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Marginal Gap Formation in Approximal "Bulk Fill" Resin Composite Restorations After Artificial Ageing

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Clinical Relevance

With regard to marginal gap formation, certain flowable "bulk fill" resin composites may be viable alternatives to packable "regular" resin composites—especially in deep cavities with extensive dentin margins.

SUMMARY

The aim of this *in vitro* study was to investigate the marginal gap formation of a packable "regular" resin composite (Filtek Supreme XTE [3M ESPE]) and two flowable "bulk fill" resin composites (Filtek Bulk Fill [3M ESPE] and SDR [DENTSPLY DeTrey]) along the approximal margins of Class II restorations. In each of 39 extracted human molars (n=13 per resin composite), mesial and distal Class II cavities were prepared, placing the gingival margins below the cemento-enamel junction. The cavities were restored with the adhesive system OptiBond FL (Kerr) and one of the three resin composites. After restoration, each molar was cut in half in the oro-vestibular direction between the two restorations, resulting in two specimens per molar. Polyvinylsiloxane impressions were taken and "baseline" replicas were produced. The specimens were then divided into two groups: At the beginning of each month over the course of six months' tap water storage (37°C), one specimen per molar was subjected to mechanical toothbrushing, whereas the other was subjected to thermocycling. After artificial ageing, "final" replicas were produced. Baseline and final replicas were examined under the scanning electron microscope (SEM), and the SEM micrographs were used to determine the percentage of marginal gap formation in enamel or dentin. Paramarginal gaps were registered. The percentages of marginal gap formation were statistically analyzed with a nonparametric analysis of variance followed by Wilcoxon-

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Mann-Whitney tests and Wilcoxon signed rank tests, and all *p*-values were corrected with the Bonferroni-Holm adjustment for multiple testing (significance level: α=0.05). Paramarginal gaps were analyzed descriptively. In enamel, significantly lower marginal gap formation was found for Filtek Supreme XTE compared to Filtek Bulk Fill (p=0.0052) and SDR (p=0.0289), with no significant difference between Filtek Bulk Fill and SDR (p=0.4072). In dentin, significantly lower marginal gap formation was found for SDR compared to Filtek Supreme XTE (p<0.0001) and Filtek Bulk Fill (p=0.0015), with no significant difference between Filtek Supreme XTE and Filtek Bulk Fill (p=0.4919). Marginal gap formation in dentin was significantly lower than in enamel (p<0.0001). The percentage of restorations with paramarginal gaps varied between 0% and 85%, and for all three resin composites the percentages were markedly higher after artificial ageing. The results from this study suggest that in terms of marginal gap formation in enamel, packable resin composites may be superior to flowable "bulk fill" resin composites, while in dentin some flowable "bulk fill" resin composites may be superior to packable ones.

INTRODUCTION

Today, placement of direct resin composite restorations is a routine treatment in restorative dentistry. Since the introduction of resin composites more than 50 years ago, they have undergone constant development and have proved to be clinically effective.[1] Esthetic and mechanical properties have been improved, and handling, polishability, and abrasion resistance have been optimized.[1-4] Despite these improvements, the dentist is still faced with some challenges when using resin composites. One of these challenges is shrinkage due to polymerization. Polymerization shrinkage creates stress within resin composites, at the interface between the resin composite restoration and the tooth substance as well as within the tooth structure. Polymerization shrinkage can lead to marginal or paramarginal gap formation and, thus, to marginal discoloration, nanoleakage, or secondary caries.[1-3,5,6] One clinical means of minimizing these negative effects of polymerization shrinkage is the incremental technique.

According to this technique, regular resin composites are applied in increments of a maximum thickness of 2 mm, with each increment being light-cured separately.[1,2] Generally, the incremental technique is time consuming—particularly in posterior teeth with deep cavities. In response to the demand for simplified application and reduced application time, so-called "bulk fill" resin composites have been developed for restoration of Class I and Class II cavities. "Bulk fill" resin composites can be applied in a single increment of 4-5 mm thickness, depending on the product,[1,7-9] which obviously simplifies application and reduces the application time.[1] "Bulk fill" resin composites can be divided into two categories: 1) packable "bulk fill" resin composites and 2) flowable "bulk fill" resin composites. Packable "bulk fill" resin composites can be used for restoration of the entire cavity, including the occlusal surface. Flowable "bulk fill" resin composites, however, are to be used as a "base" restoration and are intended to be covered by a final, occlusal layer of a packable resin composite. This final layer of packable resin composite is necessary because flowable "bulk fill" resin composites have lower surface hardness, elastic modulus, and abrasion resistance due to their reduced filler content.[10]

