

Randomized clinical split-mouth study on the performance of CAD/CAM-partial ceramic crowns luted with a self-adhesive resin cement or a universal adhesive and a conventional resin cement after 39 months

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ABSTRACT

Objectives To determine the clinical performance of partial ceramic crowns (PCCs) luted with a conventional resin cement combined with a universal adhesive without or with selective enamel etching or luted with a self-adhesive resin cement.

Methods In a split-mouth design, each three CAD/CAM-PCCs (Vita Mark II, Cerec) were placed in 50 patients. Two PCCs were luted with a conventional resin cement (RelyX Ultimate) combined with a universal adhesive (Scotchbond Universal) without (SB-E) or with (SB+E) selective enamel etching. The third PCC was luted with a self-adhesive resin cement (RelyX Unicem 2; RXU). Chi-square tests ($\alpha \leq 0.05$) were applied. Based on clinical failures (complete debonding or need for replacement of the restorations), Kaplan-Meier survival analysis was performed.

Results 31 patients were evaluated clinically using FDI criteria at 39 months. Clinically acceptable results were detected over time, except for “fracture of material and retention” (inacceptable fractures and debondings). Within materials, statistically significant differences ($p \leq 0.003$) between baseline and 39 months were found for “marginal adaptation” and “marginal staining”. At 39-month, SB+E and SB-E showed significantly better results compared to RXU in “marginal adaptation” ($p \leq 0.021$) and “marginal staining” ($p \leq 0.013$). Kaplan-Meier analysis showed higher survival rates after 39 months for SB+E (96%) and SB-E (88%) compared to RXU (69%) with statistically significant differences between RXU vs. SB-E ($p = 0.022$) and RXU vs. SB+E ($p \leq 0.001$).

Conclusions After 39-months, PCCs luted with the self-adhesive resin cement exhibited a statistically significant inferior survival rate compared to restorations luted with the conventional resin cement combined with a universal adhesive without or with selective enamel etching.

Clinical significance Currently, self-adhesive resin cements cannot be recommended for luting partial ceramic crowns. However, the standard adhesive luting procedure comprising a universal adhesive and luting composite yielded good clinical results for more than 3 years irrespectively of application of a selective enamel etching step.

1. Introduction

Partial ceramic crowns (PCCs) enable functional, esthetic and defect-oriented restorations of posterior teeth that exhibit major loss of tooth substance. The long-term clinical success of PCCs is affected by many parameters such as amount and quality of the remaining tooth structure, properties of the ceramic material and a strong biomechanical unit consisting of the prepared tooth, the adhesive materials and the indirect

restoration [1]. With regard to the bond between the luting material and the tooth surface, different materials and pretreatment steps are discussed [2]. Adhesive procedures consisting of multiple steps are time consuming, technically sensitive and thus prone to errors in a clinical situation [1,2], but *in vitro* studies indicate superior adhesive performance of multi-step adhesive systems compared to single-step adhesive systems [3–5]. There is no clear evidence from clinical studies, if glass ceramic restorations should favorably be luted using conventional resin

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cements combined with universal adhesives or self-adhesive resin cements alone [2]. *In vitro* studies and clinical studies investigating direct class-V composite restorations have shown that selective enamel etching may increase the retention and marginal color stability of restorations luted with conventional resin cements, especially when mild universal adhesives are used [6,7]. In context with composite materials for direct restoration procedures the silane- and MDP-containing universal adhesive system Scotchbond Universal (SBU; 3M Oral Care) showed promising short- and midterm-results with a survival rate of more than 85% for class-V restorations after up to three years [8–12] and a survival rate of more than 80% class-I or class-II restorations in primary molars after up to 18 months [13,14]. Indirect ceramic CAD/CAM-restorations showed high clinical success in the literature when 3-step etch and rinse adhesives and conventional dual-curing resin cements were used [15–18]. A systematic review and meta-analysis revealed a survival rate of 91% after 10 years for glass-ceramic and feldspathic ceramic materials [19].

In a previous publication [20] our group investigated CAD/CAM-fabricated PCCs for their clinical success and survival depending on whether they were luted with a self-adhesive resin cement or with a conventional resin cement combined with a universal adhesive without or with selective enamel etching. Up to 18 months, the PCCs luted the self-adhesive resin cement showed a significant lower survival rate than the conventional resin cement combined with a universal adhesive. Besides this study, clinical data on self-adhesive resin cements compared to conventional resin cements with observation periods of more than one year are sparse [21]. However, long-term investigations of at least three years are generally recommended for investigating the success of novel dental materials or operative techniques [22]. Therefore, the aim of the present follow-up investigation of this controlled, prospective randomized split-mouth study was to evaluate the clinical performance and survival of CAD/CAM-fabricated PCCs luted according to the three different luting procedures using a self-adhesive resin cement and the conventional resin cement combined with a universal adhesive without or with selective enamel etching after clinical service of 39 months. To the best knowledge of the authors, the present follow-up is still the only one using SBU as adhesive system in self-etch mode or with selective enamel etching for luting indirect CAD/CAM-restorations with conventional resin cements in comparison with a self-adhesive resin cement [20]. The null hypothesis of this study was that there was no significant difference in clinical performance and clinical survival between the three different luting procedures over an observation period of 39 months.

