Original Article

A comparative assessment of bracket survival and adhesive removal time using flash-free or conventional adhesive for orthodontic bracket bonding: *A split-mouth randomized controlled clinical trial*

Thorsten Grünheid[a]; Brent E. Larson[b]

ABSTRACT

Objectives: To compare bracket survival and adhesive removal time between a flash-free and a conventional adhesive for orthodontic bracket bonding.

Materials and Methods: Forty-five consecutive patients had their maxillary incisors, canines, and premolars bonded with ceramic brackets using a flash-free adhesive (APC Flash-Free Adhesive, 3M Unitek, Monrovia, Calif) on one side and a conventional adhesive (APCII Adhesive, 3M Unitek) on the other side. The side allocation was randomized. Bracket failure was recorded at 4-week intervals. The adhesive remnant index (ARI) was scored on debond and adhesive removal timed to the nearest second. The primary outcome was adhesive removal time per quadrant. Secondary outcomes were bracket failure rate, time to first-time failure of a bracket, and ARI score on debond. Paired *t*-tests were used to compare adhesive removal times and ARI scores between the adhesives with $P < .05$ considered statistically significant.

Results: Bracket failure rates were 4.3% for the flash-free adhesive and 1.9% for the conventional adhesive, with mean times to first-time failure of 31 weeks for the flash-free adhesive and 42 weeks for the conventional adhesive; neither failure rates nor times to first failure were significantly different. Although the flash-free adhesive left significantly more adhesive on the tooth surface after debonding, the adhesive removal times were 22.2% shorter than with the conventional adhesive.

Conclusions: Bracket survival with the flash-free adhesive was equivalent to the conventional adhesive when ceramic brackets were bonded. Adhesive removal was significantly faster when using the flash-free adhesive, which may result in time savings of more than 20% compared with the conventional adhesive. (*Angle Orthod.* 2019;89:299–305.)

KEY WORDS: Bracket survival; Adhesive removal time; Adhesive; Bonding

INTRODUCTION

A recently developed flash-free adhesive for orthodontic bracket bonding (APC Flash-Free, 3M Unitek [3M], Monrovia, Calif) promises to eliminate the flash removal step in bracket bonding. The flash-free adhesive is contained within a nonwoven polypropylene fiber mesh on the bracket base, which can be applied to any orthodontic bracket during the manufacturing process. When such a bracket is placed on a tooth, some of the low-viscosity adhesive is squeezed out of the mesh and forms a filleted edge around the bracket with no flash to clean up. The low viscosity is achieved by a lower filler content of the flash-free adhesive in comparison to conventional adhesives. In the past, low filler content has been associated with reduced bond strength,[1] which in turn may result in increased bracket failure. Since bracket failure is undesirable for both the patient and clinician, a good orthodontic adhesive should enable the brackets to stay bonded to the teeth for the entire duration of treatment. In general, bracket failure rates below 10% have been suggested to be clinically acceptable.[2–4]

At the completion of orthodontic treatment, the brackets are removed from the teeth. When a bracket is debonded, bond failure can occur at any one of three

[a] Associate Professor, Division of Orthodontics, School of Dentistry, University of Minnesota, Minneapolis, Minn, USA

[b] Professor and Director, Division of Orthodontics, School of Dentistry, University of Minnesota, Minneapolis, Minn, USA

Corresponding author: Dr Thorsten Grünheid, Division of Orthodontics, School of Dentistry, University of Minnesota, 6-320 Moos Health Science Tower, 515 Delaware Street SE, Minneapolis, MN 55455, USA
(e-mail: tgruenhe@umn.edu)

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sites: at the bracket-adhesive interface, within the adhesive, or at the enamel-adhesive interface. If a strong bond has been achieved, failure at the enamel-adhesive interface is undesirable because the adhesive may cause enamel tear-out defects as it pulls away from it. For this reason, the bracket-adhesive interface is the failure site preferred by most orthodontists,[5] and it is considered ideal if the adhesive remains on the tooth surface.[6] Obviously, the remaining adhesive needs to be removed from the teeth. The time spent on adhesive removal after debonding is a large contributor to what tends to be one of the longest appointments in orthodontic treatment. As longer appointments require more of the patient's time and are more expensive for the clinician, it is desirable to reduce the adhesive removal times as much as reasonably possible.