Previous studies[11-14] have shown that mechanical properties such as surface hardness and abrasion resistance of flowable "regular" resin composites are inferior to those of their packable counterparts. This might also apply to flowable "bulk fill" resin composites, and whereas the occlusal surface of a Class II flowable "bulk fill" resin composite restoration is covered by a final layer of packable resin composite, the flowable "bulk fill base" in the gingival part of the approximal surface is not. Because of inferior mechanical properties, flowable "bulk fill" resin composites used as "base" restorations in Class II cavities are likely to undergo degradation when exposed to the various incidents that commonly occur in the oral cavity (eg, toothbrushing and interdental hygiene procedures as well as thermal variations). Thus, the aim of the present *in vitro* study was to investigate the marginal gap formation along the approximal margins of Class II flowable "bulk fill" resin composite restorations and to compare it with the marginal gap formation of packable "regular" resin composite restorations after artificial ageing. The null hypothesis was that there would be no difference between the two flowable "bulk fill" resin composites investigated and the packable "regular" resin composite in terms of marginal gap formation before and after artificial ageing.

METHODS AND MATERIALS

Cavity Preparation and Restoration

A total of 39 extracted human permanent molars were used (n=13 molars/group; three groups: one

Table 1: *Resin Composites and Restorative Procedures*

Resin Composite	Restorative Procedure
Filtek Supreme XTE (3M ESPE, St Paul, MN, USA) Lot No. N628811	1. Increment Filtek Supreme XTE 2 mm; light-curing 20 s 2. Increment Filtek Supreme XTE 2 mm; light-curing 20 s 3. Increment Filtek Supreme XTE 2 mm; light-curing 20 s
Filtek Bulk Fill (3M ESPE, St Paul, MN, USA) Lot No. N421893	1. Base restoration Filtek Bulk Fill 4 mm; light-curing 10 s 2. Occlusal layer Filtek Supreme XTE 2 mm; light-curing 20 s
SDR (DENTSPLY DeTrey, Konstanz, Germany) Lot No. 1408000235	1. Base restoration SDR 4 mm; light-curing 10 s 2. Occlusal layer Filtek Supreme XTE 2 mm; light-curing 20 s

packable "regular" resin composite [Filtek Supreme XTE (3M ESPE, St Paul, MN, USA)] and two flowable "bulk fill" resin composites [Filtek Bulk Fill (3M ESPE) and SDR (DENTSPLY DeTrey, Konstanz, Germany)]). Before extraction, patients had been informed about the use of the teeth for research purposes, and verbal consent had been obtained. After extraction, the teeth were pooled. The local ethics committee categorizes pooled teeth as an "irreversibly anonymized bio-bank" and, thus, no ethical approval was needed. The molars to be used were cleaned under tap water with a scaler to remove debris and then stored in 2% chloramine solution in the refrigerator (4°C) until needed. Before preparation of the cavities, the roots of the molars were shortened under water-cooling with a grinding machine (Struers LaboPol-21; Struers, Ballerup, Denmark) and silicon carbide abrasive papers of #220 grit size (Struers). After grinding and to facilitate handling, the molars were embedded in cylindrical stainless-steel molds with self-curing acrylic resin (Paladur; Heraeus Kulzer, Hanau, Germany). After curing of the acrylic resin, the stainless-steel molds were removed. In each molar, a standardized mesial and distal Class II cavity was prepared through use of a coarse-grained preparation and a fine-grained finishing diamond bur (Intensiv 8113NR and FG 223B; Intensiv AG, Montagnola, Switzerland). The dimensions of the standardized cavity were 4 mm in oro-vestibular width, 6 mm in occluso-cervical height (including a margin below the cemento-enamel junction), and 2 mm in mesio-distal depth. The margins of the cavity were not beveled. Then, a circular curved transparent matrix (Lucifix Molar; KerrHawe, Bioggio, Switzerland) was placed, on which the thickness of the future increments of resin composite (depending on the group, as listed in Table 1) was marked with a water-resistant felt pen. The cavities were pretreated with the three-step etch-and-rinse adhesive system OptiBond FL (Kerr, Scafati, Italy) according to the manufacturer's instructions (etching of the cavity for 15 seconds with 37.5% phosphoric acid [Kerr Gel Etchant, Lot No. 5329366; Kerr], 15-second water spray, three-second air-dry, 15-second application of OptiBond Prime [Lot No. 48574776; Kerr], five-second air-dry, 15-second application of OptiBond Adhesive [Lot No. 4851978; Kerr], three-second air-dry, and 10-second light-cure). Subsequently, the restorations of both cavities were carried out as specified in Table 1 (n=13 molars/group, resulting in n=26 cavities per resin composite; three resin composites). All light-curing was conducted with an LED curing unit (Demi LED; Kerr; irradiance 1500 mW/cm^2; validation of the light efficiency by a radiometer [MARC PS; BlueLight Analytics Inc, Halifax, NS, Canada]). After removal of the matrix, the restorations were finished and polished with Sof-Lex XT Discs (Sof-Lex XT Discs coarse, medium, fine, and superfine; 3M ESPE). The discs were changed after polishing of each restoration. The restored molars were then kept in tap water for 24 hours at 37°C.

