One-year Clinical Results of Restorations Using a Novel Self-adhesive Composite Hybrid

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Research Article

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Abstract

This prospective study assessed the dual-curing self-adhesive composite hybrid Surefil one. The restorations were placed and reviewed by dental practitioners who are members of a practice-based research network in the United States. Seven practitioners filled 60 cavities (20 class I, 19 class II and 21 class V) in 41 patients with Surefil one without adhesive, according to the manufacturer's instructions. The restorations were evaluated using modified rating criteria at baseline and after 3 months and 1 year. Patients were also contacted to report postoperative hypersensitivity 1 to 4 weeks after placement. Recall rates were 98% after 3 months and 82% after 1 year. The only patient that showed moderate hypersensitvity after 1 year had previously reported symptoms that were unlikely associated to the class I molar restoration. One class II restoration in a broken maxillary molar was partially lost. The remaining 48 restorations were found to be in clinically acceptable condition resulting in an annual failure rate of 2%. The lowest number of acceptable scores (88%) was for color match. Self-adhesive composite hybrid restorations showed promising results in stress-bearing class I and II as well as non-retentive class V cavities at 1-year recall.

Introduction

Resin-based composites have become the standard filling material in dental practices for anterior and posterior restorations. Long-term clinical studies confirmed that the longevity of direct composite restorations in posterior teeth is comparable to that of amalgam restorations[1–4]. Innovations in composite technology simplified the application of composites in 4 to 5 mm layer thickness due to their reduced polymerization shrinkage stress and high reactivity to light curing[5,6]. Clinical data of up to ten years confirmed the safe applicability of these bulk-fill composites as alternative to conventional posterior composites restorations[6–9]. Further simplification involved the development of self-adhesive composites that eliminated the use of an adhesive, thus minimizing the time in which blood or saliva contamination could compromise the restoration. The most common approach was modifying the reactive diluents with acidic moieties to facilitate the bonding with enamel and dentin. This approach was commercialized as self-adhesive flowable composites, but their contradictory clinical performance, particularly in load-bearing areas did not lead to a breakthrough[10–14].

Alternatively, the structural monomers can be modified with acidic groups to achieve sufficient adhesion. To its extreme this approach is realized in the polyacids used in glass ionomer cements. However, polyacids cannot contribute to the radically polymerized network due to lack of polymerizable groups. Recently, a modified polyacid system (MOPOS) has been formulated and patented to merge the self-adhesive properties of classical polyacids known from glass ionomer cements with the crosslinking ability of structural monomers known from composites[15]. This self-adhesive composite hybrid has been launched under the brand name Surefil one (Dentsply Sirona, Konstanz, Germany). By using a self-cure initiator system in addition to camphorquinone in the powder-liquid formulation the self-adhesive

composite hybrid allows unlimited bulk-filling. The light curing option allows for faster finishing of the restoration.

In vitro research confirmed comparable mechanical strength of the self-adhesive composite hybrid to clinically established composites and similar or better wear resistance to newer self-adhesive restorative materials[16,17]. The level of self-adhesiveness to enamel and dentin was comparable to contemporary adhesives and glass ionomer cements[18,19]. However, limited information is available on the clinical performance of the novel self-adhesive restorative material. Thus, the aim of this prospective practice-based research (PBR) network study was to report the one-year clinical performance of the self-adhesive composite hybrid.

Methods

Study design and population.

The direct restorations were placed and reviewed by seven general dental practitioners (GDPs) who are members of a PBR network in the United States (The McGuire Institute, Houston, TX). The GDPs practiced in Houston and Missouri City (TX, USA). The Advarra Institutional Review Board in Columbia (Maryland, USA) approved the study (Protocol Number 00036511). All methods were conducted in accordance with good clinical practice, national guidelines, and regulations. A total of 41 patients from the dental practices (21 female, 20 male) satisfying the inclusion and exclusion criteria were enrolled. The patients were included into the study if they were over 18 years of age, required at least one class I, II or V direct restoration, had dentition free of active periodontal disease and rampant caries, and were in good general health. The patients were excluded from the study if they had language barriers, severe medical conditions or drug use, allergic history concerning methacrylate, lack of compliance, or were pregnant. The average age of patients was 55.4 years with a range of 21 to 78 years. All patients participated voluntarily and were required to provide informed written consent with having the right to withdraw from the clinical study at any time.

