) arch wire, depending on their specific needs. Nevertheless, the following wire sequence was mainly used: round HANT, rectangular HANT, and rectangular stainless steel wires. Elastic and wire ligatures were used as needed.

Instructions for oral hygiene and care were provided to all patients and parents (if the patient was under the age of 18). All patients used the same orthodontic toothbrush (TePe, Sweden), floss (Oral-B Super floss), and toothpaste (Sensodyne

Promine, Glaxo SmithKline, Brantford, Middlesex, UK). Patients were meticulously instructed to immediately report any issues concerning their appliances to the clinician for record keeping purposes (Table 2). The ARI is scored on a scale of 0 to 3, with higher scores indicating greater amounts of adhesive remaining on the tooth surface. To interpret the ARI values the following scale, based on the work of Artun and Bergland,¹⁴ was used: ARI score 0: no adhesive remaining on the tooth surface; ARI score 1: less than half of the adhesive remaining on the tooth surface; ARI score 2: more than half of the adhesive remaining on the tooth surface; ARI score 3: all adhesive remaining on the tooth surface.¹³ Only the first bond failure was registered. All clinical procedures were performed by one operator (DB) under the supervision of one faculty member (SET).

Statistical Analysis

Data were analyzed using a Statistical Package for the Social Sciences [(SPSS Inc., Chicago; IL, USA)]. The bond failure rates were determined for each bracket adhesive system, dental arch, type of tooth (incisor, canine, and premolar), and patients' gender. The chi-square test was used to compare the failure rates. The survival rates were estimated with the Kaplan-Meier

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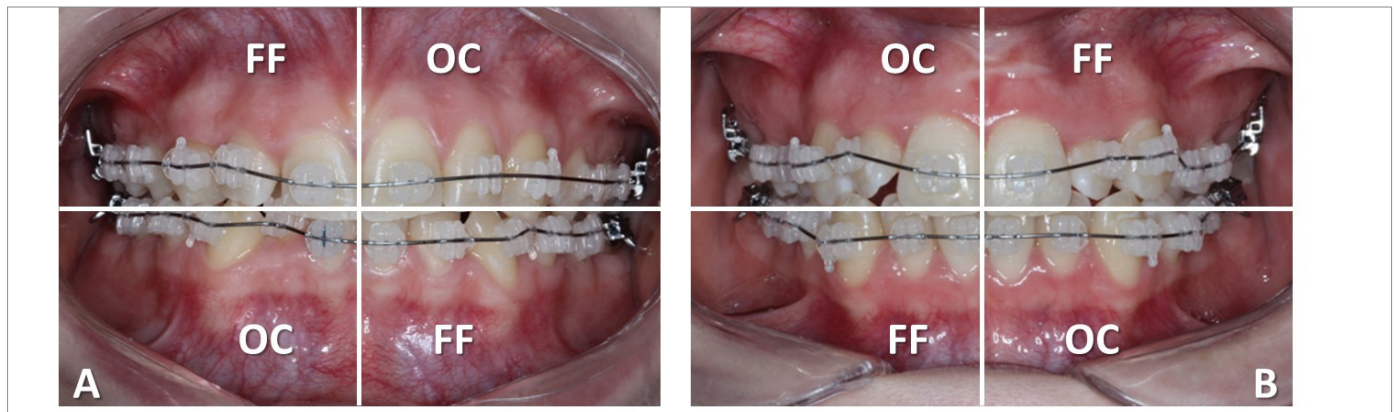


Figure 1. Intervention A and intervention B
FF, flash-free; OC, operator-coated

Table 2. Bond failure details*									
Case	Gender	FF				OC			
		1 st 3 months	2 nd 3 months	ARI	Reason	1 st 3 months	2 nd 3 months	ARI	Reason
TA	♀	31 & 32**	---	0 & 0	Unknown	---	---	---	---
INU	♀	31	---	0	Unknown	---	---	---	---
USA	♀	31 & 33***	---	0 & 0	Popcorn and unknown	---	---	---	---
CA	♀	45	---	0	Olive pit	---	---	---	---
YD	♀	---	35	0	Olive pit	---	---	---	---
MD	♂	---	4**	0	Bread crust	---	15**	3	Bread crust
MBK	♂	---	22	3	Football trauma	12	---	3	Football trauma