Based on internal data, the manufacturer of the flash-free adhesive claims reliable bond strength and bracket failure rates lower than 2%.[7] While recent in vitro studies appear to support the claim of favorable bond strength,[8,9] bracket survival with the APC flash-free system has not been independently studied in vivo, and questions remain regarding the time required for adhesive remnant cleanup using this adhesive. Therefore, the objectives of this trial were to compare bracket survival and time required for adhesive remnant removal between the new flash-free and a conventional adhesive resin for orthodontic bracket bonding.

MATERIALS AND METHODS

Trial Design and Ethical Approval

Approval to conduct this single-center, split-mouth randomized controlled trial was granted by the Institutional Review Board at the University of Minnesota (Study Number 1305M33841).

Participants and Study Setting

Consecutive patients presenting for comprehensive orthodontic treatment at the Post-graduate Program in Orthodontics at the University of Minnesota, who were willing to participate, were recruited from September 2013 to April 2015 using the following inclusion criteria: (1) fully erupted permanent incisors, canines, premolars, and first molars; (2) sound, noncarious buccal enamel and no pretreatment with chemical agents, such as hydrogen peroxide; and (3) no previous orthodontic treatment with fixed appliances. Exclusion criteria were (1) inability to give consent, (2) craniofacial anomalies, (3) extractions or orthognathic surgery as part of the treatment, and (4) congenital enamel defects. Informed consent was obtained from all study participants. In cases of minors, consent was obtained from a parent or guardian and assent was obtained from the minor. Patients could withdraw from the study at any time. Such dropouts were not replaced, and any data collected from these patients were excluded from analysis.

Interventions

The patients had their maxillary incisors, canines, and premolars bonded with adhesive precoated ceramic orthodontic brackets (Clarity Advanced Ceramic Brackets, 3M) using a system with a flash-free adhesive (APC Flash-Free Adhesive Coated Appliance System, 3M) on one side and a system with a conventional adhesive (APCII Adhesive Coated Appliance System, 3M) on the other side. These systems use identical brackets and differ only regarding the adhesive on the brackets. The side allocation was randomized using a randomization scheme with equal distribution of the two side allocations generated with the online randomization tool at http://www.graphpad.com/quickcalcs.

Prior to bonding, the patients' teeth were polished with a fluoride-free prophylaxis paste (Topex Prep& Polish, Sultan Healthcare, Hackensack, NJ), etched with 35% orthophosphoric acid (Temrex, Freeport, NY) for 30 seconds, rinsed with water, air-dried, and primed using a light-cure adhesive primer (Transbond XT Light Cure Adhesive Primer, 3M). The teeth were then bonded according to the predetermined side allocation using a direct bonding technique. The bonding sequence was standardized and started with the left second premolar, progressed around the arch, and ended with the right second premolar for each patient. Excessive adhesive around brackets precoated with the conventional adhesive was removed with a dental explorer. The adhesive was light-cured through the bracket for 3 seconds per tooth with a new light-emitting diode curing light (Ortholux Luminous Curing Light, 3M). The distance between the exit window and the adhesive was maintained at less than 5 mm in order to obtain optimum polymerization.

Bond failure was recorded at standardized appointment intervals of 4 weeks. In addition, the patients were instructed to visit the clinic immediately in case of breakage. In case of a bond failure, the adhesive remnant index (ARI)[10] was scored to categorize the failure mode (ie, fracture at the bracket-adhesive interface, within the adhesive, or fracture at the enamel-adhesive interface), and the patients were asked about a possible explanation for the bond failure. Remaining adhesive was removed from the tooth surface using a tungsten carbide finishing bur (H283-21-012, Brasseler, Savannah, Ga) in a low-speed handpiece,[11] the enamel surface etched and primed as detailed above, and the tooth rebonded with a new bracket per the assigned protocol.