After a web-based introduction to the self-adhesive restorative and on-site training, each practice placed ten restorations. One practice with two trained GDPs performed five restorations each. Reasons for placement were replacement restorations (n = 24) and caries lesions (n = 36). All restorations were inserted in permanent vital teeth that did not require direct pulp capping and showed no (n = 59) or slight (n = 1) preoperative hypersensitivity. Twenty-two patients received one restoration and 19 patients two restorations. The sample size was based on previous similar study designs and recommendations of at least 50 restorations per material with maximum two restorations per patient at baseline[20]. The distribution of the involved teeth and restorations is detailed in Table 1.

Table 1
Distribution of the self-adhesive composite hybrid restorations at baseline (n = 60).

		Maxillary			Mandibular	
	Total	Canine	Premolar	Molar	Premolar	Molar
Class I	20	1	2	14	2	1
Class II	19	0	7	5	5	2
Class V	21	2	5	0	10	4
Total	60	3	14	19	17	7

Restorative procedure.

Before starting restorative procedures, although experienced, the GDPs applied the self-adhesive restorative on model teeth to become familiar with its handling properties. The composition of the restorative material is given in Table 2.

Table 2
Composition of the self-adhesive composite hybrid evaluated.

Material (Manufacturer)	Composition	Lot number	Application
Surefil one (Dentsply Sirona, Konstanz, Germany)	Aluminium-phosphor-strontium-sodium-fluoro-silicate glass, water, highly dispersed silicon dioxide, acrylic acid, polycarboxylic acid, ytterbium fluoride, bifunctional acrylate, self-cure initiator, iron oxide pigments, barium sulfate pigment, manganese pigment, camphorquinone, stabilizer.	Shade A3: 1807004175	Bulk application, dual-curing

At the time of restoration placement, only the shade A3 was available. Where indicated, local anesthesia was administered. The outline of the cavity was determined by the size of the restoration to be replaced and/or the caries lesion (defect-oriented preparation). No bevels were prepared. Prior to restorative treatment, the GDPs assessed the cavity size and distance between cavity floor and pulp. The isthmus width of class I and II cavities was ≤ 1/3 (n = 25) and ≤ 2/3 (n = 14) of the intercuspal distance, respectively. Dentin thickness was less than 1 mm in seven cavities, between 1 and 2 mm in 21 cavities, and more than 2 mm in 32 cavities. In two cavities, a hard-setting calcium hydroxide liner (Dycal, Dentsply Sirona) was used to selectively cover the dentin close to the pulp. Isolation of the operative field was achieved either with cotton rolls or, in three cases, with rubber dam. Matrices and other devices to facilitate the placement of the restoration were selected depending on the cavity class and personal preferences of the GDPs placing the restoration. The cavities were cleaned by air-water spray leaving a moist cavity surface. The activated capsules (Surefil one) were mixed for 10 seconds using a capsule

mixer according to the manufacturer's instructions. The self-adhesive material was dispensed immediately into the cavity from the capsule tip using a capsule extruder, starting dispensing at the deepest portion of the cavity, and keeping the tip close to the cavity floor. The tip was gradually withdrawn as the cavity was filled in bulk and contoured with a hand instrument. Number of capsules applied depended on the cavity size. After the material was set (approximately in 6 minutes) or optionally light cured on the restoration surface for 20 seconds with a controlled light curing unit (radiant emittance $\geq$ 800 mW/cm^2), the occlusal contacts were evaluated with marking paper. The finishing and polishing with silicon instruments (Enhance Finishing System, Dentsply Sirona) was performed in the same session keeping the restoration moist using air-water spray.

Evaluation procedure.

The restorations were placed between January and March 2019, and examined at baseline, three months, and one year. Patient's one-year recall was performed January up to August 2020 (mean service time 394 ± 44 days) due to the COVID-19 pandemic. Registration and baseline assessment forms were completed after placement of the restorations. To evaluate the immediate postoperative hypersensitivity, patients were contacted by telephone, text, or e-mail once a week after the placement for four weeks. These interviews were used as follow-up procedure to minimize recall loss as the patient was not required to return to the practice until the three-month recall. However, patients were instructed to return for an evaluation should any discomfort occur. At the recalls, the patients were asked again about persisting or new hypersensitivity. Modified Ryge (USPHS) criteria were used for the evaluation[20] (Table 3). Evaluation tools were dental mirrors, explorers, magnifying glasses, and intraoral photographs. Radiographs were only taken if clinically indicated, for example caries diagnostic or pain interpretation. Adverse events regarding product safety were recorded.