Specimen Preparation and Production of "Baseline" Replicas

After tap water storage for 24 hours, each molar was cut in half in the oro-vestibular direction between the two restorations with a water-cooled diamond saw (IsoMet Low Speed Saw; Buehler, Lake Bluff, IL, USA), resulting in two specimens per molar. These specimens were also embedded in cylindrical stainless-steel molds with self-curing acrylic resin (Paladur; Heraeus Kulzer), letting the restorations protrude from the acrylic resin. After curing of the acrylic resin, the specimens were cleaned with deionized water in an ultrasonic bath (TUC-150; Telsonic AG, Bronschhofen, Switzerland) for three minutes and then thoroughly air-dried. From each specimen, polyvinylsiloxane impressions were taken (addition-type silicone, surface-activated PRESIDENT heavy body [Lot No. F93948] and regular body [Lot No. F83175]; Coltène/Whaledent, Altstätten, Switzerland). The impressions were poured with epoxy resin (EpoFix; Struers) to produce "baseline" replicas.

Artificial Ageing of the Specimens

The specimens were divided into two groups of artificial ageing: At the beginning of each month during six months' storage, one specimen per molar was subjected to mechanical toothbrushing (syndicad LR1; syndicad Dental Research, Munich, Germany) for 500 cycles (~8.5 minutes) using a toothpaste slurry (50 g with a ratio of 1:1 deionized water and toothpaste [M-Budget toothpaste; Migros Genossenschaftsbund, Zurich, Switzerland; RDA ~70]), while the other specimen was subjected to thermocycling (1000 cycles; 5°C/55°C, 30-second exposure time). During the six months' storage, all specimens were kept in tap water at 37°C.

Production of "Final" Replicas and Measurement of Marginal Gap Formation

After storage, all specimens were again cleaned with deionized water in an ultrasonic bath (TCU-150; Telsonic AG) for three minutes, polyvinylsiloxane impressions were taken from each specimen, and new impressions were poured with epoxy resin, as previously described, resulting in "final" replicas.

The baseline and the final replicas were mounted on aluminum stubs and sputter-coated (100 seconds, 50 mA) with gold/palladium by use of a sputter-coating device (Balzers SCD 050; Balzers, Liechtenstein). Baseline and final replicas were then examined under a scanning electron microscope ([SEM] JEOL JSM6010PLUS/LV; JEOL, Tokyo, Japan), and SEM micrographs were produced. Since the restorations were located partly in enamel and partly in dentin (ie, below the cemento-enamel junction), marginal gap formation of the restorations was assessed separately at the "margin located in enamel" and at the "margin located in dentin." For the "bulk fill" resin composite restorations and in analogy to the clinical situation, the restorations were each regarded as one unit, and no distinction was made between the layer of flowable "bulk fill" resin composite and the top layer of packable "regular" resin composite.