♀, female; ♂, male
 *FDI (Fédération Dentaire Internationale) dental numbering system was used
 **Failure at the same time point
 ***Failures at different time points
 ARI, adhesive remnant index; FF, flash-free; OC, operator-coated

test. Bracket survival distributions with respect to the bracket adhesive system, dental arch and type of tooth (incisor, canine and premolar) as well as patients' gender were compared with the log-rank test.

The differences in ARI scores between the failed brackets were determined with the chi-square analysis. Bonding time was measured in seconds for each adhesive bracket system in the two quadrants and divided into 10 (number of teeth). The difference between bonding times was compared with the Mann-Whitney U test. The significance was set at $p < 0.05$ for all tests.

RESULTS

During the observation period (6 months), 11 brackets failed: 2 (0.7%) for OC and 9 (3.0%) for FF (Table 3). A significant difference was found between the failure rates ($\chi^2=4,538$; $p=0.033$). The survival curves were plotted with the Kaplan-Meier estimate (Figure 2). The bracket type showed a significant influence on the survival rates (Table 3; $p=0.033$). The probabilities of having brackets in place at the end of the observation period were 0.993 and 0.970 for the OC and FF brackets, respectively. Bond failure rates were 1.0% (3 brackets) and 2.7% (8 brackets) in the upper and lower arches, respectively. The difference was not statistically significant (Table 4; $p=0.128$).

