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ORIGINAL ARTICLE

Effect of selective enamel etching on clinical performance of CAD/CAM partial ceramic crowns luted with a self-adhesive resin cement

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Abstract
Objectives This study was conducted to evaluate a self-adhesive resin luting cement [RelyX Unicem 3MESPE–RXU] for luting partial ceramic crowns (PCCs) with and without selective enamel etching in a prospective, randomized clinical trial.
Materials and methods Thirty-four patients had received the intended treatment. Two PCCs (Vita Mark II; Cerec 3D; Sirona) had been placed in a split-mouth design: one with RXU without enamel etching (RXU), the other with RXU with selective enamel etching (RXU+E). Restorations were evaluated at baseline (BL) and after 12, 24, and 36 months (USPHS criteria). For statistical analysis, the Chi-square test was applied (α=0.05). Clinical survival of all restorations (n=68) after 3 years was determined using Kaplan–Meier analysis.
Results Twenty three patients (12 male/11 female) were available for clinical evaluation after 3 years. 19 RXU-PCCs were placed in molars, four in premolars, 18 RXU+E–PCCs in molars, five in premolars. Concerning clinical changes, no significant differences were found between luting strategies RXU/RXU+E at all recalls. Statistically significant changes over time were observed for *marginal adaptation* and *marginal discoloration* between BL and 36 m for RXU and RXU+E. For RXU+E, *postoperative hypersensitivities* decreased significantly from BL (n=6) to 36 m (n=0). Of the 68 restorations originally included, eight RXU and four RXU+E restorations failed. At 3 years, Kaplan–Meier survival of RXU was 72.9 %, that of RXU+E 87.6 %. Survival rates were not statistically significant different.
Conclusions Although clinical survival of RXU+E is slightly better at 3 years, restorations of both groups perform similar with respect to clinical changes over time as evaluated by modified USPHS criteria.
Clinical relevance The self-adhesive resin cement RXU can be used in conjunction with selective enamel etching, because survival rates of PCCs in the RXU+E group were not lower but, as a trend, even better than without enamel etching.

Keywords Controlled · Prospective clinical study · Partial ceramic crowns · Clinical evaluation · Self-adhesive cement · Selective enamel etching

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Introduction

One major development in order to make the process of adhesive luting less technique-sensitive and time-consuming has been the introduction of self-adhesive universal luting materials in the beginning of the 21st century [12, 19, 29, 37]. As lined out by Stamatacos and Simon [37], self-adhesive universal luting materials can bond to an unconditioned tooth surface, respectively, the smear layer, without pretreatment with an acid or adhesive. Thus, incorporation of the restoration is accomplished in one single step. Self-adhesive resin cements contain phosphoric acid and/or carboxylic acid methacrylate monomers. After mixing, the phosphoric acid groups react with the hard tooth tissue, on the one hand, and with basic fillers incorporated in the luting material, on the other hand (cement reaction), thus forming a bond. Parallel to the cement reaction, polymerization of the methacrylate monomers is initiated (radical polymerization). While the material sets, the acid groups are neutralized, and it turns from hydrophilic to hydrophobic [17, 43]. The pretreatment of the ceramic restoration usually follows the ceramic manufacturer's recommendations

and includes etching with hydrofluoric acid and silanization with silicate-based ceramics.

The question whether self-adhesive luting materials are a valid alternative to conventional resin cements employing an adhesive system in combination with a corresponding luting composite has been addressed in many laboratory studies [12, 19, 29, 37]. It has been shown that the physico-mechanical properties of the most investigated self-adhesive luting material, RelyX Unicem (3 M ESPE, Seefeld, Germany) are in the range of those of conventional resin luting materials [20, 31]. Bonding to dentin is similar to that of conventional adhesive luting systems. With respect to microleakage data, it may even exceed their performance, although self-adhesive materials only superficially react with the dentin smear layer, without forming a distinct hybrid layer [2, 3, 6, 33]. Regarding bonding to enamel, the majority of in vitro data show that adhesion of self-adhesive luting materials to enamel is inferior as compared to that of conventional etch and rinse adhesive/luting composite combinations [5, 6]. There is evidence that an increase in bonding performance to enamel can be obtained when selective enamel etching is applied [6, 24]. However, it is critically discussed for self-etch adhesives as well as for self-adhesive cements that accidental etching of dentin in the course of selective enamel etching may compromise the bond formed [6, 16, 41] and could eventually clinically result in postoperative hypersensitivities [5, 6].