Table 3

Rating criteria for evaluation of the self-adhesive composite hybrid restorations. *unacceptable scores

Criteria	
Restoration quality	0 = Intact
	1 = Chipping
	2* = Fracture
	3* = Loss
Marginal quality	0 = Smooth
	1 = Step
	2* = Gap
Tooth quality	0 = Sound
	1 = Cracking
	2* = Fracture
Proximal contact	0 = Yes (Class II only)
	1* = No (Class II only)
Caries	0 = No
	1* = Yes
Vitality	0 = Yes
	1* = No
Hypersensitivity	0 = No sensitivity is experienced at any time
	1 = Slight sensitivity is experienced occasionally but it is not uncomfortable
	2* = Moderate sensitivity is experienced intermittently, and it is uncomfortable
	3* = Severe discomfort is noted routinely with cold or pressure stimulation
Color match	0 = Perfect color match
	1 = Good color match
	2 = Slight color mismatch
	3* = Obvious color mismatch
	4* = Not at all satisfied
Color match (Patient view)	0 = Perfect color match
	1 = Good color match

Criteria	
	2 = Slight color mismatch
	3* = Obvious color mismatch
	4* = Not at all satisfied

Statistical analysis.

Statistical unit was one restoration. The endpoint of the restoration, i.e., the need for replacement or repair, was defined as clinical failure. Data were analyzed with the Statgraphics Centurion XVI 16.2.04 (Statgraphics Technologies, Inc., The Plains, Virginia, USA). Changes over time were calculated with the non-parametric Friedman test at the $P \leq 0.05$ level.

Results

Dropouts occurred for one patient with one class V restoration after three months and for seven patients with 11 restorations (four class II and seven class V) after one year, which results in recall rates of 98% and 82%, respectively. The only patient that showed moderate hypersensitivity after one year (2%) had also reported symptoms at the three-month recall that were unlikely associated to the class I molar restoration. One lower premolar was reported as non-vital and fractured distally to the buccal class V restoration which remained intact and was not considered as reason for failure. One class II restoration in a fractured maxillary molar was partially lost resulting in an annual failure rate of 2%. Illustrations of a representative sample of restorations are presented in Figures 1-4. No adverse events associated with the use of the restorative material (other than the failure rate) were observed. The lowest number of acceptable scores after one year was found for color match (88%). However, the color match of the restorations significantly improved between baseline and three-month and one-year recall, respectively ($P < 0.05$ each) (Table 4).

Table 4
Results (%) of the self-adhesive composite hybrid restorations evaluated at baseline and the recalls. Significant difference was found for color match between baseline and both recalls (Friedman test), - not determined

Criteria		Baseline (n = 60)	Three-month recall (n = 59)	One-year recall (n = 49)	Failure
Restoration quality	0	100	100	94	
	1	0	0	4	
	2	0	0	0	
	3	0	0	2	n = 1
Marginal quality	0	97	98	88	
	1	0	0	8	
	2	3	2	4	
Tooth quality	0	98	100	98	
	1	2	0	0	
	2	0	0	2	
Proximal contact	0	95	100	100	
	1	5	0	0	
Caries	0	100	100	100	
	1	0	0	0	
Vitality	0	100	100	98	
	1	0	0	2	
Hypersensitivity	0	100	98	96	
	1	0	0	2	
	2	0	0	2	
	3	0	2	0	
Color match	0	5	17	25	
	1	10	37	16	
	2	42	22	47	
	3	28	17	12	
	4	15	7	0	

Criteria		Baseline (n = 60)	Three-month recall (n = 59)	One-year recall (n = 49)	Failure
Color match (Patient view)	0	-	42	51	
	1	-	37	18	
	2	-	14	23	
	3	-	7	8	
	4	-	0	0	

Discussion

This prospective practice-based research network study evaluated a dual-curing self-adhesive composite hybrid (Surefil one), which is indicated as a permanent restorative material for class I to V restorations. The novel restorative material underwent thorough preclinical screening with encouraging results in terms of bond durability, long-term mechanical stability, and wear resistance. The individual studies were previously published in a compilation on 'Self-adhesive restorative materials – State-of-the-Art'[16–19, 21].

