Clin Oral Invest (2012) 16:451–461
DOI 10.1007/s00784-011-0516-0

ORIGINAL ARTICLE

Controlled, prospective, randomized, clinical evaluation of partial ceramic crowns inserted with RelyX Unicem with or without selective enamel etching. Results after 2 years

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Received: 1 December 2009 / Accepted: 23 January 2011 / Published online: 23 March 2011
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Abstract Among the materials used for luting indirect restorations, growing interest has been directed towards the use of self-adhesive resin cements. The aim of this prospective randomized controlled clinical trial was to evaluate the clinical performance of the self-adhesive resin cement RelyX Unicem (RXU) for luting partial ceramic crowns (PCCs). In addition, the influence of selective enamel etching prior to luting (RXU+E) was assessed. Two-year results are reported. Thirty-four patients (68 PCCs) had originally received the intended treatment at baseline (BL). Twenty-nine patients (14 male, 15 female) with a total of 58 PCCs participated in the 2-year recall. In each patient, one PCC had been placed with RXU, one PCC with RXU+E. Restorations were evaluated at BL and 24 months after placement using modified United States Public Health Service criteria for postoperative hypersensitivity, anatomic form, marginal adaptation, marginal discoloration, surface texture and recurrent caries. Additionally, the "percentage failure" within the 2-year recall period for all restorations (n=68) was calculated according to ADA Program Guidelines. Target value for acceptability of each procedure was <5% failure within 24 m. For statistical analysis of the data, the chi-square test was applied (α=0.05). The median patient age was 41 years (24–59 years). Median PBI was 8% (5–10%). Twenty-two RXU PCCs were placed in molars, seven in premolars. Twenty-one RXU+E PCCs were placed in molars, eight in premolars. Statistically significant changes were observed for marginal adaptation (MA) and marginal discoloration (MD) between BL and 2 years but not between the two groups (RXU, RXU+E). Percentage of alfa values at BL for MA (RXU, 97% and RXU+E, 100%) and for MD (RXU, 97% and RXU+E, 97%) decreased to RXU, 14% and RXU+E, 28% for MA and to RXU, 50% and RXU+E, 59% for MD after 24 months. Within the observation period, three failures were recorded with RXU (5.1% failure), one failure was recorded for RXU+E (1.7% failure), but a significant influence of selective enamel etching on failure could not be verified. Although the results of the present study reveal a slight tendency for more favourable results if selective enamel etching is applied prior to insertion of ceramic PCCs with a self-adhesive luting material, longer-term evaluation is needed to confirm this. Additional selective enamel etching with a self-adhesive luting material does not considerably improve clinical performance of the restorations within the observation period reported, neither does it impose a hazard with respect to postoperative hypersensitivity.

Keywords Partial ceramic crowns · Clinical evaluation · RelyX Unicem · USPHS criteria · CEREC III

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Introduction

Classical methods for adhesively luting ceramic restorations based on enamel/dentin adhesives are regarded as technique

sensitive [1–3] and time consuming as they require up to four steps for application. Therefore, during the last decade, simplifications of adhesive procedures have gained substantial interest.

To reduce technique sensitivity and to simplify adhesive luting, in 2002, a completely new material for luting of all-ceramic restorations was introduced (RelyX Unicem, 3M Espe, Seefeld, Germany). RelyX Unicem was the first self-adhesive dual-cured resin cement marketed to lute all-ceramic restorations without any pre-treatment of tooth hard tissues. The adhesion to tooth hard tissues of this material is based upon phosphoric acid methacrylates that create micromechanical retention. In a second reaction, a chemical adhesion to hydroxyapatite from glass-ionomer components is claimed [4–6]. The basic inorganic fillers are capable of performing an acid-base reaction with acidic monomers. The main setting reaction can be initiated either by light activation or by a redox system, as known from dual-curing resin cements.

In the literature, marginal sealing of dentin margins with RelyX Unicem was reported to be superior to that of conventional luting agents in several in vitro investigations [1, 7–9]. According to an in vitro study by Behr et al [8], who compared the marginal adaptation of the conventional resin cement Variolink II, the compomer cement Dyract Cem Plus and the self-adhesive universal resin cement RelyX Unicem for the insertion of all-ceramic crowns, the lowest microleakage values at the dentin interface were found with the self-adhesive universal resin composite RelyX Unicem. These findings are in line with in vitro investigations of Schenke et al. [7], who evaluated marginal adaptation of RelyX Unicem to dentin, and Abo Hamar et al. [1], who investigated the bond strength of this self-adhesive universal resin cement to dentin. Regarding the adhesion to enamel, lower bonding efficiency of RelyX Unicem to enamel as compared to etch-and-rinse and self-etching luting composites is reported in the literature [9–11]. De Munck et al. [9] showed that microtensile bond strength of RelyX Unicem to enamel was significantly lower than that of control cement employing a self-etching primer. Acid etching of enamel prior to luting with RelyX Unicem raised enamel bond strength to that of the control, whereas acid etching of dentin significantly reduced bond strength of RelyX Unicem (RXU) to dentin. The authors concluded that best bonding effectiveness is achieved with *selective* acid etching of enamel prior to luting with RXU [9]. These findings are confirmed by Hikita et al. [11] who investigated the bond strengths of etch-and-rinse, self-etch and self-adhesive luting cements to enamel and dentin.