First, the length of the entire enamel margin of each restoration was measured (in micrometers). In the case of gaps along the margin, the length of each gap was measured (in micrometers) and the individual gap lengths were added. The percentage of the total gap length was then calculated relative to the entire enamel margin. This procedure was repeated for the restorative margin located in dentin. All measurements of marginal gap formation were performed with the SEM software InTouch Scope Version 2.01 (JEOL) by one operator (SM) and were performed twice in order to calculate the intraoperator reliability.

The paramarginal gap formation was registered as being either present or absent, and the percentage of paramarginal gaps was calculated for each group.

Statistical Analysis

The intraoperator reliability of the two measurements of marginal gap formation was calculated using the Kendall Tau. The percentages of marginal gaps in enamel as well as in dentin were statistically analyzed with a nonparametric analysis of variance (ANOVA) to test for an effect of the three factors "resin composite" (ie, Filtek Supreme XTE, Filtek Bulk Fill, or SDR), "artificial ageing" (ie, baseline or final), and "type of artificial ageing" (ie, mechanical toothbrushing or thermocycling) and of their interactions. In case of a significant effect of one of the factors, post hoc analysis was performed using the Wilcoxon-Mann-Whitney test. The comparison between gap formation in enamel and dentin was done using the Wilcoxon signed rank test.

All *p*-values were corrected with Bonferroni-Holm adjustment for multiple testing. The statistical analysis was performed with R, version 3.3.1 (The R Project for Statistical Computing, Vienna, Austria) using the packages "irr" and "nparLD" after the level of significance had been set at $\alpha=0.05$. The distribution of paramarginal gaps was analyzed descriptively.

RESULTS

Representative SEM micrographs of restorative margins in enamel and dentin are shown in Figure 1 for margins without gap formation and in Figure 2 for margins with gap formation.

The Kendall Tau value regarding the intraoperator reliability between the two measurements of marginal gap formation was 0.96 for enamel and 0.97 for dentin. As a result of the high Kendall Tau for both tooth substances, the percentages of marginal gap formation in enamel as well as in dentin from the first measurement were pooled with the percentages of the second measurement for each of the 13 restorations in each group. These results are shown in Table 2 as mean values and standard deviations whereby differences in dentin gap forma-

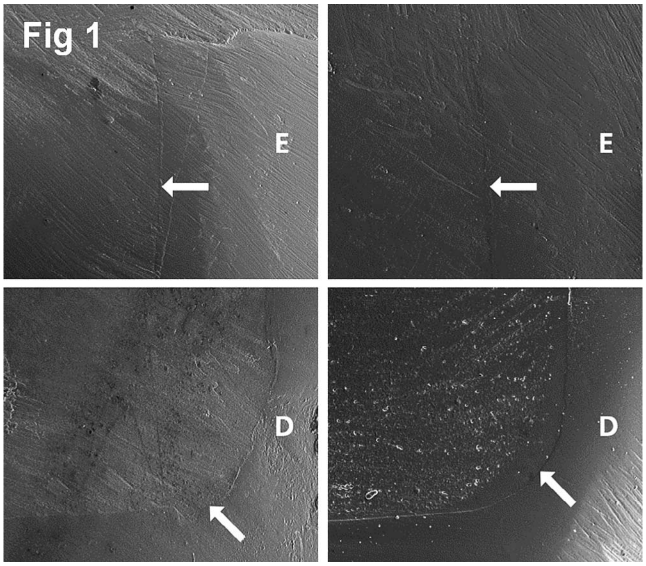

Figure 1. *Representative scanning electron microscope micrographs of restorative margins in enamel (E) and dentin (D) without gap formation.*