A practice-based setting was chosen to investigate the material's clinical performance during daily routine treatment, i.e., its effectiveness. The seven participating dentists were part of a United States-wide practice-based research group consisting of 23 private practice surgical investigators at 17 sites with 980 referrers and 15 restorative sub-investigators at 12 sites representing a wide variety of dentists and having conducted over 24 clinical studies to date. Although the evaluation criteria were not as strict as demanded by university-based studies and were lacking a comparative group, the fact the material was used by dentists in general dental practices may have given the results a realistic validity[22]. The survival rate of posterior composite restorations tended to be lower in dental practice than predicted in university-based studies under clinically ideal conditions for composite placement[23].

The material was applied in bulk without any preconditioning of enamel and dentin, as specified by the manufacturer. Cotton rolls isolation was used in 95% of the cases. When the follow-up periods were analyzed, postoperative hypersensitivity within an unacceptable range (scores 2 and 3) was 0% at baseline, 4% at two weeks, and 2% at the following clinical evaluations. Postoperative hypersensitivities of 4 to 14% were reported in the first week after composite placement, decreasing over the weeks and with an occurrence being higher in deeper cavities and Class II restorations[24]. Postoperative hypersensitivity of a self-adhesive flowable composite was comparable with that of a hybrid composite in conjunction with a self-etching adhesive, decreasing two weeks after class I restoration placement[25]. In another clinical study, postoperative hypersensitivities of (self-adhesive) bulk-fill restoratives decreased over one month from 4.2–0% for Activa Bioactive, from 12.5–4.2% for Equia Forte, and from 29.2–10.4% for Cention N, respectively[26]. The present study confirms previous evaluations, in which a Germany-based group of 24 dentists placed over 1200 Surefil one restorations mostly in class I and II cavities of over

1000 patients and reported 0.8% hypersensitivity postoperatively[27]. The low values of postoperative hypersensitivity could be attributed to sufficient self-adhesive properties of the material as well as reduced polymerization shrinkage stress and adequate curing depth even in deeper layers of the restoration. According to the manufacturer the key component of Surefil one is the hydrolytically stable MOPOS monomer, which both promotes adhesion to enamel and dentin and acts as a copolymerizing crosslinker in the cured material[15,27]. The bonding mechanism is primarily based on chemical (ionic) bond between the carboxylic acid groups in both MOPOS and acrylic acid to calcium ions of the hydroxyapatite. A micromechanical bond through modification of the smear layer and surface demineralization or hybridization could also contribute to self-adhesion.

The clinical bond of the restorations having only a slight decrease in marginal quality from 97% acceptable (scores 0 and 1) to 96% within the first year of clinical service confirms in vitro data on bond strength and marginal quality of Surefil one restorations after aging procedures [16,19,21]. In particular, this applies for the 100% retention rate of the 14 class V restorations, as their cavities are non-retentive in both the enamel and dentin indicating the self-adhesive effectiveness. Çelik et al. evaluated a self-adhesive flowable composite in non-carious cervical lesions for six months. A 33% retention rate was observed when compared with 100% for a hybrid composite placed in conjunction with its adhesive[10]. Clinical studies also compared a self-adhesive flowable composite to flowable composites applied with an adhesive. While the self-adhesive flowable composite was least retentive as a fissure sealant after two years (62.9%)[11], there was no clinical difference between the flowable composites with or without self-adhesive formulation in minimally invasive Class I cavities of adult patients after two and five years, respectively[12,13].

The one-year recall results of the 35 class I and II self-adhesive composite hybrid restorations suggest that the material performs clinically acceptable in load-bearing areas of permanent teeth. The resulting failure rate was 2% after one year and 1.9% when calculated after the mean service time of 394 days. One clinical failure was reported in a three-surface class II restoration that the examining dentist believed was affected by occlusal factors, because both the restoration and the second upper molar partially fractured, and part of the restoration remained still bonded in place. Another two-surface class II restoration in the first upper molar in the same patient was found to be performing satisfactorily. After one year of clinical service, catastrophic failure rates for posterior restorations have been observed with some restorative materials. A composite releasing calcium, fluoride and hydroxyl ions showed a 6% failure rate[28], a calcium aluminate cement a 16.7% failure rate[29], and the use of the self-adhesive restorative Activa Bioactive led to a 24.1% failure rate[14], which indicates to follow-up new material categories also at shorter terms. In the present study, no clinical evidence for such catastrophic early failures of the restorations was found. In vitro studies revealed that several mechanical properties such as flexural strength, fracture strength and long-term mechanical stability of class II restorations were similar for self-adhesive composite hybrid and composite materials[16–18]. There is previous evidence that another self-adhesive resin-based bulk-fill restorative being not commercially available performed as well as a bulk-fill composite plus adhesive of the same manufacturer in class II cavities after one year[30].