In a clinical study investigating ceramic inlays luted with either a self-adhesive or a conventional adhesive luting material, Taschner et al. [39] reported that the self-adhesive resin cement showed clinical outcomes similar to the conventional, multistep cementation procedure after 2 years. Only with respect to criteria tooth integrity and marginal integrity, the conventional luting system revealed better results. Peumans et al. [28] compared the clinical behavior of ceramic inlays/onlays with one cusp covered at maximum luted with a self-adhesive luting material with and without selective enamel etching. The authors concluded that after 4 years, the self-adhesive luting cement can be recommended for bonding of ceramic inlays/onlays, and they line out that additional selective enamel etching does not improve the clinical performance of the restorations within the observation period of 4 years. Clinical data for the performance and longevity of partial ceramic crowns (PCCs), which are advocated for the restoration of large defects with reduced cavity wall thickness, are comparatively rare [28, 35]. Furthermore, to date, only limited evidence is available to show whether selective enamel etching improves adhesion of self-adhesive universal luting materials to enamel in the clinical situation [28, 35].

The aim of the present prospective, randomized, controlled split-mouth study was to compare the performance of PCCs inserted with RelyX Unicem either with or without selective enamel etching (RXU+E and RXU, respectively). The null hypothesis tested was that there is no significant difference in clinical behavior and failure rate between PCCs inserted the RXU+E or RXU. The results of the 1-year and 2-year observation periods were reported previously [34, 35]. Here, the results of the 3-year observation period are reported.

Materials and methods

Materials and methods have been previously described in detail when reporting the 1- and 2-year findings [34, 35]. Therefore, in this place, only a summary of materials and methods shall be given.

The study was designed as a prospective, controlled, randomized, clinical trial in a split-mouth design, following recommendations outlined by the American Dental Association (ADA) Acceptance Program Guidelines [1], as well as the CONSORT statement and guidelines [25, 27, 36] and previously published protocols [10, 35]. The ethics committee of the University Clinic of Regensburg approved the study design (IRB 06/092). Patients were recruited from the patient pool of the Department of Operative Dentistry and Periodondology, Dental School, University of Regensburg. Patients received detailed information upon the proposed treatment prior to inclusion into the study and written informed consent was obtained from each patient for participation in the study and for enrollment in a 3-year recall program.

For inclusion into the study, patients had to meet the following criteria: patients had to present with two large defects in the posterior region, including insufficient amalgam or composite restorations, suitable for the restoration with all-ceramic PCCs. Furthermore, teeth to be restored were required not to reveal any symptoms of pain, application of rubber dam needed to be possible for insertion of the restorations and tooth mobility was required to be lower or equal to degree I. A moderate level of oral hygiene was required, represented by a papilla bleeding index lower or equal to 35 %.

Depending upon the size and extension of the lesions, PCC preparations were performed with a design adapted to the individual situation in the particular patient. The preparation followed the current standards for preparation for all-ceramic restorations published in the literature [7–9, 34, 35]. For design and fabrication of the PCCs, a dental CAD/CAM system was employed: the Cerec 3D system (Sirona, Bensheim, Germany, Software version 3.0 600/800). Application of the system is part of the curriculum at the University of Regensburg, Department of Operative Dentistry and Periodontology. An indirect method including impression taking (Silaplast/Silasoft, Detax, Ettlingen, Germany) and fabrication of a die cast model was used for fabrication of the PCCs. Prepared teeth were provisionally restored with temporary restorations (Luxatemp, DMG, Hamburg, Germany; Temp Bond NE, Kerr, Scafati, Italy) for 7–10 days prior to try-in. PCCs were milled from

industrially prefabricated ceramic blocks (Vita 3D Master Cerec Mark II, Vita, Bad Säckingen, Germany) and consecutively fitted on the die casts with respect to occlusion, articulation, and proximal contact points.

In a second appointment with the patient, fit of the restorations was carefully evaluated using a try-in silicone (Fit Checker, GC, Tokyo, Japan), a dental probe, and magnifying eye glasses (×2). Minor adjustments were made if applicable. In the case of insufficient fit (tip of the dental probe catches at the dental margin and penetrates gap, luting gap>100 μm), a new restoration was fabricated. Consecutively, randomization of the restoration to either the control group (RXU) or the experimental group (RXU+E) was performed, following a "coin-toss method." Then after application of rubber dam, the two PCCs were inserted following the respective luting strategy.

In the RXU group, the restoration was etched with 5 % hydrofluoric acid gel (HF; Vita Ceramics Etch, Vita) and silanized (Monobond S, Ivoclar Vivadent, Schaan, Liechtenstein). The prepared tooth was cleaned with a slurry of pumice, rinsed with water spray, dried shortly avoiding overdrying and RXU was applied directly into the cavity, without any further pretreatment of the hard tooth tissues, before placing the restoration.

In the RXU+E group, the restoration was etched with HF and silanized. With the prepared tooth, selective enamel etching was applied using 37 % phosphoric acid gel (Total Etch, Ivoclar Vivadent, Schaan, Liechtenstein) on the enamel margins surrounding the cavity. The acid was carefully rinsed off after 30 s, taking care not to contaminate the dentin. Consecutively, the tooth tissue was dried avoiding overdrying, RXU was applied into the cavity, and the restoration was seated.

With both strategies, restorations were kept under constant light pressure with an instrument after insertion while removing excess luting material and during light-activated polymerization. Consecutively, the occlusion was adjusted and the restorations were finished and polished.