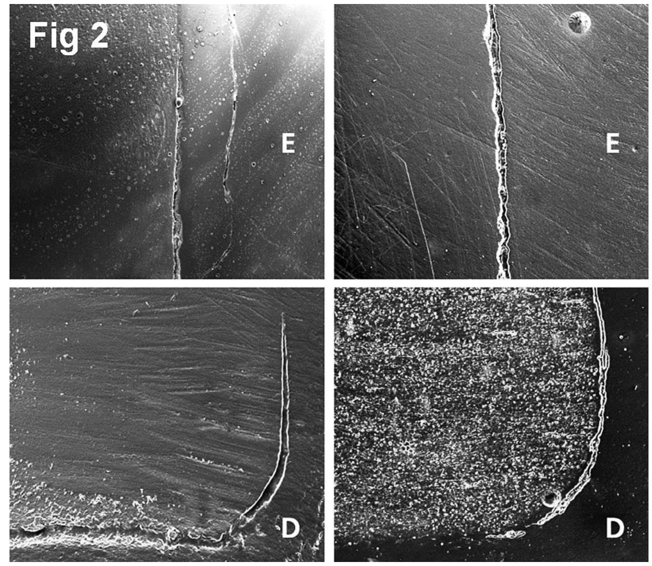

Figure 2. *Representative scanning electron microscope micrographs of restorative margins in enamel (E) and dentin (D) with gap formation.*

tion, undisclosed by median values, become apparent.

For enamel, the nonparametric ANOVA showed a significant effect of the factors "resin composite" (p=0.0068) and "artificial ageing" (p<0.0001) but no significant effect of the factor "type of artificial ageing." There were no significant interactions between the three factors. With regard to the effect of artificial ageing, gap formation increased significantly for all three resin composites after mechanical toothbrushing or thermocycling. With regard to the effect of resin composite, this factor did not interact significantly with the factor "artificial ageing" or with the factor "type of artificial ageing." Consequently, the percentages of marginal gap formation in enamel from the two points in time (baseline and final) and from the two types of artificial ageing were pooled for each of the three resin composites (Figure 3). Subsequently, Wilcoxon-Mann-Whitney tests showed significantly lower marginal gap formation in enamel for Filtek Supreme XTE compared to Filtek Bulk Fill (p=0.0052) and SDR (p=0.0289) and no significant difference between Filtek Bulk Fill and SDR (p=0.4072).

For dentin, the nonparametric ANOVA showed a significant effect of the factor "resin composite" (p=0.0317) but no significant effect of the factors "artificial ageing" or "type of artificial ageing." There were no significant interactions between the three factors, and consequently the percentages of marginal gap formation in dentin from the two points in time (baseline and final) and two types of artificial ageing were pooled for each of the three resin composites (Figure 3). Subsequently, Wilcoxon-Mann-Whitney tests showed significantly lower marginal gap formation in dentin for SDR compared to Filtek Supreme XTE (p<0.0001) and Filtek Bulk Fill (p=0.0015) and no significant difference between Filtek Supreme XTE and Filtek Bulk Fill (p=0.4919).

Furthermore, a Wilcoxon signed rank test found significantly lower marginal gap formation in dentin than in enamel (p<0.0001).

The distribution of paramarginal gaps is presented in Table 3. The percentage of restorations with paramarginal gaps varied between 0% and 85%, and the percentages were markedly higher after artificial ageing for all three resin composites, regardless of type of ageing. There were no characteristic or systematic differences between the three resin composites.

DISCUSSION

The present study investigated marginal gap formation along the approximal margins of Class II restorations and showed significant differences between the three resin composites compared. In enamel, the packable "regular" resin composite Filtek Supreme XTE showed less gap formation than did the two flowable "bulk fill" resin composites, Filtek Bulk Fill and SDR, before as well as after artificial ageing. In dentin, on the other hand, one of the "bulk fill" resin composites (SDR) showed less

Table 2: *Marginal Gap Formation (%) in Enamel and Dentin Before ("Baseline") and After the Two Types of Artificial Ageing ("Final") (Mean Values and Standard Deviations)*

Type of Artificial Ageing	Resin Composite		
	Filtek Supreme XTE (n=13)	Filtek Bulk Fill (n=13)	SDR (n=13)
Mechanical toothbrushing			
Enamel			
Baseline	29.7 ± 21.8	49.6 ± 21.2	46.9 ± 28.5
Final	68.6 ± 24.2	81.6 ± 11.6	72.1 ± 19.6
Dentin			
Baseline	2.9 ± 4.8	7.9 ± 27.7	0 ± 0
Final	4.1 ± 6.2	9.1 ± 26.9	7.0 ± 25.3
Thermocycling			
Enamel			
Baseline	29.0 ± 14.0	48.5 ± 28.5	47.0 ± 21.2
Final	66.6 ± 21.5	84.1 ± 13.9	81.0 ± 15.4
Dentin			
Baseline	4.6 ± 8.5	7.9 ± 27.5	0 ± 0
Final	4.6 ± 8.9	19.1 ± 28.6	0 ± 0