2. Materials and methods

2.1. Ethical aspects

This clinical study was approved by the Internal Review Board of the University of Regensburg, Germany (IRB 11–101–0065) and registered with the German Clinical Trials Register (DRKS 00,003,059). Written informed consent was obtained from all individual patients before they were included in the study. The study was planned, realized and reported in accordance with the 1964 Helsinki Declaration and its later amendments [23] or comparable ethical standards and the CONSORT statement [24].

2.2. Patient recruitment

Patients were recruited from the patient pool of the Department of Conservative Dentistry and Periodontology (University Hospital Regensburg, Germany). They had to show three posterior teeth with large defects of the dental hard tissues (occlusal cavity width > 1/3 of the width in oro-vestibular direction) suitable for restorations with PCCs.

Inclusion and exclusion criteria were described in detail in a previous

publication presenting clinical results up to 18 months [20] and are listed in Table 1.

2.3. Restorative procedures

The clinical restorative procedures were performed by dental students in their last year before graduation under permanent supervision of experienced dentists. Experienced dentists examined all main treatment steps (diagnosis, restoration removal, caries-excitation, build-up, preparation, impression, optical scan, digital construction, restoration characterizing and finishing). Dental students always had the possibility to consult an experienced dentist in between the treatment steps.

The procedures have been described in detail earlier [20] and thus are summarized briefly here. The defect-oriented preparation of the PCCs included the reduction of the functional cusps. As the PCCs replaced extended insufficient restorations with wide occlusal and proximal boxes these virtually “internal inlay designs” served as elements of guidance for correct placement during the luting procedure. PCC preparation guidelines require elements for guidance besides rounded internal line angles and minimum layer thickness for the ceramic material. Nonfunctional cusps were left uncovered if applicable. Conventional impressions (Two-step correction impression: Silaplast futur and Silasoft N condensation silicone, Detax, Ettlingen, Germany or One-Step impression: Impregum Penta Soft polyether, 3M Oral Care, Seefeld, Germany) were taken. Temporary restorations were made chairside using a self-curing bis-acrylic resin (Luxatemp, DMG, Hamburg, Germany) and inserted using a eugenol-free temporary cement (RelyX Temp NE, 3M Oral Care). Master models were made with Type 4 dental stone (GC Fujirock, GC Europe, Leuven, Belgium) and used for the CAD/CAM fabrication (Sirona CEREC sw 4.0, Bluecam, Optispray; all Sirona, Bensheim, Germany) of monolithic silicate glass PCCs (VITA Mark II, VITA Zahnfabrik, Bad Säckingen, Germany). The restorations were characterized and glazed according to the manufacturer’s instructions (Vita Akzent Plus Glaze Powder, Vita Akzent Plus Glaze Fluid, VITA Zahnfabrik). The luting material for each of the three teeth in every patient was randomized by drawing a lot by the student in presence of the supervising dentist to RXU (RelyX Unicem 2, 3M Oral Care), SB-E (no selective enamel etching, SBU, RelyX Ultimate, both 3M Oral Care) or SB+E (selective enamel etching, SBU, RelyX Ultimate). Restorations were placed under rubber dam isolation. Cavities and restorations were pretreated for every luting procedure as summarized in Table 2.

Following to the pretreatment, all restorations were seated and stabilized by constant finger pressure and cement excess was removed. Light polymerization was performed from buccal, oral and occlusal aspects of the restoration for 20 s each (BluePhase C8, Ivoclar Vivadent GmbH, Schaan, Liechtenstein; 1360 mW/cm²). The occlusal contacts were, if necessary, adjusted. Excess removal and final polishing were

Table 1
Inclusion and exclusion criteria for study patients and teeth [20].