Color match was an aspect of the evaluation in which 12% unacceptable ratings (scores 3 and 4) were recorded at one year. The only shade A3 supplied at the prelaunch time of restoration placement was the principal reason for the degree of color mismatch. However, 27 restorations were rated at least one score better at one year compared to baseline, while 11 restorations each were rated worse or showed no difference in clinical appearance. Overall, 92% of the patients were satisfied with the appearance of their restorations. At the market launch of Surefil one, five different shades were introduced. It can be assumed that the color mismatch that have been identified in the study would be improved by the wider shade range available in the commercially available product.

Conclusion

The self-adhesive composite hybrid Surefil one placed in a general dental practice setting showed acceptable short-term clinical results out to one year in stress-bearing class I and II as well as non-retentive class V cavities. The prospective clinical study will be continued to confirm these early findings.

Declarations

Conflict of Interest:

A.R., F.P. and R.S. are employees of Dentsply Sirona in Konstanz, Germany. M.M. and R.H. declare that they have no conflict of interest.

Funding:

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Ethical approval:

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Data availability:

Upon reasonable request and according to ethical approval.

Informed consent:

Written informed consent was obtained from all individual participants included in the study.

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Figures

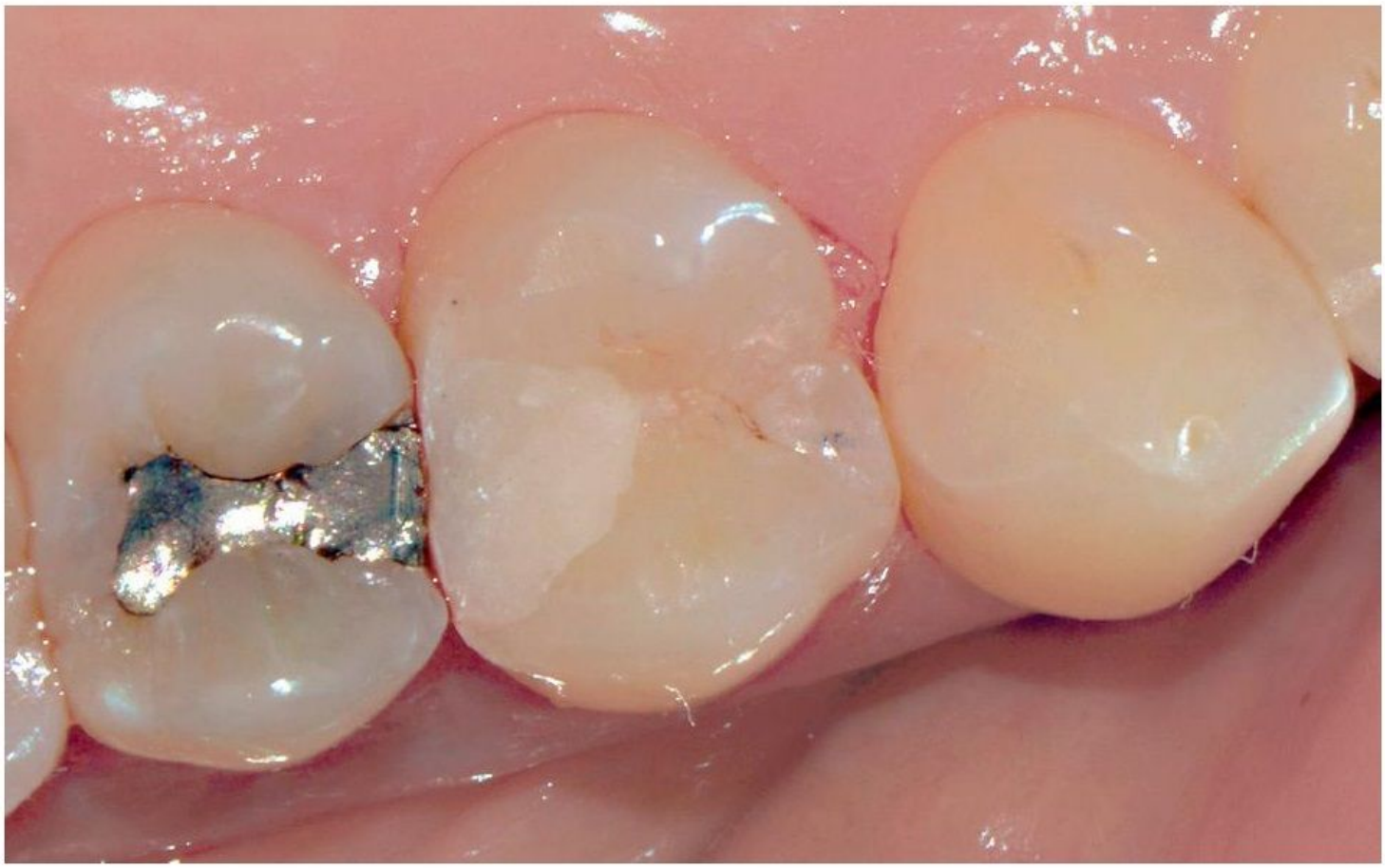

Figure 1

Class II restoration in upper premolar at baseline.