Table 3: *Distribution of Paramarginal Gaps (%) Before ("Baseline") and After the Two Types of Artificial Ageing ("Final")*

Type of Artificial Ageing	Resin Composite		
	Filtek Supreme XTE (n=13)	Filtek Bulk Fill (n=13)	SDR (n=13)
Mechanical toothbrushing			
Baseline	23.1	30.8	23.1
Final	84.6	46.2	65.4
Thermocycling			
Baseline	7.7	0	38.5
Final	53.9	61.5	50.0

gap formation than the other two resin composites. These results lead to rejection of the null hypothesis.

Whether or not marginal gaps are formed and the extent to which gaps are formed depend on an interplay between multiple factors,[15-23] some related to the resin composite, others related to the specific cavity and restorative procedure. In this study, we sought to keep constant the factors related to the cavity and the restorative procedure. Thus, care was taken during cavity preparation to obtain standardized cavities and, consequently, a constant C-factor for all restorations. Furthermore, a gold standard adhesive system was chosen[24] and applied strictly according to the instructions for use to ensure best possible adhesion, and light-curing was performed with a high-performance LED curing unit, the power intensity being continuously monitored.

Two factors related to the resin composite are of key importance to gap formation: polymerization shrinkage[16,17,25,26] and elastic modulus.[11,27,28] In adhesively bonded resin composite restorations, polymerization shrinkage generates stress at the tooth-restoration interface,[16,29,30] which has undesirable consequences, such as marginal gap formation, tooth deflection, and paramarginal enamel fractures.[30-34] According to Hooke's Law, polymeri-

Fig 3

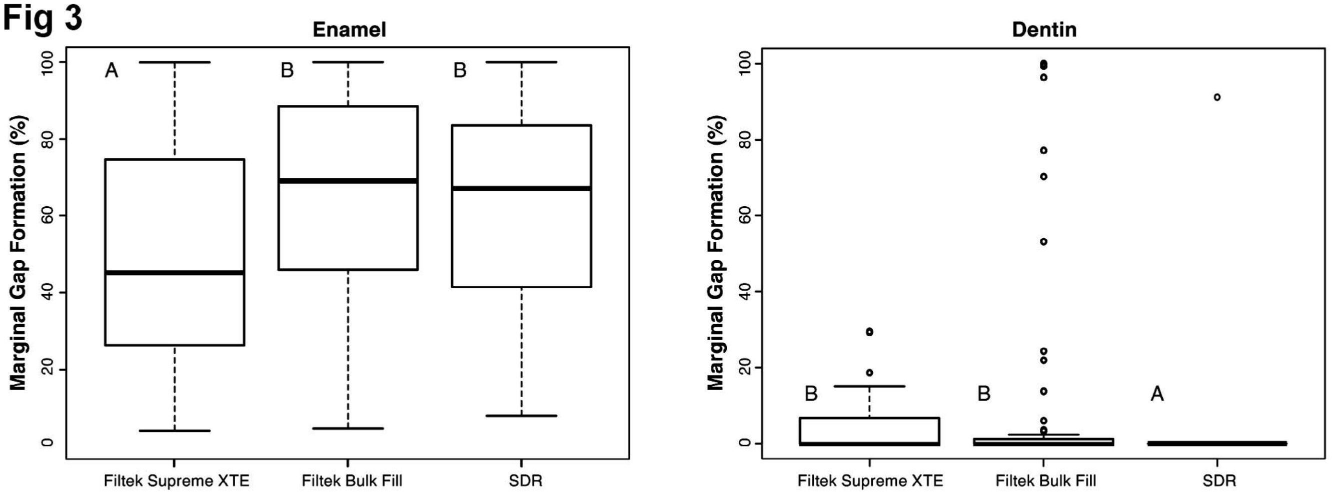

Figure 3. *Percentages of marginal gap formation in enamel and dentin (n=52 per group; for each of the resin composites, the percentages were pooled because of the absence of significant interactions between the three factors "resin composite" [ie, Filtek Supreme XTE, Filtek Bulk Fill, or SDR], "artificial ageing" [ie, baseline or final], and "type of artificial ageing" [ie, mechanical toothbrushing or thermocycling]; different letters indicate significant differences between the three resin composites within enamel or dentin).*