Inclusion criteria	Exclusion criteria
Three posterior teeth with large defects of the dental hard tissues (occlusal cavity width > 1/3 of the width in oro-vestibular direction) suitable for restorations with PCCs	Anamnesis of bruxism or parafunctional habits
Positive sensitivity test to cold of all teeth intended for treatment	Periodontitis (Periodontal Screening Index >2)
Tooth mobility degree ≤ 1	Approximal plaque index (API) or papilla bleeding index (PBI) ≥ 35%
Rubber dam application for the insertion of PCCs is possible	Intolerances to the materials used
Written informed consent to participate in the study over the entire observation time	Alcohol and drug abuses, malign tumors, HIV and general diseases that lead to a reduction of life expectation
	Participation in other clinical studies

Table 2

Pretreatment procedures of cavity and restoration surfaces for RXU, SB-E and SB+E.

	RXU	SB-E	SB+E
Cavity	-	20 s application of Scotchbond Universal in self-etch mode (3 M Oral Care)	15 s selective enamel etching (37% H ₃ PO ₄ , Scotchbond Universal, 3 M Oral Care), 20 s application of Scotchbond Universal (3 M Oral Care)
restoration	60 s etching the basal ceramic surface (5% hydrofluoric acid, VITA ceramics etch, VITA Zahnfabrik)		
	Silane ceramic primer (RelyX Ceramic Primer, 3 M Oral Care)	20 s Scotchbond Universal (3 M Oral Care) application	20 s Scotchbond Universal (3 M Oral Care) application

performed.

2.4. Clinical examination

Clinical examinations were performed at baseline (BL; first week after insertion), as well as 6, 12, 18, 24, and 39 months after insertion. The present study reports the results at BL and 39-months. All restorations were examined according to modified FDI criteria [25] consecutively and independently by two calibrated dentists which were not involved in the treatment procedure and therefore blinded to the treatment as described earlier [20]. In case of disagreement during the evaluations, they had to come to an agreement while the patient was still present. Restorations were rated as clinically excellent/very good (score 1), clinically good (score 2), clinically sufficient/satisfactory (score 3), clinically unsatisfactory (score 4) and clinically poor (score 5). Restorations rated from clinically excellent to clinically sufficient were considered “clinically acceptable” (scores 1–3). Restorations rated as clinically unsatisfactory and clinically poor were considered as “clinically not acceptable” (scores 4 and 5). To evaluate the performance at respective timepoints, all FDI criteria were evaluated and the following criteria possibly influenced by the luting material and procedure were depicted in detail:

- **Esthetic properties**
 - marginal staining (A2b)
- **Functional properties**
 - fracture of material and retention (B5)
 - marginal adaptation (B6)

At each clinical evaluation, standardized photodocumentation was performed and the papillary bleeding index (PBI, [26]) was recorded in

order to assess the patient's oral hygiene level. Replacement of the restoration, e.g. complete debonding, fractures of dental hard tissues or restorations, endodontic treatment and score 4 and score 5 ratings according to FDI criteria and were considered as failures at the end of each recall period, accordingly. An exemplary clinical follow-up with photographs before insertion, at BL, 18-months and 39-months is shown in Fig. 1.

2.5. Statistical analysis

Non-parametrical analyses ($\alpha = 0.05$) were performed using SPSS version 25 (SPSS, Chicago, USA). FDI criteria were analyzed using Chi-square tests for pairwise differences among the three luting procedures and within each luting procedure over time. Based on clinical failures causing complete debonding or replacement of the restorations, the Kaplan-Meier survival rates were calculated [27] and log rank (Mantel-Cox) test was used for testing the equality of survival distributions for the different luting procedures. All evaluated patients with at least one restoration under risk were included in the statistical analysis.

3. Results

The patient flow of the initial 50 patients with three restorations each is shown in Fig. 2. Two patients were lost to follow-up directly after insertion of the restorations and could not be recalled for the BL examination. 31 (65%) were evaluated at the 39-months examination, which was performed after a median (25–75% percentile) observation time of 39 months (36–44). The age of the patients at 39-months examination ranged between 33 and 78.8 years (median 55.9 years) Sex distribution of patients and location of restorations are shown in Table 3.

3.1. Clinical performance according to FDI criteria

3.1.1. Marginal staining

Significantly more marginal staining was found for all luting procedures after 39-months as compared to baseline ($p \leq 0.001$). After 39-months, significantly less marginal staining was recorded for SB-E ($p = 0.013$) and SB+E ($p = 0.005$) as compared to RXU. There was no significant difference between SB-E and SB+E. No restoration with clinically unacceptable marginal staining was detected in any of the three groups (Table 4).