After completion of treatment, the brackets were debonded following the manufacturer's instructions using a purpose-designed instrument (Self-Ligating Bracket Debonding Instrument, 3M). Similar to the bonding sequence, debonding started with the left second premolar, progressed around the arch, and ended with the right second premolar for each patient. Once the brackets were debonded, the ARI was scored and remaining adhesive was removed from the tooth surfaces using a new tungsten carbide finishing bur as detailed above. Adhesive removal also started with the left second premolar, progressed around the arch, and ended with the right second premolar for each patient. Satisfactory removal of the remnant adhesive was verified by visual inspection under a dental operating light. Adhesive removal in each quadrant was timed to the nearest second using a digital stopwatch.

All study procedures were performed by a single, calibrated operator. The patients were treated by 12 orthodontic residents under the supervision of 13 orthodontic faculty members. In cases of incorrectly placed brackets, compensating bends were placed in the archwire to avoid repositioning of brackets associated with the trial.

Outcomes

- Primary: Adhesive removal time per quadrant for each adhesive.
- Secondary: Bracket failure rate, time to first-time failure of a bracket, bond failure type, and amount of adhesive remnant on the tooth surface after bracket debonding using the ARI.

Blinding

Blinding of the operator at bracket bonding was not possible due to the nature of the intervention. However, assessment was blind because it was not possible to distinguish between the adhesives when recording bracket failures, scoring the ARI, or removing adhesive remnants.

Sample Size and Power of the Study

With a sample size of 45, a paired *t*-test has 81% power to detect an effect size of 0.43 at the 0.05 significance level.

Statistical Analysis

Descriptive statistics were used to summarize the data. A Mann-Whitney rank sum test was used to compare ages between males and females. Bracket failure rates were expressed as percentage of failed brackets for each adhesive. A TOST (two one-sided *t*-tests) test of equivalence was used to test for equivalence between mean bracket failure rates. The adhesives were considered equivalent if the confidence interval for the difference between bracket failure rates fell within a margin of equivalence $\pm 5\%$. A figure of 5% was chosen as this would signify one additional bracket failure per patient. A Wilcoxon signed rank test was used to compare ARI scores upon bond failure between the adhesives. A Kaplan-Meier plot and a Cox regression model with a robust sandwich covariance matrix (for within-patient correlation) were used to compare bracket survival times between the adhesives. Paired *t*-tests were used to compare adhesive removal times and ARI scores on debond (mean per patient) between the adhesives. In addition, a linear mixed effect model was used to compare the mean adhesive removal times between the adhesives while adjusting for ARI score (included as a predictor in the model). A random patient effect was included to account for potential correlation of the paired adhesive removal times. Statistical analyses were performed using SAS 9.3 for Windows (SAS Institute Inc., Cary, NC) with $P < .05$ considered statistically significant.

RESULTS

Fifty patients were approached for inclusion in the study; 45 patients met the inclusion criteria, agreed to participate, and received the allocated interventions. Once enrolled, three patients were later excluded as their treatment plan was changed to include extractions, or they moved away from the study site (Figure 1). Baseline sample demographics are shown in Table 1. The treatment duration was 19.9 $\pm$ 5.4 months (range: 9–32 months).

The bracket failure rates over the entire treatment duration were 4.3% for the flash-free adhesive and 1.9% for the conventional adhesive, resulting in a difference in the percentage failure rate of 2.4%. A life table with bracket failures by adhesive at various time points is shown in Table 2. The number of bracket failures by adhesive and tooth type is shown in Table 3. With the exception of one patient who had 2 failures, all failures came from different patients. None of the patients noticed that any of the brackets had failed. Equivalence testing showed equivalence of the adhesives with regard to bracket failure rates (90% confidence interval 0.004, 0.048; $P = .040$).