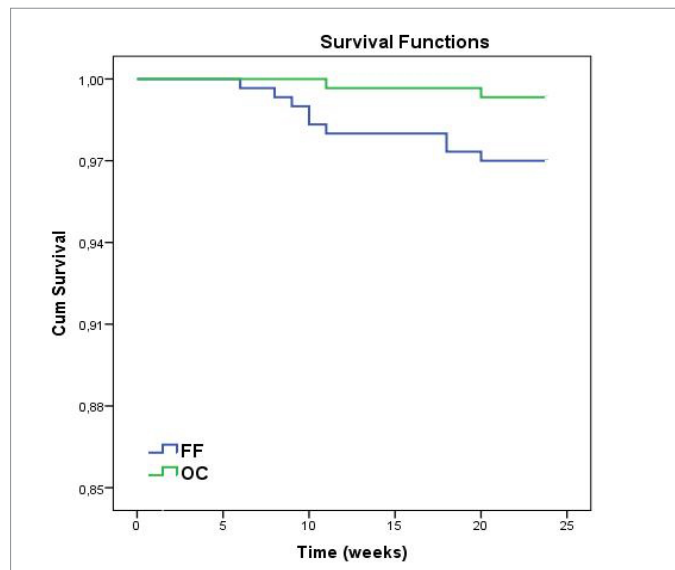


Figure 2. Bracket survival distributions
FF, flash-free; OC, operator-coated

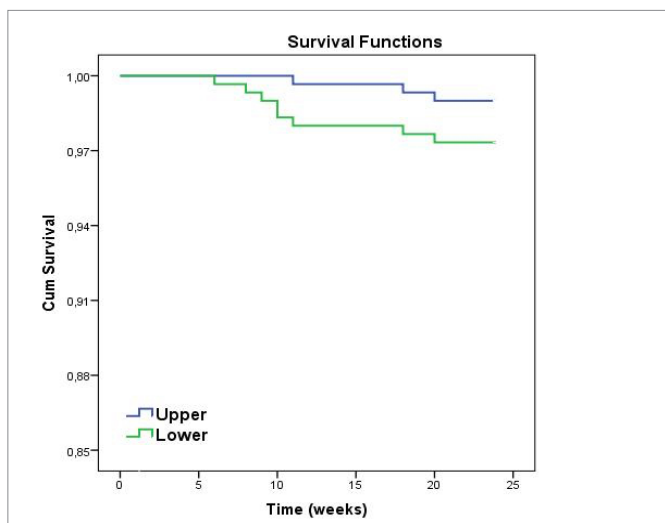


Figure 3. Bracket survival distribution for the dental arches

Table 3. Bond failure rate

OC			FF			p-value	Log-rank test
No failure	Failure	Failure rate	No failure	Failure	Failure rate		
298	2	0.7%	291	9	3.0%	0.033*	0.033

$\chi^2=4,538$ on 1 df
FF, flash-free; OC, operator-coated, *: $p < 0.05$

Table 4. Bond failure rates for the upper and lower dental arches*, for tooth type (incisor, canine and premolar)** and for female and male subjects***

	No failure	Failure	Failure rate	Log-rank test
Upper	297	3	1.0%	0.128
Lower	292	8	2.7%	
Incisor	233	7	2.9%	0.261
Canine	119	1	0.8%	
Premolar	237	3	1.3%	
Females	436	7	1.6%	0.463
Males	153	4	2.5%	

* $\chi^2=2,315$ on 1 df; $p=0.128$
 ** $\chi^2=2,686$ on 2 df; $p=0.261$
 *** $\chi^2=0,539$ on 1 df; $p=0.463$

The influence of the dental arches on the bracket survival rate is depicted in Figure 3. The log-rank test showed no significant difference between the upper ($S[t]=0.990$) and lower ($S[t]=0.973$) dental arches ($p=0.126$). Bond failure rates were 2.9% (7 brackets) for incisor, 0.8% (1 bracket) for canine, and 1.3% (3 brackets) for premolar teeth (Table 4). Significant differences did not exist for the failure rates of incisor, canine, and premolar teeth (Table 4, $p=0.261$). Figure 4 depicts the influence of tooth type on the bracket survival rate. The log-rank test demonstrated no significant differences between the incisor, canine, and premolar teeth in terms of survival rate ($p=0.260$).

Female and male patients presented with a 1.6% (7 brackets) and 2.5% (4 brackets) failure rate, respectively (Table 4). This difference was not statistically significant ($p=0.463$). The influence of gender on the bracket survival rate is shown in Figure 5. No significant difference between females ($S[t]=0.984$) and males ($S[t]=0.975$) was obtained using the log-rank test ($p=0.473$). The frequency distribution and the result of the χ^2 analysis of the ARI scores are given in Table 5. A significant difference was obtained ($p=0.011$).

Bonding times demonstrated a significant difference ($p=0.174$).

DISCUSSION

During the first 6 months of treatment, the failure rates were 0.7% (2 failures) for the OC brackets and 3.0% (9 failures) for the

FF brackets. These bond failure rates demonstrate a statistically significant difference, which is consistent with the findings of Tümoğlu and Akkurt.⁷ Nevertheless, these researchers compared the FF brackets (1.21%) with the APC Plus brackets (1.81%). The findings of our study did not concur with the findings of Grünheid and Larson.^{5,6} These researchers did not obtain a significant difference in the failure rates between FF brackets (3.7%; 4.3%) and APC II brackets (0.9%; 1.9%) during a longer observation period of 1 year and 19.9±5.4 months, respectively. In this study, the survival analysis for the OC (0.993) and FF brackets (0.970) showed a statistically significant difference. The survival analysis graph for the FF brackets and Table 2 demonstrate that most FF brackets (6 brackets out of 9 brackets) failed within the first 3 months of the 6 months observation period. Two patients reported specific reasons (olive pit, popcorn) for their bond failures (tooth 45, tooth 31). The remaining bond failures occurred in teeth 31 (2 failures), 32 and 33 with no specific reasons given by the patients. These failures may have resulted from inadequate enamel etching, poor moisture isolation, or inexpert handling of the brackets by the operator (DB), a second year resident. One OC bracket failed within the first 3 months (tooth 12) due to a soccer trauma.