3.1.2. Fracture of material and retention

Fractures of the restoration (score 5) were the most frequent event leading to a renewal of restorations in all groups and exclusion from further clinical evaluation. Fractures rated as clinically unacceptable (score 4 or 5) were found for 7 restorations in group RXU, for 4 restorations in group SB-E and for 1 restoration in SB+E (Table 5). Fractures rated as clinically acceptable (score 2 or 3) were found for 2 restorations in group RXU, 4 restorations in group SB-E and 4 restorations in group

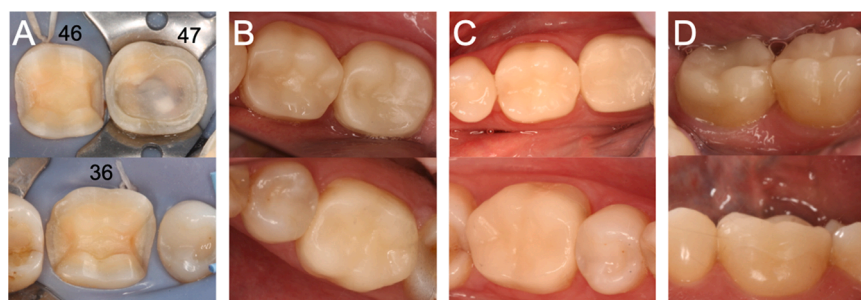


Fig. 1. Clinical follow-up of teeth 47 (SB+E), 46 (SB-E) and 36 (RXU) in the same patient

A: Preparation after core build-up and rubber dam application before insertion; B: Baseline examination, occlusal view; C: 39-months examination, occlusal view; D: 39-months examination, buccal view.

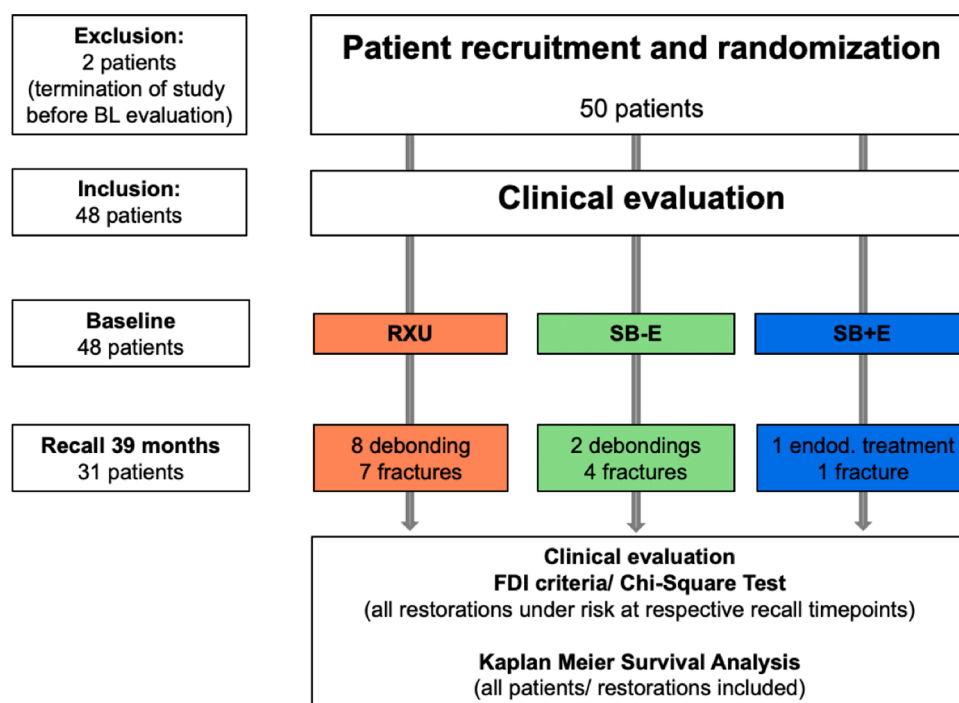


Fig. 2. Flowchart showing number of examined patients and restoration failures within groups at respective time points.

Table 3

Sex distribution of patients and location of restorations.

Sex of patients at 39 months		Restoration location						
female	male		Premolars			molars		
19 (61.3%)	12 (38.7%)		RXU	SB-E	SB+E	RXU	SB-E	SB+E
		Baseline	13 (27.1%)	15 (31.2%)	14 (29.2%)	35 (72.9%)	33 (68.8%)	34 (70.8%)
		39 months	4 (23.5%)	9 (36%)	7 (25%)	13 (76.5%)	16 (64%)	21 (75%)

SB+E (Table 4). Over time, RXU ($p \leq 0.001$) and SB-E ($p = 0.022$) showed a significant deterioration in criterion fracture of material and retention. Significantly more fractures were recorded for RXU compared to SB+E ($p = 0.026$) after 39-months.