The mean time to first-time failure of a bracket was 31 weeks for the flash-free adhesive (range: 6–77 weeks) and 42 weeks for the conventional adhesive

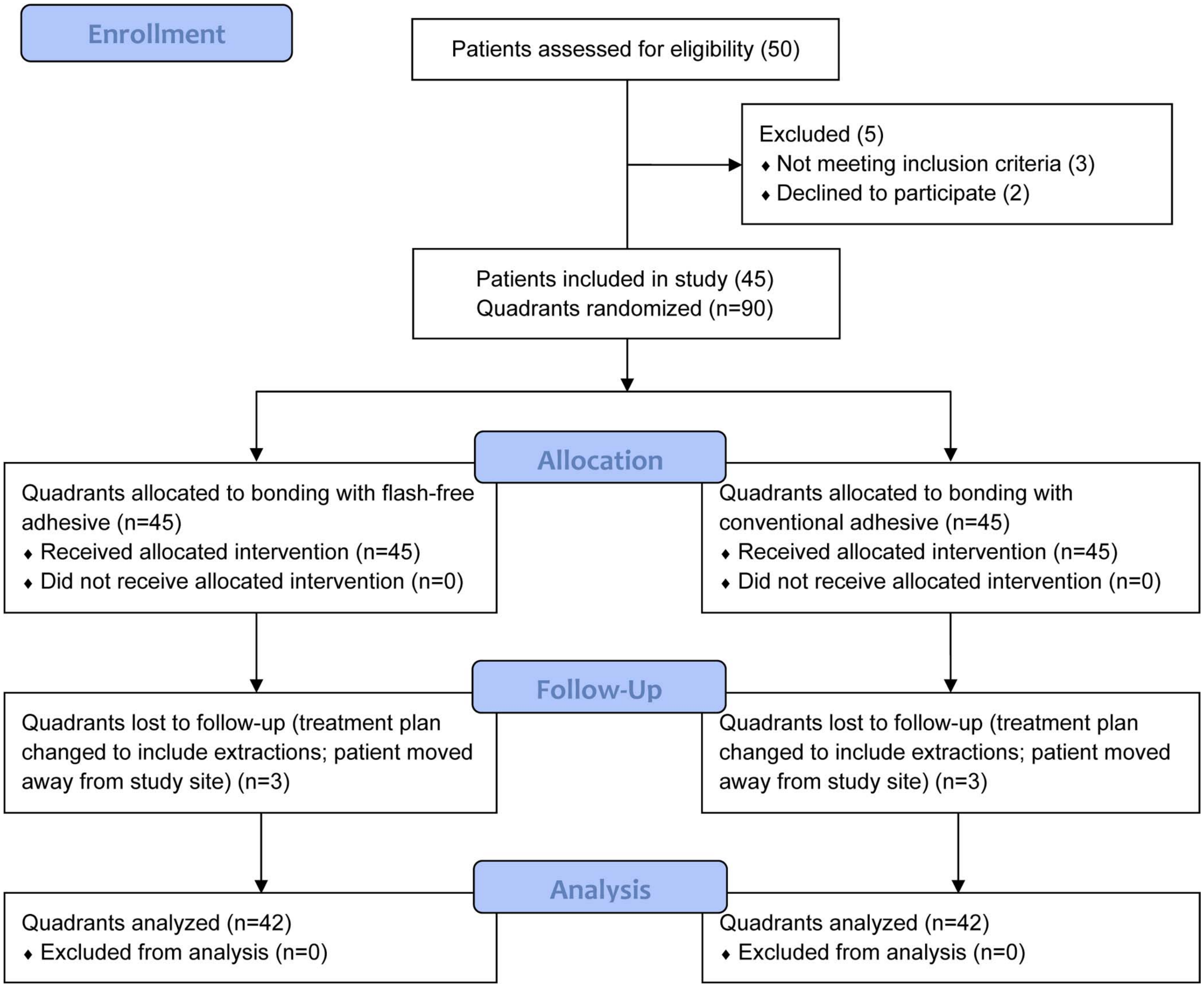

Figure 1. CONSORT flow chart showing patient flow during the trial.

(range: 10–90 weeks). There were no second-time failures. The time to failure was not significantly different between the adhesives ($P = .186$). A Kaplan-Meier survival graph is shown in Figure 2. The ARI scores on failure are shown in Table 4. These scores were not significantly different between adhesives ($P = .681$).