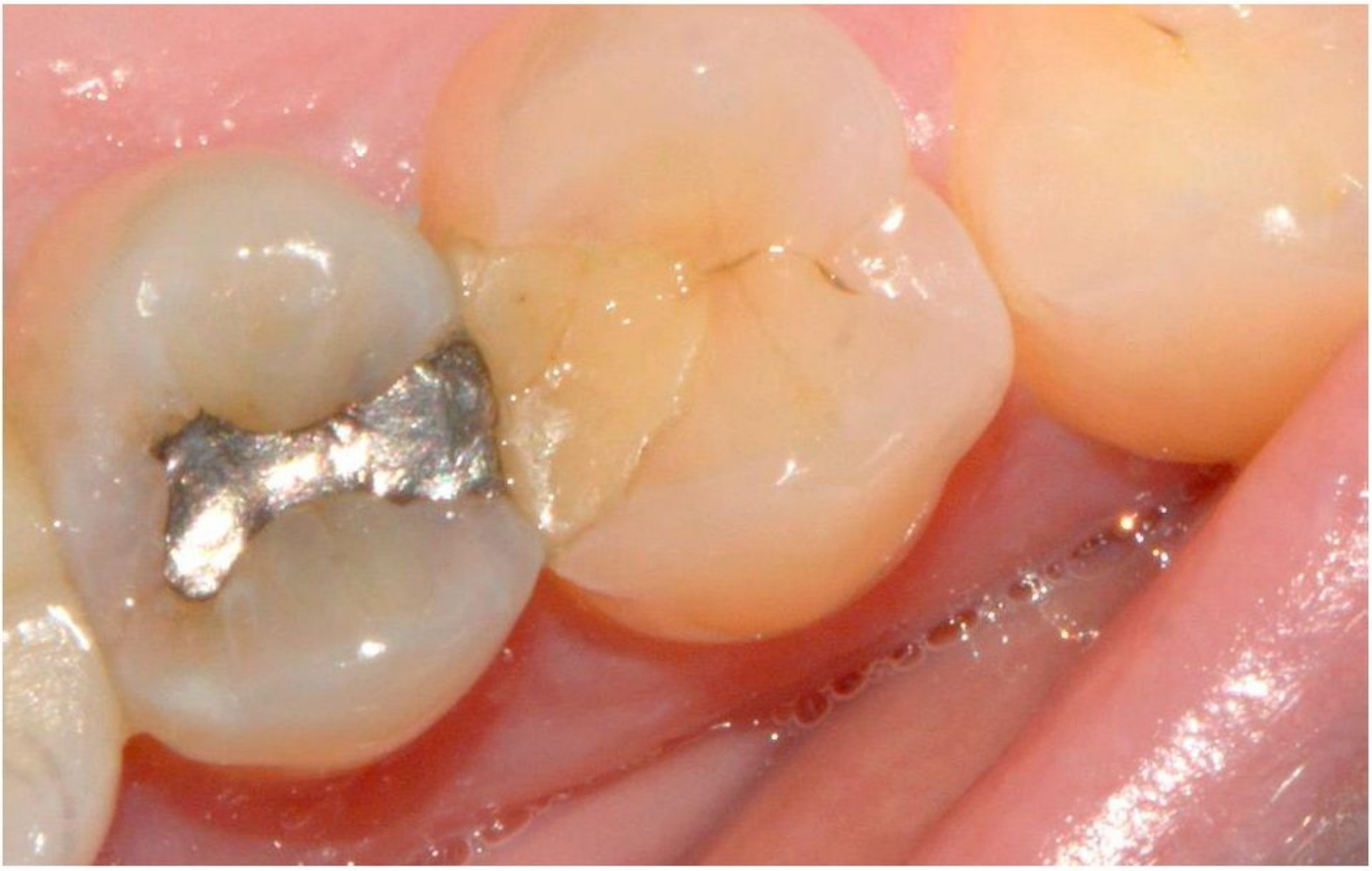

Figure 2

Same class II restoration at 1-year recall. Color change and occlusal steps at the enamel margin.