3.1.3. Marginal adaptation

For the criterion marginal adaptation, a significant deterioration was found for all groups at 39-months as compared to baseline ($p \leq 0.003$) in terms of minor (score 2) or moderate marginal gaps (score 3). At 39-months, marginal adaptation was rated significantly better for SB-E ($p = 0.021$) and SB+E ($p \leq 0.001$) as compared to RXU. No restorations showing clinically unacceptable marginal adaptation were detected in any of the three groups at any time point (Table 4). A clinical example of all three restorations in one patient is shown in Fig. 4, which exhibit a decrease in marginal adaptation and an increase in marginal staining for RXU after 39-months.

3.1.4. Kaplan-Meier survival rate

The survival rates (95% confidence intervals) of the restorations at 39-months recall were 69% (62%; 76%) for RXU, 88% (83%; 92%) for SB-E and 96% (93%; 99%) for SB+E (Fig. 3). The log rank (Mantel-Cox) test revealed significantly lower survival rate of group RXU at 39-months recall compared to SB-E ($p = 0.022$) and SB+E ($p \leq 0.001$). No significant difference was observed between SB+E and SB-E ($p = 0.142$). The reasons resulting in need of replacement of the restorations are shown in Table 5.

4. Discussion

4.1. Study design

The present study investigated three PCCs per patient randomly assigned to luting with a self-adhesive resin cement (RXU) compared to a conventional resin cement combined with a universal adhesive in self-etch mode (SB-E) or with additional selective enamel etching (SB+E). The study was performed in a prospective randomized examiner-blinded design in accordance with the requirements outlined in the CONSORT 2010 statement and the requirements of the American Dental Association (ADA) Acceptance Program Guidelines for direct and indirect restorative materials (i.e. split-mouth design with at least 20 patients with two restorations each) [28,29]. Due to the inclusion of 48 patients at the beginning of the study, 31 patients still could be reevaluated at 39-months despite a dropout-rate of 35% [30]. A split-mouth design is regarded more favorable than a parallel design for clinical studies investigating dental restorations because individual aspects such as oral hygiene, diet, smoking or parafunctional habits, which influence clinical survival and success of the restorations, affect all groups equally. Furthermore, in a split-mouth design with all three luting procedures employed in the same patient, the loss to follow-up of a patient implies the drop-out of all three luting procedures in this given patient. This means that in split-mouth studies attrition occurs in a rather balanced way and attrition bias is reduced by a higher probability of random missing data [31]. On the other hand, drop-outs of patients without further knowledge about failures for any of the three luting procedures need to be kept in mind. The patient selection from the pool of a public

Table 4
Clinical performance according to FDI criteria.
Clinically acceptable scores (1–3) are highlighted in green, non-acceptable scores (4–5) are highlighted in orange. Provided *p*-values show significant differences between luting procedures at a respective examination time point (bold) or within one luting procedure over time (italic); ns=not statistically significant ($p > 0.05$).

FDI criterion	time	RXU					SB-E					SB+E					Significance (p-value)				
		FDI score		1	2	3	4	5	FDI score		1	2	3	4	5	RXU vs SB-E RXU BL vs Recall		RXU vs SB+E SB-E BL vs Recall		SB-E vs SB+E SB-E BL vs Recall	
A2b Marginal staining	BL	n	47	1	-	-	-	-	47	1	-	-	1	-	-	ns	ns	ns	ns		
		%	97.9	2.1					97.9	2.1			2.1			-	-	-	-		
	39- mo	n	11	2	5	-	-	-	11	10	6	-	-	7	-	0.013	0.005	ns	ns		
B5 Fracture of material and retention	BL	%	61.1	11.1	27.8				40.7	37	22.2					0.000	0.000	0.000	0.000		
		n	47	-	1	-	-	-	46	1	1	-	-	1	-	ns	ns	ns	ns		
	39- mo	%	97.9	2.1	2.1	2	1	4	95.8	2.1	2.1			2.1		-	-	-	-		
B6 Marginal adaptation	BL	n	15	-	2	1	5	2	21	2	2	1	4	2	2	ns	0.026	ns	ns		
		%	65.2		8.7	4.3	21.7	70	6.7	6.7	3.3	13.3		6.9				ns	ns		
	39- mo	n	36	11	1	-	-	35	12	1	-	-	1	-		ns	ns	ns	ns		
	BL	%	75	22.9	2.1			72.9	25	2.1			39.6	2.1		-	-	-	-		
		n	3	13	2	-	-	10	13	4	-	-	10	10	9	0.021	0.000	ns	ns		
	39- mo	%	16.7	72.2	11.1			37	48.1	14.8			34.5	34.5	31	0.000	0.003	0.001	0.001		

Table 5

Reasons for restoration failure in relation to materials and location.