Grünheid and Larson^{5,6} also carried out a survival analysis of their data and did not obtain a statistically significant difference. In fact, an equivalent number of bonds (two for each adhesive)

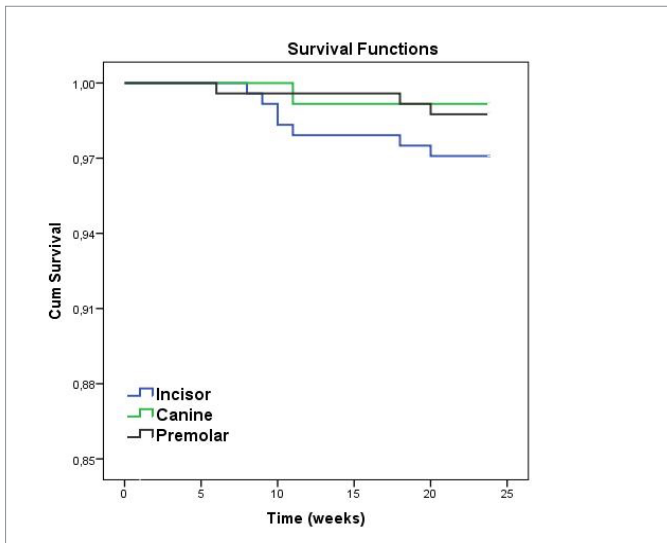


Figure 4. Bracket survival distribution for tooth type (incisor, canine and premolar)

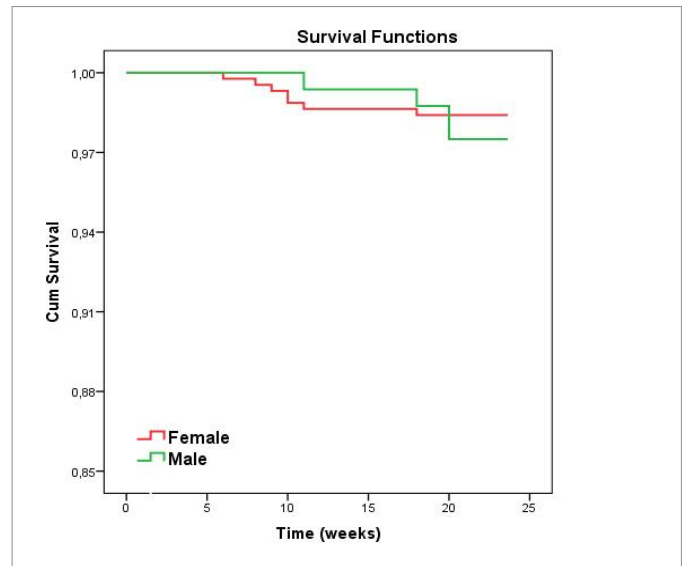


Figure 5. Bracket survival distributions for gender

Table 5. Frequency distribution and the result of the χ^2 analysis for the ARI*

	ARI scores				Total
	0	1	2	3	
OC	-	-	-	2	2
FF	8	-	-	1	9

* $\chi^2=6,519$ on 1 df; $p=0.011$
ARI, adhesive remnant index; FF, flash-free; OC, operator-coated

failed during the first 3 months. However, these authors only evaluated the maxillary arch.