Treatment of patients included in the study was performed by students in their last year of dental school, supervised by an experienced dentist. The preparation was outlined and performed by the students under the supervision of an experienced dentist. The latter checked and finally accepted the restorations for accuracy and final fit, as well as for completion of the procedure after insertion and finishing of the PCCs by the dental student.

Clinical evaluation according to modified USPHS criteria [23, 26, 30] was performed by two calibrated dentists not involved in the fabrication or insertion of the restorations. Clinical assessment was performed at baseline (BL), 6, 12, 24, and 36 months after insertion of the restorations. Criteria assessed included *postoperative hypersensitivities*, *anatomic form*, *marginal adaptation*, *marginal discoloration*, *surface texture*, and *recurrent caries*. Restorations were documented by digital photography within each respective recall session. The PBI as described by Saxer and Mühlemann [32] was employed to evaluate and document the patients' oral hygiene (Table 1).

For the evaluation of clinical changes over time and comparison of luting strategies as documented by modified USPHS criteria, 23 patients with both restorations under risk were available for the 36-month recall appointment. The USPHS BL data of these 23 patients as well as the data for the recall intervals are reported, referring to all pairs of restorations under risk until 3 years. The two luting strategies were compared to each other for every recall interval to detect differences between the luting procedures. Additionally, changes of clinical criteria over time between BL and 36 m for all USPHS categories were evaluated for each luting procedure separately. For statistical analysis of the data, the Chi-square test was applied (α=0.05).

Furthermore, the survival rate of the RXU and RXU+E restorations over time with respect to the 34 patients/68 restorations originally enrolled in the investigation was calculated using the Kaplan–Meier algorithm. The Mantel–Cox test,

Table 1 Modified USPHS-criteria

Postoperative sensitivity	Alfa[a]	No postoperative sensitivity
	Bravo	Postoperative sensitivity
	Charlie	Postoperative sensitivity with treatment need
Anatomic form	Alfa	Correct contour
	Bravo	Slightly undercontoured or overcontoured
	Charlie	Distinctly undercontoured or overcontoured
	Delta	Restoration fractured or mobile
Marginal adaptation	Alfa	Margin not discernible, probe does not catch
	Bravo	Probe catches on margin but no gap; dentin or liner exposed
	Charlie	Probe catches on margin and gap on probing, dentin or liner exposed
	Delta	Restoration fractured or missing
Marginal discoloration	Alfa	No marginal discoloration
	Bravo	Marginal discoloration, not penetrated towards pulp
	Charlie	Marginal discoloration penetrated towards pulp
Surface texture	Alfa	Smooth, glazed, or glossy surface
	Bravo	Slightly rough or dull surface
	Charlie	Surface with deep pores, cannot be refinished
Recurrent caries	Alfa	No recurrent caries
	Bravo	Caries without treatment need
	Charlie	Caries with treatment need

[a] According to the "Clinical criteria" by Ryge [30]

aimed at testing the null hypothesis that survival functions do not differ across groups RXU and RXU+E was applied. Any restoration that was mobile, fractured or missing or needed renewal for reasons determined by USPHS ratings within the 3-year observation period was considered a failure. The patients usually attended 6-month recall appointments. If the patient reported to the clinic in case of an adverse event, this date was recorded as failure time. If the subject did not report to the clinic, or if failure occurred unnoticed, the respective failure was, at the latest, recorded at the end of a 6-month recall period, which was then recorded as the timepoint of failure.

Results

Participant flow through the stages of the study is depicted in Fig. 1 for the BL evaluation and recall evaluations at 1, 2, and 3 years. Figure 1 depicts patients recruited, patients randomized and allocated to groups RXU and RXU+E, as well as patients excluded and patients receiving the intended treatment. For the BL and each recall appointment, the number of patients with both restorations under risk at the respective recall timepoint is indicated. For each group, RXU and RXU+E, losses to follow up and failures are disclosed, also giving the reasons for failure.

After 3 years, 23 patients with both restorations (n=46) under risk were available for the clinical evaluation, representing a recall rate of 67.4 % with respect to patients initially included in the study (n=34). Four restorations (3RXU, 1RXU+E) had failed within the first 2 years and patients were not evaluated for comparison of clinical changes over time within the 3-year recall. Four patients had terminated participation in the study between BL and 3-year follow-up. In three patients, failure of the restoration (2RXU, 1RXU+E) was recorded between the 2- and 3-year recall, so the patients did not participate in the 3-year recall, but data regarding failure were available. Of the 46 restorations available for clinical evaluation, 19 RXU PCCs had been placed in molars, four in premolars, 18 RXU+E PCCs in molars, five in premolars. Median patient age for this group was 41 years (31/46 year=25/75 % percentiles). The PBI indicating the quality of oral hygiene within the respective patient group was ≤20 % in 21 patients (91.3 %) and >20 % in two patients (8.7 %). Mean age of the restorations was 36±1 month for 52.2 % of the patients recalled, ranging from 35 to 43 months (17.4 %/78:3 %).