The ARI scores on debond are shown in Table 5. The mean ARI scores per patient were 2.53 ± 0.36 for the flash-free adhesive and 2.29 ± 0.40 for the conventional adhesive, with the flash-free adhesive leaving significantly more adhesive on the tooth surface than the conventional adhesive ($P = .003$). Adhesive removal times are shown in Table 6. The adhesive removal times were significantly shorter with

Table 1. Baseline Study Sample Demographics[a]

	Age (y)	
	Mean ± Standard Deviation	Range
Male (n = 23)	17.2 ± 6.7	12.7–43.5
Female (n = 22)	22.4 ± 11.0	11.9–50.9

[a] No statistically significant age difference between sexes (Mann-Whitney rank sum test, $P = .256$)

Table 2. Bracket Failures by Adhesive at Various Time Points

	Flash-free Adhesive			Conventional Adhesive		
Time Point	N	Censored	Failure Rate	N	Censored	Failure Rate
1 month	0	210	0%	0	210	0%
3 months	2	208	1.0%	2	208	1.0%
6 months	3	207	1.4%	2	208	1.0%
12 months	8	202	3.8%	2	208	1.0%
18 months	9	201	4.3%	3	207	1.4%
24 months	9	201	4.3%	4	206	1.9%
Overall	9	201	4.3%	4	206	1.9%

Table 3. Bracket Failure by Adhesive and Tooth Type

Tooth	Flash-free Adhesive		Conventional Adhesive	
	Censored	Failures	Censored	Failures
Central incisor	41	1	41	1
Lateral incisor	41	1	42	0
Canine	40	2	42	0
First premolar	41	1	41	1
Second premolar	38	4	40	2

Table 4. Adhesive Remnant Index (ARI) Scores on Failure[a]

ARI Score	Flash-free Adhesive		Conventional Adhesive	
	N	Percent	N	Percent
0 = No adhesive left on the tooth	4	44.4%	2	50.0%
1 = Less than half of the adhesive left on the tooth	3	33.3%	0	0.0%
2 = More than half of the adhesive left on the tooth	1	11.1%	0	0.0%
3 = All adhesive left on the tooth	1	11.1%	2	50.0%

[a] No significant difference in ARI scores between adhesives (Wilcoxon rank sum test, $P = .681$)

the flash-free adhesive than with the conventional adhesive ($P = .004$) resulting in time savings of 22.2% when the flash-free adhesive was used. A linear mixed effect model to compare the mean adhesive removal times between the adhesives while adjusting for ARI score yielded a mean difference of 58.3 seconds per quadrant ($P < .0001$) between adhesives.

DISCUSSION

The present findings suggest that bracket survival with the adhesives tested did not differ significantly in a clinical setting. The overall bracket failure rates found here, that is, 4.3% for the flash-free adhesive and 1.9% for the conventional adhesive, were considerably lower than in most other studies, which reported bracket failure rates ranging from 2.7% to 9.5% with adhesive precoated brackets.[12–15] Although the bracket failure rate with the flash-free adhesive was higher than the 2% claimed by the manufacturer, it was well below the 10% generally considered acceptable for clinical use.[2–4] The minor difference in bracket failure rates between the two adhesives tested seems clinically irrelevant and acceptable in return for the proposed secondary benefits of the flash-free adhesive, such as elimination of the flash removal step, reduced time for bracket bonding, and improved ability to focus on bracket positioning.[7]

Because the bracket failure rate does not provide any information on the time to failure, survival analysis was performed on the data. This showed that the mean time to failure of a bracket did not differ significantly between the adhesives. In fact, the same number of failures (two with each adhesive) occurred within the first 3 months of treatment, and a similar number of failures (one with the flash-free adhesive and two with the conventional adhesive) occurred later than 12 months after treatment began. Early failure of a bracket, that is, failure within 3 months, is often operator related and caused by such factors as inadequate enamel etching or poor moisture isolation during bonding, or patient related as they chew restricted foods while getting acclimatized to wearing a bonded appliance.[16] In contrast, late failure of a bracket, that is, failure later than 12 months, may be related to changes in the material properties of an adhesive during long-term exposure to the oral environment. For instance, it is well-established that the temperature dynamics in the oral cavity reduce the bond strength of orthodontic adhesives to tooth structure, which may result in bond failure.[17,18] The present results suggest that the material properties of neither adhesive were affected significantly enough to result in an increased bond failure rate over time.