zation stress is the product of elastic modulus and strain.[30] This implies that resin composites with a combination of high polymerization shrinkage and high elastic modulus are expected to result in the highest polymerization stresses. Polymerization shrinkage and elastic modulus both depend highly on the filler content of the resin composite: the higher the filler content, the lower the polymerization shrinkage[16,35] and the higher the elastic modulus.[11,28,29] To allow for a higher increment thickness while maintaining an acceptable degree of monomer-polymer conversion, "bulk fill" resin composites need to be more translucent than "regular" resin composites. This is mainly obtained through a reduction in filler content.[36] Indeed, whereas the "regular" resin composite Filtek Supreme XTE had a filler content of 63.3%vol, that of Filtek Bulk Fill was 42.5%vol and that of SDR 45%vol.[8,9,36] As anticipated, the latter two materials have been reported to show higher polymerization shrinkage (3-4%vol vs 2%vol)[8,9,11,37,38] and lower elastic modulus (4-5 GPa vs 10-11 GPa).[11,26,36,37,39] While higher polymerization shrinkage would be expected to increase gap formation, lower elastic modulus would be expected to have the opposite effect.

The present study found higher gap formation in enamel of the two flowable "bulk fill" resin composites Filtek Bulk Fill and SDR compared to the packable "regular" resin composite Filtek Supreme XTE. Apparently, the lower elastic modulus of the "bulk fill" resin composites did not compensate for the higher polymerization shrinkage. In their study of four "bulk fill" and two "regular" resin composites, Kim and others[37] reported lower polymerization shrinkage stress of SDR compared with Filtek Z250, whereas Filtek Bulk Fill showed similar polymerization shrinkage stress as the "regular" resin composite. Despite an overall, strong positive correlation between polymerization shrinkage stress and tooth-composite interfacial debonding in Class I cavities for all six resin composites tested, no significant difference in interfacial debonding was found between Filtek Bulk Fill, SDR, and Filtek Z250, and the study[37] does not corroborate our findings. This may be explained by the numerous differences in study design between the two studies, such as cavity type, adhesive system, and methodology used to determine marginal integrity. However, a favorable effect of high elastic modulus of resin composites on enamel gap formation in Class II cavities has been reported by Benetti and others.[27] Of particular relevance for the present results is the finding that the use of a resin composite with low elastic modulus and high polymerization shrinkage (Charisma, Heraeus Kulzer) resulted in more severe gap formation in enamel than did the use of a resin composite with higher elastic modulus and lower polymerization shrinkage (Grandio, VOCO, Cuxhaven, Germany), and this result is in agreement with our findings. Unfortunately, after thermocyclic and mechanical loading the lower gap formation of Grandio was accompanied by a higher frequency of paramarginal enamel fractures. In the current study, a tendency was indeed observed toward more paramarginal gaps for Filtek Supreme XTE than for the two "bulk fill" resin composites after the artificial ageing involving mechanical toothbrushing but not after the artificial ageing involving thermocycling.

In dentin, one of the "bulk fill" resin composites (SDR) showed significantly less marginal gap formation than did Filtek Supreme XTE and the other "bulk fill" resin composite (Filtek Bulk Fill). This positive result for SDR may be explained by SDR having generated less polymerization shrinkage stress than Filtek Supreme XTE and Filtek Bulk Fill,[14,37] possibly as a result of containing a "polymerization modulator" embedded in the backbone of the polymerizable resin,[40] which supposedly counteracts polymerization stress through lower polymerization rate.[14] The positive results for SDR also corroborate with findings of previous studies[26,41,42] in which SDR was used as a base filling in Class II cavities and which found the marginal integrity to be as good as that of a conventionally layered "regular" resin composite. Moreover, the result indicates that the elastic modulus is not as important for gap formation in dentin as it is for gap formation in enamel. This result is in harmony with that of Benetti and others,[27] who found no difference in dentin gap formation among three "regular" resin composites of highly varying elastic modulus.