Clinical assessment

Results of the clinical assessment from BL to 36 m are summarized in Table 2 for the 46 restorations under risk at the 3-year recall. The major outcomes with respect to the following categories of USPHS criteria are reported: postoperative hypersensitivity–anatomic form–marginal adaptation–marginal discoloration–surface texture–recurrent caries.

In one patient, both restorations were considered failures at 3 years, as the RXU restoration had debonded and partially fractured and the RXU+E restoration had fractured and been lost which is reflected in respective Delta ratings. Both restorations had to be renewed. Two more RXU restorations and one RXU+E restoration needed intervention due to debonding/fracture and were rated unacceptable at the 3-year recall.

With respect to postoperative hypersensitivities, three cases (13 %) were rated Bravo and 20 cases were rated Alfa (87 %) in the RXU group at BL. After 3 years, no postoperative hypersensitivities were recorded for RXU. In the RXU+E group, 17 cases (73.9 %) were rated Alfa and six cases (26.1 %) Bravo at BL. After 3 years, no postoperative hypersensitivities were recorded for RXU+E as well. This decline of postoperative hypersensitivities within the RXU+E group is statistically significant different between BL and 36 months (p≤0.018). No statistically significant differences were recorded between the two luting strategies RXU and RXU+E at 3 years regarding the criterion postoperative hypersensitivities.

With respect to clinical changes over time within each group separately, statistically significant differences were determined between BL and the 3-year recall regarding criteria marginal adaptation and marginal discoloration. Criteria marginal adaptation and marginal discoloration both showed a statistically significant increase in Bravo ratings over time for both luting procedures, RXU and RXU+E, along with a statistically significant decrease in Alfa ratings (p≤0.001; Table 2 and Fig. 2).

Considering the comparison between the two luting strategies, RXU vs. RXU+E, at BL and the different timepoints of recall, no statistically significant differences could be determined between RXU and RXU+E at either timepoint of recall (BL, 1 year, 2 years, 3 years) with respect to criteria marginal adaptation and marginal discoloration, which showed the most distinct changes over time. Marginal deterioration was generally less pronounced with RXU+E than with RXU, but this difference was statistically not significant (Table 2).

USPHS criteria anatomic form, recurrent caries, and surface texture revealed no statistically significant differences between RXU and RXU+E or within each group over time (BL/3 years). The null hypothesis that there is no significant difference in clinical behavior and failure rate between PCCs inserted with RXU+E and RXU was not rejected.

Survival analysis

All patients that had originally been included in the study and received the respective treatment (n=34) were considered for survival analysis. Figure 1 shows the flow of participants