The comparison of clinical studies is difficult and must be carried out with caution due to differences in various aspects. For instance, the observation periods, number and experience of the operators, arch evaluation (maxillary arch only or both maxillary and mandibular arches), type of arch evaluation (an emphasis on quadrants), type of adhesives and bracket slot systems used. It has been reported that 0.018-inch slot brackets result in a greater number of bond failures than 0.022-inch slot brackets.¹⁵ Furthermore, the inability to maintain the light-tip distance of 5 mm may have affected the degree of polymerization and bond durability.¹⁶ In this study, the failure rate was 1% (3 brackets) for the maxillary arch and 2.7% (8 brackets) for the mandibular arch, with no statistical difference obtained for the failure and the survival rates. Nevertheless, the mandibular bonds failed more frequently and sooner when compared to the maxillary bonds. This outcome may be attributed to factors such as not abiding by the diet recommendations and potential traumatic occlusal contacts on the mandibular bonds. Poor control of moisture and saliva contamination control during bonding, when compared to the maxillary arch, may also have occurred. An effort to mitigate potential traumatic occlusal contacts, through a layer of cement placed on the molar occlusal surfaces for disclusion, might have lowered the failure of the mandibular bonds.¹⁵

It is noteworthy that all of the mandibular bonds (8 brackets) that failed belonged to the FF brackets. An *in vitro* study¹⁷ compared 3 bonding systems (3M Unitek). The first group was bonded with the FF system, the second group with the APC Plus system, and the third group was manually bonded with the Transbond XT adhesive. One type of ceramic bracket (Clarity Advanced, 3M Unitek) was used. The three adhesive systems achieved comparable values; however, the mean shear bond strength (SBS) value for the FF group was lower when compared to the other groups. It is important to note that the FF adhesive is a low viscosity adhesive. Previous research has linked low viscosity, i.e., lower filler content, with reduced SBS.¹⁸ Based on this information and the data from our study for the mandibular arch, it is possible that there is a threshold level for the FF adhesive, beyond which bond failure is likely to occur. The manufacturer determines the precise amount of low viscosity adhesive for each tooth type in the FF bracket mat. However, variations in tooth crown contour can weaken bond formation and compromise reliability. In contrast, Tümoğlu and Akkurt⁷ reported only one FF bond failure for the mandibular arch. The significant difference between their study and the current study, which found eight FF bracket failures is likely due to the difference in methodology. Tümoğlu and Akkurt⁷ worked on a quadrant basis; whereas in the current study acid etching was performed simultaneously on both upper and lower arches, making saliva and/or moisture contamination a possible factor.

During the current study, bond failures occurred with seven incisors, one canine, and three premolar brackets. Nevertheless,

no significant differences were observed for the failure or survival rates. What is striking is that, despite the lack of a statistical significance, the anterior teeth (incisors and canine) experienced more bond failures than the posterior teeth. This finding contrasts with other studies, where more posterior than anterior bond failures were observed.^{1,7,9,12,15} Similar to the current study, Manning et al.¹⁹ also reported more anterior bond failures and suggested that habits, such as nail biting and pen chewing might contribute to this outcome. It has been reported that canines demonstrate the lowest bond failure rate.¹ Linklater and Gordon¹⁵ stated that a potential contributing factor might include increased masticatory loading of the canines. Furthermore, these researchers¹⁵ pointed out that moisture control of the mandibular canines is a greater challenge compared to the maxillary canines during bonding. In this study, one failure occurred with the mandibular left canine. No specific reason for this failure could be provided by the patient; thus, saliva and moisture contamination during the bonding process and inexpert handling by the right handed operator might have been the culprit for this bond failure. Right-handedness has been linked to superior bonding accuracy and moisture control on the right compared to the left side of the mouth.^{7,20} A mild Class II canine relationship may have compounded this outcome.