Failures at 39 months		All	RXU	SB-E	SB+E	Reasons
All Failures	Premolars	9	5	3	1	
	Molars	14	10	3	1	
	All	23	15	6	2	
Irreparable fractures	Premolars	5	2	2	1	
	Molars	7	5	2	-	
	All	12	7	4	1	
Debondings	Premolars	4	3	1	-	
	Molars	6	5	1	-	
	All	10	8	2	-	
Others	Premolars	-	-	-	-	-
	Molars	1	-	-	1	Endodontic treatment (restoration remained <i>in situ</i>)

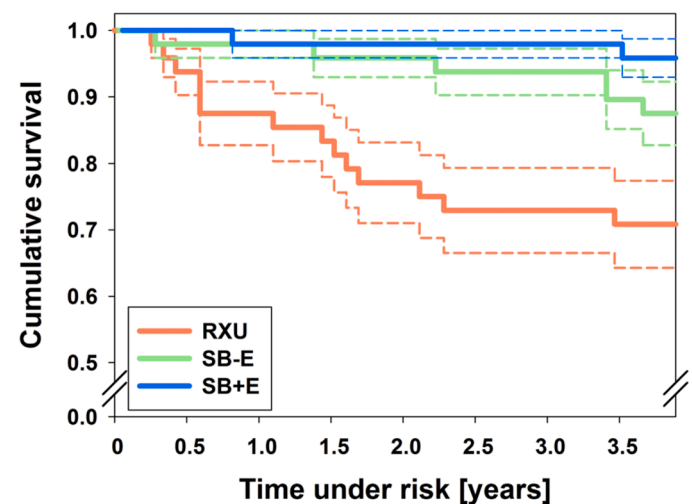


Fig. 3. Kaplan-Meier survival curves of RXU, SB-E and SB+E (bold lines) over time. Dashed lines indicate the respective upper and lower confidence intervals. The survival rate of RXU was significantly inferior compared to SB+E ($p \leq 0.001$) and SB-E ($p = 0.022$). No significant difference was observed between SB+E and SB-E ($p = 0.142$).

health care institution and treatment procedures conducted by a trained group of student operators under the supervision of experienced dentists have been discussed before [20]. The examinations scheduled for 3 years were performed with a slight delay after a median period of 39 months. While all FDI criteria were recorded during every clinical evaluation time point (Table 4) [25], only those FDI criteria that are directly influenced by the luting material are shown in detail (criteria A2b, B5 and B6) here. FDI criteria are well established for a precise assessment of the clinical performance of differently extended direct and indirect tooth-colored restorations over time [25,32–35]. Within each group, all restorations under risk at the respective recall time points were evaluated clinically irrespective of the fact that one of the three restorations might have been lost during the observation period. Over time, losses or failures of single restorations resulted in varying restoration numbers between the groups RXU, SB-E and SB+E.

4.2. Kaplan-Meier survival rate

In the present study, PCCs luted with the self-adhesive resin cement showed significantly lower survival rates due to higher failure rates with respect to fractures leading to restoration renewal and debondings compared to PCCs luted with the conventional resin cement combined

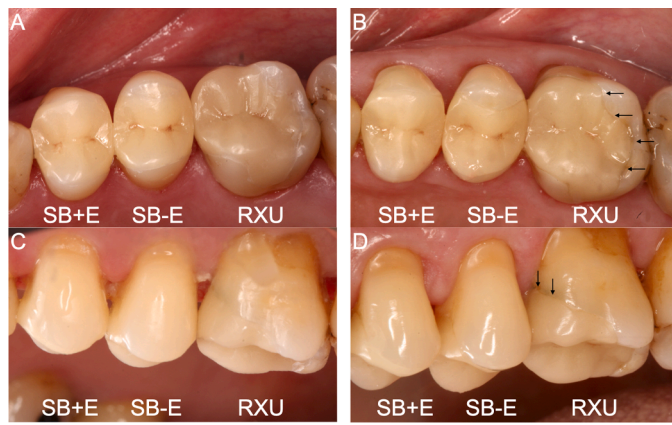


Fig. 4. Clinical evaluation: 26 (RXU) showing decreased marginal quality (B) and increased marginal staining (D) after 39-months. Good clinical performance of PCCs 24 (SB+E) and 25 (SB-E) at BL and 39-months examination. A: BL examination, occlusal view; B: 39-months examination, occlusal view; black arrows: decreased marginal integrity; C: BL examination, buccal view; D: 39-months examination, buccal view; black-arrows: increased marginal staining.