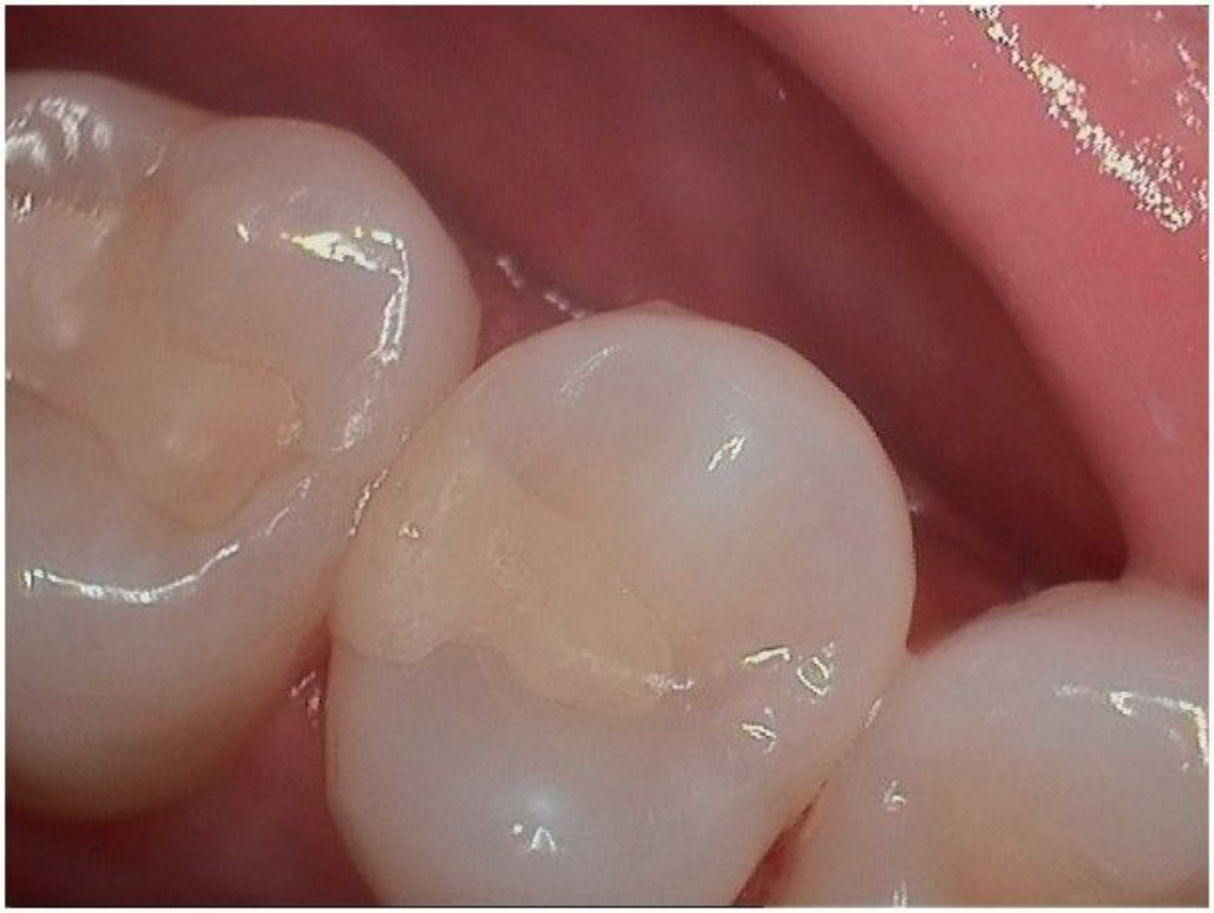

Figure 3

Class II restoration in second upper premolar at 1-year recall.