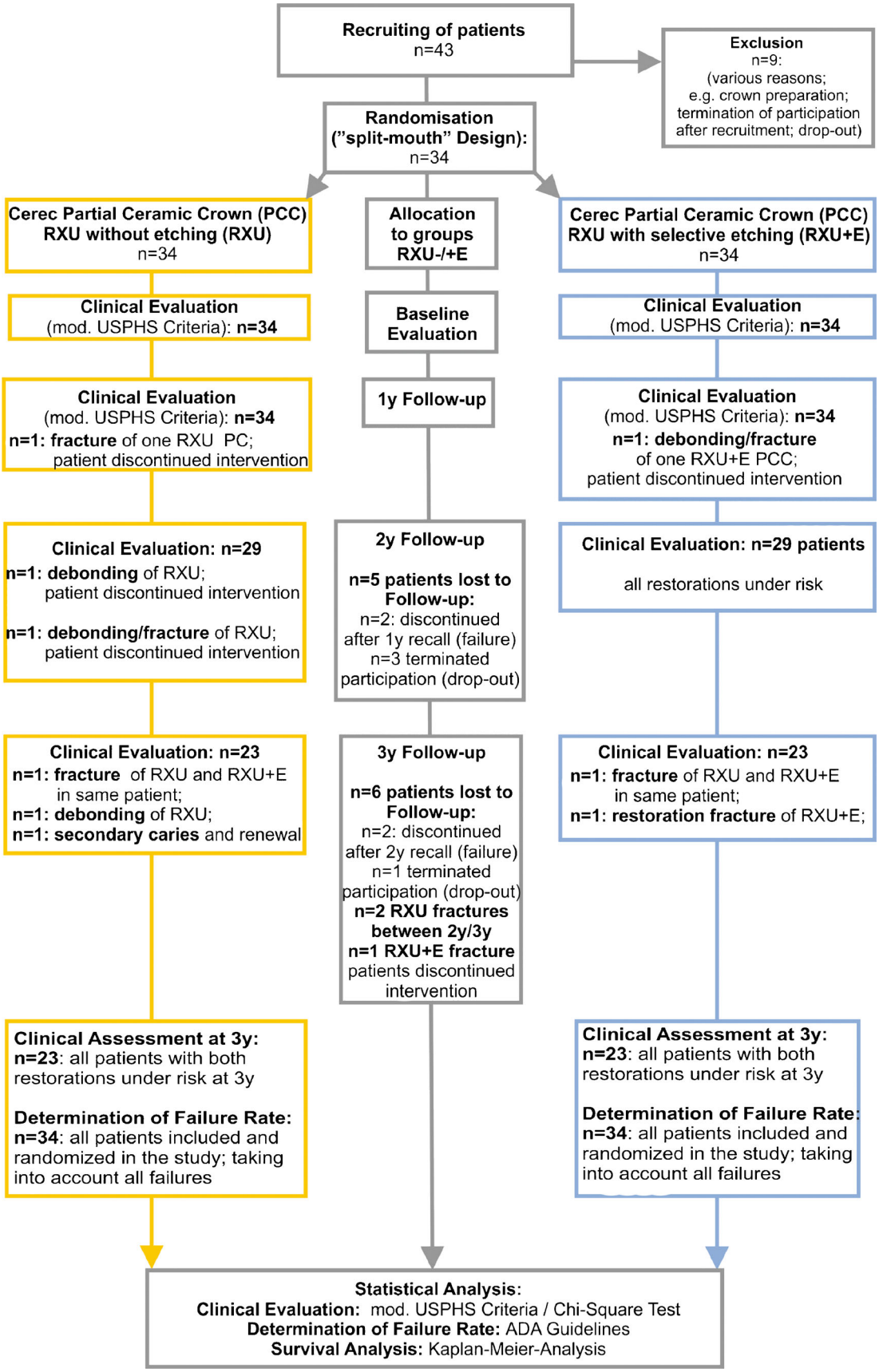

Fig. 1 Flow of participants through the stages of the investigation

Table 2 Results of the clinical evaluation of patients with both restorations under risk at the 3-year recall timepoint (n=23 patients with 46 restorations) for the different USPHS criteria

	Time		Postoperative hypersensitivity			Anatomic form				Marginal adaptation*				Marginal discoloration*				Surface texture			Recurrent caries		
			A	B	C	A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	A	B	C
RXU	BL	*n*	20	3	0	22	1	0	0	22	1	0	0	22	1	0	0	23	0	0	23	0	0
		%	87	13	0	95.7	4.3	0	0	95.7	4.3	0	0	95.7	4.3	0	0	100	0	0	100	0	0
RXU	12 m	*n*	20	2	1	22	1	0	0	13	10	0	0	17	6	0	0	23	0	0	23	0	0
		%	87	8.7	4.3	95.7	4.3	0	0	56.5	43.5	0	0	73.9	26.1	0	0	100	0	0	100	0	0
RXU	24 m	*n*	21	1	1	21	1	1	0	4	19	0	0	11	8	4	0	23	0	0	23	0	0
		%	91.3	4.3	4.3	91.3	4.3	4.3	0	17.4	82.6	0	0	47.8	34.8	17.4	0	100	0	0	100	0	0
RXU	36 m	*n*	22	0	0	20	1	0	2	4	16	1	1	10	4	7	0	21	0	0	21	1	0
		%	100	0	0	87	4.3	0	8.7	18.2	72.7	4.5	4.5	47.6	19.0	33.3	0	100	0	0	95.5	4.5	0
RXU+E	BL	*n*	17*	6*	0	23	0	0	0	23	0	0	0	22	1	0	0	23	0	0	23	0	0
		%	73.0	26.1	0	100	0	0	0	100	0	0	0	95.7	4.3	0	0	100	0	0	100	0	0
RXU+E	12 m	*n*	21	2	0	22	0	1	0	12	11	0	0	16	6	1	0	23	0	0	23	0	0
		%	91.3	8.7	0	95.7	0	4.3	0	52.2	47.8	0	0	69.6	26.1	4.3	0	100	0	0	100	0	0
RXU+E	24 m	*n*	22	1	0	22	0	1	0	6	15	0	0	13	6	4	0	23	0	0	23	0	0
		%	95.7	4.3	0	95.7	0	4.3	0	34.8	65.2	0	0	56.5	26.1	17.4	0	100	0	0	100	0	0
RXU+E	36 m	*n*	22*	0*	0	20	0	1	2	6	13	2	1	10	5	7	0	22	0	0	22	0	0
		%	100	0	0	87	0	4.3	8.7	27.3	59.1	9.1	4.5	45.5	22.7	31.8	0	100	0	0	100	0	0

RXU RelyX Unicem without selective enamel etching, *RXU+E* RelyX Unicem with selective enamel etching, *BL* baseline investigation, *12 m* investigation 12 months after placement, *24 m* investigation 24 months after placement, *36 m* Investigation 36 months after placement, *n* number of restorations, *%* Percentage of restorations

*Significantly different changes over time for RXU and RXU+E ($p \leq 0.05$)

through each stage of the study and records all failures detected within groups RXU and RXU+E at the respective timepoints of recall in those patients with both restorations under risk at the time evaluated. Furthermore, losses recorded during follow-up in those patients that did not attend recalls with both restorations under risk are also indicated in Fig. 1. Additionally, losses to follow-up are indicated for each time interval.