On debond, the flash-free adhesive left significantly more adhesive on the tooth surface than the conventional adhesive. The ARI scores indicate that bond failure generally occurred either at the bracket-adhesive interface or within the adhesive. This finding is in agreement with an earlier in vitro study that showed that, compared with the conventional adhesive, the flash-free adhesive failed more reliably and predictably at the bracket-adhesive interface.[19] It can be speculated that the nonwoven mesh at the bracket base, which contains the flash-free adhesive, may provide a

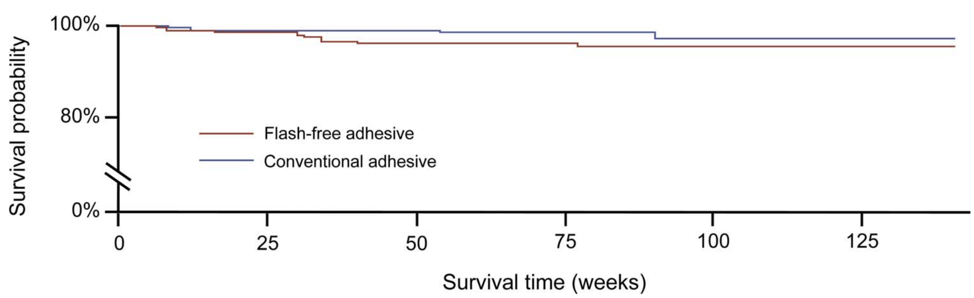

Figure 2. Kaplan-Meier survival graph for the adhesives tested.

Table 5. Adhesive Remnant Index (ARI) Scores on Debond

ARI Score	Flash-free Adhesive		Conventional Adhesive	
	N	Percent	N	Percent
0 = No adhesive left on the tooth	1	0.5%	1	0.5%
1 = Less than half of the adhesive left on the tooth	16	7.6%	37	17.6%
2 = More than half of the adhesive left on the tooth	64	30.5%	72	34.3%
3 = All adhesive left on the tooth	129	61.4%	100	47.6%

predetermined breaking point because of its lower material density. While such a fracture mode may be beneficial to orthodontic patients as it minimizes the risk of enamel tear-outs,[5] more adhesive remains on the tooth surface that requires removal.

Despite the larger amount of adhesive remaining on the tooth surface after debonding, this study showed significantly decreased adhesive removal times with the flash-free adhesive. Time savings of more than one-fifth were achieved with the flash-free adhesive compared with the conventional adhesive. Although adhesive removal with rotary instruments typically takes only a few seconds per tooth, cumulative time reductions may add up to clinically relevant savings when a patient wearing fixed appliances in both arches is debonded. Using the present settings, total time savings would have amounted to more than 3 minutes for a full debond. It may be assumed that the lower filler content of the flash-free adhesive, at least in part, explains the faster removal. While lower filler contents of orthodontic adhesives have been associated with lower bond strengths and therefore higher clinical failure rates,[20,21] this was not the case in the present study. Given the similar clinical performance with regard to bracket survival, the decrease in adhesive remnant removal time achieved with the flash-free adhesive may add to a more positive experience for both patient and clinician.

CONCLUSIONS

- The flash-free adhesive provides bracket survival rates equivalent to the conventional adhesive when ceramic brackets are bonded, and both adhesives have bracket failure rates that are more favorable than those generally considered clinically acceptable.

Table 6. Adhesive Removal Times per Quadrant with the Adhesives Tested[a]

	Time (s)	
	Mean ± Standard Deviation	Range
Flash-free adhesive	167.3 ± 63.5	69–319
Conventional adhesive	215.1 ± 79.8	78–438

[a] Statistically significant difference between adhesives (paired *t*-test, $P = .004$)

- Adhesive remnant removal is significantly faster when using the flash-free adhesive, which may result in time savings of more than 20% compared with the conventional adhesive.

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CONFLICT OF INTEREST

The authors do not have any financial interest in the company 3M Unitek or any of the products used in the study. The authors did not receive any direct compensation or other incentive for conducting the study.

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