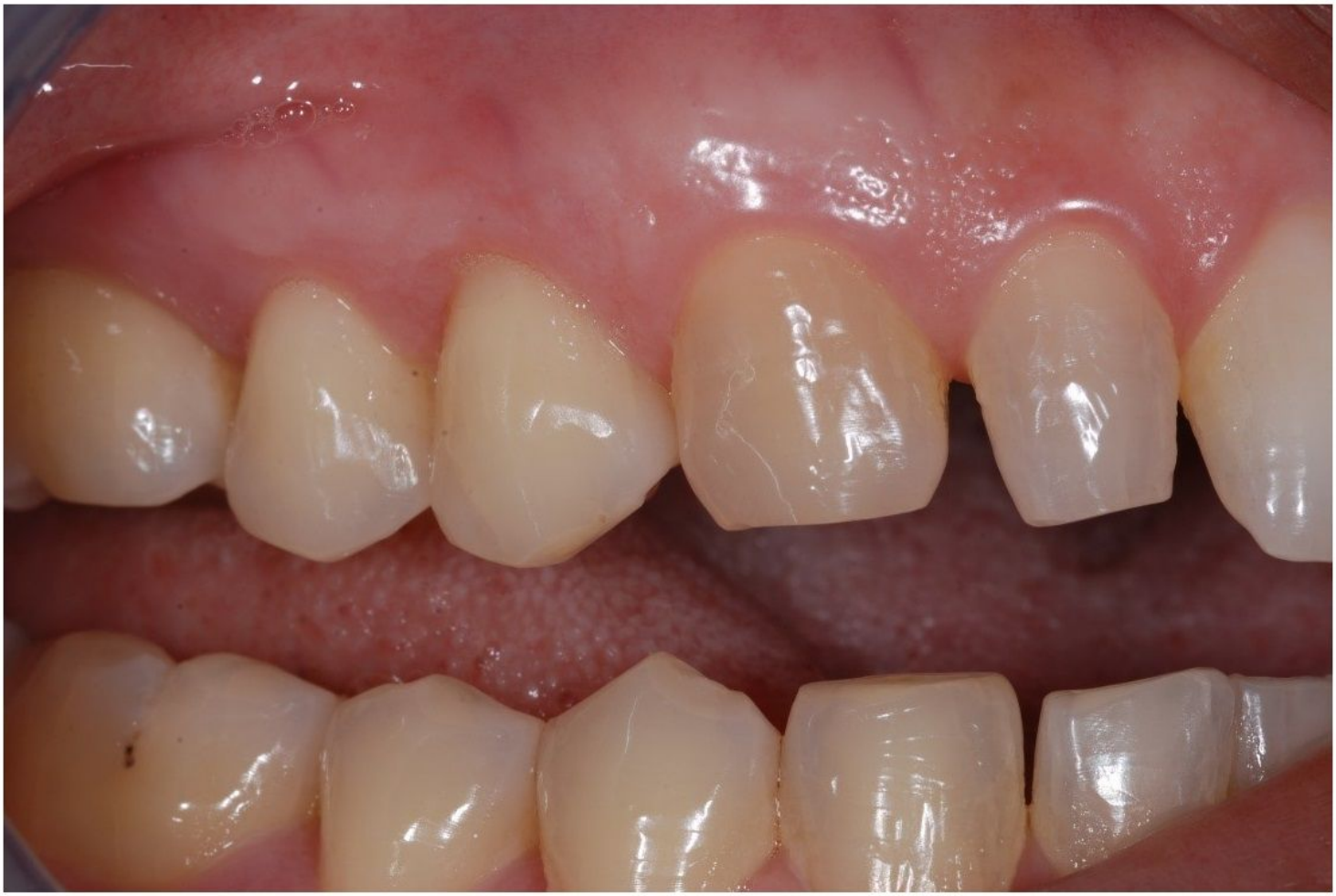

Figure 4

Class V restoration on upper first premolar at 1-year recall.