Within the observation period of 3 years, eight RXU restorations and four RXU+E restorations were rated failures, which are all identified in the flowchart (Fig. 2). All RXU and RXU+E PCCs within the group of 34 patients originally enrolled and allocated to treatment that had been replaced and were no longer in situ and those that were rated unacceptable during clinical evaluation of patients with both restorations under risk were regarded as failed restorations. Debonding without the possibility of re-luting (n=3 RXU), fracture of the restoration (n=3 RXU; n=4 RXU+E), root canal treatment with the need of renewal of the restoration during follow-up (n=1 RXU), and secondary caries were the reasons for failure (n=1 RXU).

According to Kaplan–Meier survival analysis, an 87.6 % (±3 %) cumulative survival rate was calculated for RXU+E, and a 72.6 % (±2.9 %) cumulative survival rate was calculated for RXU (Fig. 3). The Mantel–Cox test showed that survival functions did not differ significantly between groups after 3 years despite the higher percentages for survival in the RXU+E group as compared to the RXU group. The null hypothesis that there is no significant difference in failure rate and survival between PCCs inserted with RXU+E and RXU was not rejected.

Discussion

In the present study, the question was addressed whether a simplified luting material shows good clinical performance with respect to retention of the restorations and clinical criteria over time, or if better clinical performance may be achieved by an additional selective enamel etching step.

Study design

The study was performed within a prospective, controlled, and randomized clinical study design, using a split-mouth approach [1]. Limitations of the study design are a selected patient population, a limited observation period, and a relatively small number of patients [11, 22, 34, 35, 38, 42]. The allocation of treatments to the patients and respective teeth, however, as well as the distribution of patients in terms of sex and age is very homogenous.

The split-mouth design is considered applicable for evaluation of the two luting strategies RXU and RXU+E, as patient factors influencing longevity of the restorations, such as oral hygiene and diet are the same for the test and the control teeth [40]. Furthermore, the patient can directly compare the performance of the two restorations in terms of patient acceptance. Limitations to the study in terms of operator influence were ruled out in that restorations were not performed by only one experienced operator, but each set of restorations was generated by a different student in their last year of clinical education. Students had been specifically trained in the application of the restoration and insertion procedures. Simplified application of the self-adhesive luting material on the one hand should account for easy handling with low technique sensitivity, also by less experienced operators. On the other hand, as has also been reported in the literature, the influence of the factors *operator* and *clinical experience* may as well play an important role with respect to the outcome of the evaluation [14]. The possible influence of these factors upon the results of the present investigation needs to be taken into consideration in terms of clinical survival data recorded in the present study and are addressed in the following.

Clinical assessment

When assessing the clinical performance of PCC restorations luted with RXU or RXU+E after 3 years, changes were obvious in three categories of the clinical criteria evaluated according to modified USPHS criteria. These categories include *marginal adaptation*, *marginal discoloration*, and *postoperative hypersensitivities*.

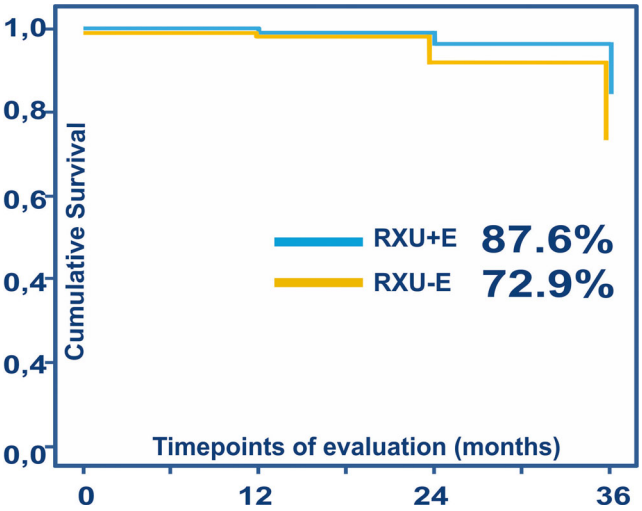

Fig. 3 Kaplan–Meier survival analysis

Marginal adaptation

Marginal deterioration over time in terms of wear of the luting composite in the luting space and detectable margins thus prone to marginal discoloration has been reported as a characteristic feature for ageing of adhesively luted restorations, in general, and has been addressed in several in vivo investigations [10, 15, 21, 28]. However, ageing of the restoration margin over time does not render the restorations inacceptable. This has