Adolfsson et al.²¹, speculated that females are more careful with their appliances than males. Thus, a higher bond failure rate for males was anticipated in this study. However, the bond failure and bracket survival rates did not demonstrate statistically significant differences. This might indicate that bond failure is strictly patient-related and gender-neutral. The bond failure sites were evaluated using the ARI. Both adhesives demonstrated a statistically significant difference. Most FF brackets (8 out of 9) had a score of 0 (no adhesive left on the tooth), indicating that bonds mainly failed at the mat-tooth interface. This outcome is consistent with Grünheid and Larson.⁵ However, Grünheid et al.¹³, suggested that the mat-tooth interface is not typically the site of failure, and that severance at the bracket base mat interface is predetermined due to a lower material density at that site. Hence, the outcome of this study, with an ARI score of 0 for 8 failures, is unexpected. ARI scores provide insight into the reason for failure, thus, this outcome may suggest inadequate etching and/or moisture or saliva contamination, which can prevent reliable bonding with the enamel. In this study, significant differences for the bonding times were obtained. This is not surprising given that two steps (adhesive application and flash clean-up) were eliminated with the FF bracket (mean: 64.43 seconds for one bracket) compared to the OC bracket (mean: 98.97 seconds for one bracket). Although, direct comparisons to the studies of Grünheid and Larson⁵ and Tümoğlu and Akkurt⁷ are not possible, these studies^{5,7} also reported a significantly shorter bonding time. Cumulative time savings during the bonding of the upper and the lower arches with the FF system may enhance patient comfort by reducing chair time. The reduction in chair time might also imply a reduction in aerosols and droplets.

The current study used identical, polycrystalline, true twin brackets with a microcrystalline base design containing a stress concentrator. These ceramic brackets differed only regarding the adhesive on the bracket base. Notably no fractures of any ceramic bracket occurred. Eleven failed brackets did not have any fractures as well, i.e., they failed “intact” and remained ligated to the arch wire. This is a reassuring outcome, because tie-wing fractures may lead to numerous problems. Such fractures prevent efficient arch wire ligation and increase the risk of complete fragmentation of the bracket. Ceramic bracket fragments may become embedded in the oral soft tissues or they may be inhaled and/or swallowed. These fragments are radiolucent. Thus, not visible on radiographs.²²

The short observation period and the Hawthorne effect are the two main limitations of this study. The Hawthorne effect has been described as an alteration in the patient's or therapist's behavior due to the awareness of being observed during a study.²³ This “good trial behavior” might lead to a superior performance of the participants. As a consequence, overoptimistic findings may be obtained. It has been pointed out that a short observation period, such as 6 months, might increase the risk of this effect.^{24,25} Furthermore, an orthodontic adhesive system must be able to withstand the challenges posed by the oral environment.²⁶ The mean orthodontic treatment duration has been reported as 30.6 months.¹ Therefore, an extended observation period of preferably more than 12 months, would be necessary for the persistent and various degrading factors affecting this new technology in the oral environment^{6,27} and mitigate the Hawthorne effect. Last but not least, future *in vitro* and *in vivo* research elucidating the effects of fluoride and non-fluoride remineralization agents with this new technology could be very interesting and beneficial, particularly since the APC FF adhesive does not release fluoride.^{28,29}

CONCLUSION

The null hypothesis was rejected for parameters 1, 5, and 6, indicating a statistical difference in failure rates between the two adhesive systems. Despite this, the results for the FF brackets are promising. A significant difference in ARI scores was also found between the two systems. Six of the nine ARI scores for the FF adhesive system had a score of 0 during the first 3 months, indicating possible saliva or moisture contamination and inadequate handling during the bonding procedure. The bonding times were also significantly different between the two adhesive systems, suggesting that the FF adhesive system may improve patient comfort.

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Ethics

Ethics Committee Approval: Ethical committee approval was received from the Ondokuz Mayıs University Clinical Research Ethics Committee (approval no: OMÜ KAEK 2018/416).

Informed Consent: Written informed consent was obtained from all participants who participated in this study.

Peer-review: Internally peer-reviewed.

Author Contributions: All of the following steps (conception of this work, data collection, data analysis and interpretation, drafting and the critical revision of this article as well as the final approval of the version to be published) were carried out by D.B. and S.E.T.

Declaration of Interests: The authors have no conflicts of interest to declare.

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