with a universal adhesive without and with selective enamel etching. Since a correlation between the fracture strength of the ceramic restoration and the luting procedure has been described in the literature, fractures were included in the survival rate in addition to debondings [36,37]. *In vitro* studies are indicative of the fact that the bond and interaction visible in Scanning electron microscope examination [38] between self-adhesive resin cements and dentin may be impaired when dentin is dried [39,40]. This must be taken into account when restorations are luted under rubber dam and by student operators under the supervision of experienced dentists as in the present study, which may imply waiting periods and a higher risk of dry dentin [39]. Accordingly, Peumans et al. observed higher survival rates of 97% with and 93% without prior selective enamel etching when investigating the clinical performance of Empress 2 (Ivoclar Vivadent, Schaan, Liechtenstein) ceramic inlays luted by experienced dentists with RXU over a period of four years [41]. Selective enamel etching may also increase the survival rate of self-adhesive resin cements, as shown by Baader *et al.*, who found a significantly higher survival rate with selective enamel etching of PCCs luted with RXU [42]. Despite the lower bond strength of some self-adhesive resin cements to dentin and glass-ceramic in an *in vitro* study, the self-adhesive resin cement used in the present study (RXU) showed similar bond strength on both, dentin and glass-ceramics, compared to a conventional resin cement (Panavia 21, Kuraray, Osaka, Japan) [43]. However, a systematic review of the literature on laboratory studies assessing bonding performance to dentin of conventional multistep resin cements and self-adhesive resin cements is indicative for a superior overall adhesive performance of conventional resin cements, especially for bond strength under the influence of long-term aging [44]. This might be caused by the lower etching and demineralization capacity of self-adhesive materials [44] and might explain the higher failure rates of self-adhesive resin cements compared to conventional resin cements especially over longer observation times as can be seen in the present study.

In the present study, the PCCs luted with the conventional resin cement combined with a universal adhesive without or with selective enamel etching showed superior survival rates of more than 88% after 39 months compared to the self-adhesive resin cement. Most restorations (69%) in the present study were placed in molars that may be exposed to higher occlusal forces compared to premolars. However, a systematic review and meta-analysis by Morimoto *et al.* could not find a

significantly higher failure risk for molars compared to premolars [19]. After an observation period of one year for IPS e.max Press (Ivoclar Vivadent, Schaan, Liechtenstein) inlays and onlays placed using a self-adhesive resin cement (G-Cem Automix, GC, Tokyo, Japan) or a conventional resin cement (Variolink N high viscosity, Ivoclar Vivadent, Schaan, Liechtenstein) used with a separately applied etch-and-rinse-multistep adhesive system (Syntac Classic, Ivoclar Vivadent, Schaan, Liechtenstein), Emiroğlu *et al.* observed survival rates of more than 90% [45]. The results of the study comply with the findings of our previous study [20] at the respective timepoint with a tendency towards higher survival rates after one year for the conventional resin cement not reaching statistical significance. Furthermore, a by tendency higher survival rate for the conventional resin cement with etched enamel margins not reaching statistical significance ($p = 0.142$) compared to the conventional resin cement without etched enamel margins was observed in the present study.

4.3. Clinical performance according to FDI criterion fractures of material and retention

In our study, after 39 months, only 2 debondings occurred for group SB-E and none in SB+E, where SBU was used for the pretreatment of both, tooth substances and etched ceramics. Four fractures with need of restoration renewal (score 5) occurred in group SB-E, only one for SB+E. For the self-adhesive resin cement RXU, 8 debondings and 7 fractures occurred. In the Emiroğlu study, in the self-adhesive resin cement group only debondings, not fractures led to a decrease of survival rates after 12 months [45].

In another study investigating 70 inlays and 13 onlays fabricated from pressed leucite-reinforced glass ceramic luted with a self-adhesive resin cement (RelyX Unicem) or a conventional resin cement (Variolink II, Ivoclar Vivadent, Schaan, Liechtenstein) used with a separately applied etch-and-rinse-multistep adhesive (Syntac Classic) over two years, no complete debonding and only one clinically unacceptable fracture at the enamel margins occurred in the conventional resin-cement group [46]. In the self-adhesive resin cement group, no clinically unacceptable fractures or complete debondings occurred [46].