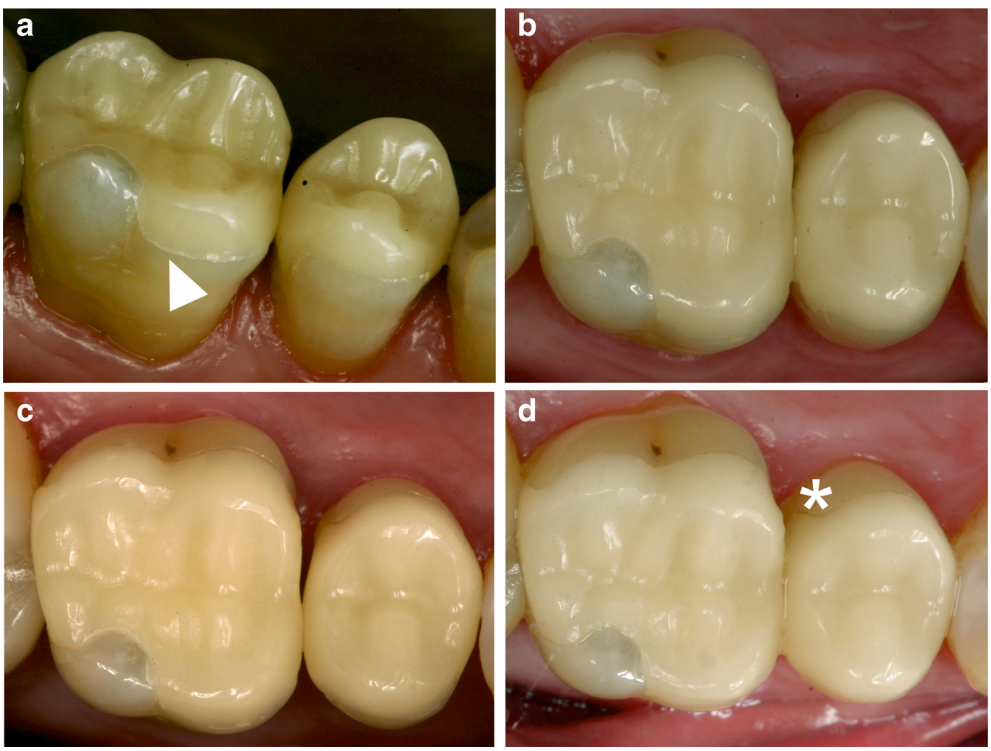

Fig. 2 Restorations of teeth 16 (RXU) and 15 (RXU+E) at baseline and after 12 (**b**), 24 (**c**) and 36 (**d**) months. Note white margins (*arrowhead*) along interface at BL (**a**), attributed to desiccation of the luting material during the luting process. (**d**) Marginal discoloration is obvious at the 36 m recall (*asterisk*)

been demonstrated for ceramic restorations that were fabricated in the dental laboratory, as well as for CAD/CAM generated restorations [10, 15, 21, 28]. In that, the findings of the present study are in line with the reports in the literature: deterioration of the restoration margins as reflected by an increase in Bravo ratings for criteria marginal adaptation and marginal discoloration over time were recorded with both luting strategies, RXU and RXU+E.

Although it was anticipated from in vitro findings that selective enamel etching would improve marginal adaptation of indirect ceramic restorations luted with self-adhesive resin cements [6], this was not confirmed for PCC restorations in this study. The clinical behavior of PCCs luted with an alternative luting strategy (RXU+E) does not differ significantly from the clinical performance of restorations luted following the manufacturer's instructions (RXU) at BL and 3 years. This complies with the findings of Peumans et al. [28] for inlay and onlay restorations inserted either with or without selective enamel etching. These authors observed a clinically acceptable marginal deterioration within a 4-year observation period for restorations luted with or without selective enamel etching using RelyX Unicem. They found no indication that selective enamel etching would improve clinical performance of restorations luted with a self-adhesive cement.

For inlays luted with RXU as compared to a conventional luting composite, Taschner et al. [39] reported that increased marginal deterioration occurred within the group luted with a self-adhesive luting material and that loss of margin integrity was higher than in the control group. With respect to all other criteria investigated, no differences between the materials were recorded within this 2-year observation period. The authors concluded that the self-adhesive luting material RelyX Unicem showed an acceptable behavior after 2 years despite lower values for marginal integrity as compared to a conventional luting agent.

Marginal discoloration

Marginal adaptation and marginal discoloration are criteria that strongly correlate to each other. This has been addressed in the literature: marginal deterioration over time was clinically associated with an increase in marginal discolorations [28, 35]. The reason for this is seen in the wear of the luting material and increased staining capacity of the margin and may depend upon the width of the luting space. Furthermore, for RXU, wear of the resin matrix and loss of fillers resulting in an increase in roughness was considered a reason for increased staining capacity over time [4]. Additionally, individual patient parameters in terms of diet, smoking habits and oral hygiene must be taken into account. Peumans et al. [28] reported that after 4 years, marginal discoloration occurred more frequently in the non-etch group than in the etch group when luting inlays/onlays with RXU with or without selective enamel etching. However, the authors point out that in general marginal integrity remained acceptable.