Clearly, gap formation was more severe at enamel margins than at dentin margins before as well as after artificial ageing. First, this indicates that the adhesive system is able to create a durable bond to dentin. Second, this may imply that the situation at the enamel margins was more challenging than at the dentin margins. One important factor could be the elastic modulus. It has often been claimed that the elastic modulus should be as similar as possible to the tooth structure so that the resin composite is able to flex with the tooth structure under mechanical load.[16,43] The elastic moduli of the three resin composites investigated in the present study (4-5 GPa to 10-11 GPa)[11,26,36,37,39] are much closer to that of dentin (13-19.0 GPa)[43-45] than to that of enamel

(80-94 GPa),[43] the much bigger difference for enamel resulting in higher stress formation. In their study of the effect of a 4-mm SDR base in Class II MOD cavities, Roggendorf and others[41] found more severe gap formation in dentin than in enamel after thermomechanical loading. This result is in contrast with our findings and cannot easily be explained. One reason could be the difference in cavity type between the two studies (Class II MO/OD cavities in the present study vs Class II MOD cavities in the other study). Another reason could be the more rigorous thermomechanical loading procedure endured by the MOD restorations, both factors exposing the MOD restorations to much higher levels of stress.

The current study subjected the Class II restorations to two artificial ageing protocols intended to simulate not only long-term exposure to the high humidity of the oral cavity but also some of the mechanical and thermal challenges that these restorations endure during normal function. Such challenges may give rise to stress formation due to cyclic, subcatastrophic mechanical loading as well as a mismatch between the coefficient of thermal expansion of the resin composite and the tooth substance. Both artificial ageing protocols led to aggravated gap formation in enamel and an increase in paramarginal gaps, but they had no detrimental effect on gap formation in dentin. The aggravation of gap formation in enamel as a consequence of the artificial ageing protocols is in agreement with previous findings,[27,41] but these studies also reported an aggravation of gap formation in dentin. The fact that we found no difference between the two artificial ageing protocols may imply that the aggravation in gap formation observed was caused primarily by the long-term water storage *per se* and that the mechanical toothbrushing and thermocycling protocols were inadequate to provoke a significant effect. Indeed, with regard to thermocycling, it has been reported[46] that simulation of one-year clinical function requires a total of 10,000 cycles, which is almost double the 6000 cycles applied in the present study.

Obviously, randomized clinical trials are the ultimate tool for evaluating the performance of dental treatments. However, clinical trials are not only extremely resource demanding and time consuming to perform, but once the results of clinical trials with a meaningful follow-up time are published, the information tends to be obsolete as the materials and techniques employed are no longer on the market. Furthermore, the large number of materials available within practically every material category gives an almost infinite and unrealistic number of combinations of materials and techniques to be investigated. For these reasons, researchers conduct preclinical screenings in the form of laboratory studies of properties and performances that are deemed clinically relevant. *In vitro* models allow for testing hypotheses in a controlled laboratory set-up that would be unviable *in vivo*. In the present study, we intended to get an impression of the middle-term performance of Class II restorations with two "bulk fill" resin composites investigated through six months' water storage combined with either mechanical toothbrushing or thermocycling. The lack of effect on dentin gap formation indicates that the protocols were not sufficiently harsh or long-lasting to challenge the materials. Furthermore, the apparent difference in paramarginal gap formation at baseline between the restorations later to be subjected to toothbrushing and those to be subjected to thermocycling implies that the registration of paramarginal gaps (absent vs present) was too crude. Although marginal integrity is not the only factor to influence clinical success, in view of the scarce amount of data on marginal gap formation of "bulk fill" resin composites, more studies applying clinically relevant thermal and mechanical simulation protocols are warranted.

CONCLUSIONS

Marginal gap formation was higher in enamel than in dentin. In enamel, the "regular" resin composite Filtek Supreme XTE showed less marginal gap formation than did the two "bulk fill" resin composites. In dentin, however, one of the "bulk fill" resin composites, SDR, showed less marginal gap formation than did Filtek Supreme XTE and the other "bulk fill" resin composite, Filtek Bulk Fill.

These results suggest that in deep Class II cavities, flowable "bulk fill" resin composites can be an alternative to packable "regular" resin composites.

Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of the Kantonale Ethikkommission KEK, Bern, Switzerland. The approval code for this study is Req-2016-00332.

Conflict of Interest

The authors declare no conflicts of interest, real or perceived, financial or nonfinancial.

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