4.4. Clinical performance according to FDI criteria marginal discoloration and marginal adaptation

In the present study, we observed a significant deterioration in criteria marginal adaptation (more than 69% clinically excellent or good at 39-months evaluation) and marginal staining (more than 72.2% clinically excellent or good at 39-months evaluation) for all materials over time. In both criteria, RXU performed significantly inferior compared to the conventional resin cement combined with a universal adhesive without or with selective enamel etching (SB-E, SB+E). Another study investigated conventionally fabricated leucite-reinforced glass ceramic inlays and onlays luted with a self-adhesive resin cement (RelyX Unicem) or a conventional resin cement (Variolink II) used with a separately applied etch-and-rinse-multistep adhesive (Syntac Classic) [46]. The authors reported a significantly deteriorated marginal integrity in both groups with 97% clinically excellent or good rated restorations in the conventional resin cement group and 67% clinically excellent or good rated restorations in the self-adhesive resin group after two years [46] which is in accordance with the findings of the present study with more extended restorations. Peumans *et al.* reported a significantly deteriorated marginal adaptation of ceramic inlays luted with a self-adhesive resin cement without or with etched enamel margins down to 76.7% clinically excellent or good rated restorations after four years [41]. Marginal staining and marginal steps were not described separately in both studies due to the use of modified USPHS criteria which combine marginal adaptation and staining in one criterion. Another *in vivo* study investigated the short-term behavior of IPS e.max Press inlays and onlays placed using a self-adhesive resin cement (G-Cem

Automix, GC, Tokyo, Japan) or a conventional resin cement (Variolink N) combined with a separately applied etch-and-rinse-multistep adhesive (Syntac Classic) over 1 year and found significantly deteriorated marginal adaptation and marginal staining only for the restorations luted with self-adhesive resin cement [45].

Increasing degradation of marginal adaptation and color stability seem to be a main concern for self-adhesive resin cements. The decreasing marginal quality might be caused by lower wear resistance and a potentially higher hydrolytical susceptibility of the self-adhesive resin cement as compared to conventional resin cements. Belli et al. examined the wear resistance of self-adhesive resin cements, conventional resin cements and a flowable composite in their *in vitro* study using confocal laser scanning microscopy in reflectance mode on gap replicas [47]. After tooth abrasion test, self-adhesive resin cements showed no significant differences compared to both conventional resin cements AllCem (FGM, Joinville, Brazil) and Variolink Base (Ivoclar Vivadent, Schaan, Liechtenstein) or the flowable composite (Grandio Flow, Voco, Cuxhaven, Germany). Following to ACTA machine wear test, all self-adhesive resin cements revealed significantly more vertical wear loss due to matrix wear and filler debonding compared to the flowable composite and one of the conventional resin cements (AllCem) [47].

For restorations luted with a conventional resin cement combined with a universal adhesive, we found a significant deterioration in marginal adaptation and marginal discoloration of restorations over time without a significant influence of selective enamel etching after 39-months. These results coincide on one hand with the study of Loguercio et al. mentioned above which examined the clinical performance of directly placed restorations in non-carious cervical lesions using the same universal adhesive system as in our study without or with selective enamel etching [9]. On the other hand, in a systematic review investigating self-etch adhesives for direct restorations in non-carious cervical lesions, Szesz et al. found a statistically significant better marginal adaptation and lower marginal discoloration in restorations of NCCLs for observation periods of longer than 12 months, when selective enamel etching was performed [7].

5. Conclusion

After 39 months, the null-hypothesis had to be rejected as the self-adhesive resin cement showed inferior marginal adaptation, more marginal staining and a significantly lower survival rate compared to the conventional resin cement combined with a universal adhesive without or with selective enamel etching when used as luting material for monolithic CAD/CAM-fabricated silicate glass PCCs. Focusing on the mid-term results, conventional resin cements in combination with a separately applied adhesive may be more suitable for luting defect-oriented PCCs as compared to self-adhesive resin cements.

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Compliance with ethical standards

Ethical approval

The study was approved by the Internal Review Board (IRB) of the University of Regensburg (IRB 11–101–0065) in accordance with the Declarations of Helsinki (1975) and Tokyo (1983) and registered with the German Registrar for Clinical Studies (DRKS 00003059).

Informed consent

All patients were required to give written informed consent prior to inclusion in the study.

Credit author statement

Konstantin J. Scholz: data analysis, formal analysis, Writing - Original Draft

Isabelle M. Tabenski: investigation, data curation, **Vanessa Vogl:** investigation, data curation, **Fabian Cieplik:** Writing - Review & Editing, data curation **Gottfried Schmalz:** conceptualization, Writing - Review & Editing, **Wolfgang Buchalla:** Writing - Review & Editing, visualization, **Karl-Anton Hiller:** formal analysis, validation, Writing - Review & Editing, **Marianne Federlin:** project administration, methodology, Writing - Review & Editing.

Declaration of Competing Interest

The authors declare that they have no conflict of interest.

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