Postoperative hypersensitivities

The third category of USPHS criteria revealing statistically significant differences in the RXU+E group over time refers to postoperative hypersensitivities. The increased number of Bravo ratings at BL as compared to 36 months could be attributed to the process of selective enamel etching. Accidental etching of dentin could result in partial removal of the smear layer, compromised infiltration of the collagen mesh by the highly viscous cement and recording of postoperative hypersensitivities [6, 35, 41]. However, it needs to be pointed out that all recorded hypersensitivities decreased over time, and in all patients with both restorations under risk no treatment need in the RXU+E group due to postoperative hypersensitivity arose.

Clinically, RXU and RXU+E strategies both perform well and no differences between the two luting approaches in terms of clinical changes could be detected. The changes that were detected in the three categories of USPHS criteria were also addressed in the literature [28, 35, 39] and were not considered a reason to question self-adhesive luting cements as an alternative to conventional luting materials.

Survival analysis

With respect to Kaplan–Meier survival analysis of PCCs luted with two different strategies, RXU and RXU+E, survival of 72.6 % was recorded for RXU restorations and survival of 87.6 % for RXU+E restorations. Despite a tendency for more favorable results for the RXU+E strategy, this difference was statistically not significant. The clinical performance of the restorations in situ at 3 years as rated by modified USPHS criteria is within the range of data reported in the literature [10, 15, 21, 28, 39]. However, data indicating a Kaplan–Meier survival rate of 72.6 % in the RXU group and failure of 27.4 % within 3 years, respectively, are lower than survival rates reported in the literature for ceramic inlays. Peumans et al. [28] performed a clinical study with a similar design. After 4 years, these authors reported an overall survival rate of 95 % (97 % for RXU+E and 93 % for RXU) for ceramic inlays which is, by far, higher than that observed for PCCs in the present investigation. The reasons for the compromised survival rates in the present investigation may be attributed to different factors.

The number of RXU restorations that failed was higher than the number of RXU+E restorations that failed. Fracture of the restoration (n=3 RXU) and debonding without the possibility for re-luting (n=3 RXU) were the most frequent reasons for considering a restoration a failure in the RXU group, both indicating insufficient bonding and deterioration

of the bond. One reason for the number of debonding failures in the RXU group could be an overdrying of dentin during the try-in and luting procedure under rubber dam, reducing the intrinsic wetness needed for the cement reaction of the self-adhesive luting cement [12, 37]. On the contrary, rinsing off the acid in the selective etch approach may include the hazard of accidentally etching dentin but also offers a rewetting of the hard tooth tissues prior to insertion of the restorations.

Operator diversity may also be a reason for an increase in failures as compared to the studies reported in the literature [13, 14]. Use of a self-adhesive luting agent requires that the restoration is kept under constant light pressure when seated, before light curing of the cement, in order to allow for proper interaction of the highly viscous luting material and the hard tooth tissue, respectively, the smear layer [18]. Spontaneous debonding and infracture or fracture may be the consequence of insufficient bonding. Therefore, operator influence in this study may be reflected by the comparatively high level of failures recorded in the present evaluation, especially for RXU.

In in vitro and in vivo studies, the advantages of adhesion of RXU especially to dentin have been pointed out. In PCCs, the surface available to establish the adhesive bond to dentin may be much lower than in full crowns or inlay preparations. In this context, referring to inlay restorations, Peumans et al. indicated that availability of more than 50 % of dentin surface for adhesion was required in their study. With respect to adhesion to enamel, selective enamel etching has been advocated for in the literature. Therefore, in PCCs selective enamel etching may additionally increase and ensure retention. The increased failure rate in the RXU group seems to support this hypothesis.

Frankenberger et al. [15] reported that there were two modes of failure for adhesively luted all-ceramic inlay and onlay restorations: catastrophic failures during the initial 3–4 years of clinical service that were attributed to fatigue fractures induced by improper polishing of the ceramics and fractures that occurred after longer years of clinical surface due to marginal breakdown and ceramic fractures at the restoration margins. The failures observed in the present investigation specially with RXU are attributed to the initial-phase failures due to insufficient bonding or deterioration of the bond. Their magnitude may be attributed to several factors identified above.

Conclusions

Within the limitations of the present study, the following conclusions can be drawn from the generated data.

First, with respect to the clinical evaluation of the restorations in situ, the 3-year data show that when a self-adhesive luting agent is used for luting PCCs, marginal adaptation and marginal discoloration are subject to significant changes, indicating increasing marginal deterioration over time, irrespective of the luting strategy used, RXU or RXU+E. No statistically significant differences concerning clinical changes over time could be found between the two luting strategies.

Second, selective enamel etching in conjunction with the use of the self-adhesive resin luting cement, RelyX Unicem is a treatment alternative with a tendency of improving survival rates of PCCs in difficult clinical situations.

Conflict of interest None

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