In the current literature, only scarce information is available on the clinical application and performance of RelyX Unicem for insertion of all-ceramic inlays [12–14]. Furthermore, to date, only limited clinical evidence exists to show whether selective enamel etching improves adhesion of self-adhesive universal luting materials to enamel in the clinical situation. Taschner et al. [14] investigated the clinical performance of ceramic inlays and onlays luted either with RXU or with the combination of a multistep adhesive and corresponding luting composite (Syntac/Variolink II: SV) using modified United States Public Health Service (USPHS) criteria. The authors showed that the self-adhesive resin composite RelyX Unicem revealed acceptable clinical behaviour after 2 years of clinical service. For ceramic inlays, Peumans et al. reported that selective enamel etching prior to luting with a self-adhesive resin cement (RelyX Unicem) had no significant influence upon clinical performance rated according to modified USPHS criteria after an observation period of 2 years [12].

Clinical data for the performance and longevity of partial ceramic crowns (PCCs) which are increasingly advocated for the restoration of large defects with reduced cavity wall thickness are comparatively rare [15–18]. No clinical data on luting of partial ceramic crowns with self-adhesive materials are available in the accessible literature.

The aim of the present prospective, randomized, controlled split-mouth study was to evaluate the clinical performance of partial ceramic crowns inserted with RelyX Unicem either with (RXU+E) or without (RXU) selective enamel etching. In detail, two aspects were addressed:

(1) To evaluate clinical changes over time using modified USPHS criteria for the restorations under risk after 24 months (versus BL) for the two groups (RXU and RXU+E)
(2) To determine the overall percentage of failure according to ADA Guidelines [19] of all the restorations (RXU and RXU+E) that had been placed

The null hypothesis tested was that there is no significant difference in clinical behaviour and failure rate between restorations inserted with RelyX Unicem with or without selective enamel etching. Presently, the results of the 2-year observation period are reported.

Materials and methods

The study design of this controlled, prospective, randomized clinical split-mouth study followed the requirements outlined in the American Dental Association (ADA) Acceptance Program Guidelines [19], the CONSORT Statement [20] as well as established and previously published protocols [17, 21]. The study design of the present evaluation was approved by the ethics committee of the University of Regensburg (IRB no. 06/092) in accordance with the Declarations of Helsinki (1975) and Tokyo (1983). All patients received a detailed description of the

proposed treatment for written informed consent. Patients participating in the study were free to terminate their participation at any point of time without giving any reasons for it. The restorations were fabricated free of charge for the patient.

The patients were recruited from the patient pool of the Department of Operative Dentistry and Periodontology of the University of Regensburg. They were included in the study if

- They were suffering from at least two large defects of the dental hard tissues suitable for the restoration with partial ceramic crowns. No initial carious lesions were treated. All defects were formerly insufficient amalgam or composite restorations.
- The teeth to be restored did not reveal any symptoms of pain.
- The application of rubber dam for the insertion of the restorations was possible.
- Tooth mobility was lower than or equal to degree 1 (mobility of the tooth is discernible but not visible) [22].

Additionally, all patients participating in the study exhibited a moderate level of oral hygiene represented by a papillary bleeding index (PBI) <35%.

The treatment of the selected patients was performed by clinical students within the last year of their dental training programme (one patient/student) supervised by one experienced dentist. Prior to the study, the students had successfully accomplished a training course on the fabrication of CAD/CAM fabricated PCCs. The patients were enrolled in a recall programme of 3 years, with two appointments within the first year and one appointment per year within the following years.

For the PCCs, a modified partial crown cavity preparation was performed with slight modifications adapted to the given situation in the particular patient, following the findings of an in vitro investigation [23]. Functional cusps were either covered by horizontal reduction or by cusp coverage with a butt joint, according to the individual demands. Non-functional cusps were left uncovered if applicable. An experienced dentist designed the cavity preparation to each individual, supervised the preparation, checked it clinically and finally accepted it (Fig. 1). After preparation, impression taking was performed using Silaplast/-soft (Detax, Ettlingen, Germany). Temporary restorations (Luxatemp, DMG, Hamburg, Germany) were cemented with a Eugenol-free cement (Temp Bond NE, Kerr, Scafati, Italy).

After impression taking and temporization, all PCCs were CAD/CAM designed and machined with the CEREC III system (Sirona CEREC III Software Version 3.0 (600/800), Sirona, Bensheim, Germany) using an indirect method on a die cast. The PCCs were milled from industrially fabricated ceramic blocks (Vita 3D Master CEREC Mark II, Vita, Bad Säckingen, Germany, nos. 6650, 6655, 6880, 6946 and 6987) and fitted on the die casts (Fig. 1).

In a second appointment with the patient, accuracy and intraoral fit of the PCCs were evaluated by the supervising dentist using a dental probe (EX9, HuFriedy, Chicago, USA) and a try-in silicone for revealing high spots and pressure points (Fit-Checker, GC Corporation, Tokyo, Japan). Accuracy of the ceramic restoration was rated to be sufficient when the tip of the dental probe did not catch at the margin (maximum luting gap=100 μm). Adjustments were made if applicable. If the fit of the restorations did not meet the clinical requirements (i.e. probe tip did catch), a new restoration was fabricated. The randomization of sample teeth into the experimental (RXU+E) and the control (RXU) group followed a "coin-toss-method", executed by the supervising dentist: one tooth for insertion of a PCC with RelyX Unicem with selective enamel etching (RXU+E) and one tooth for insertion of a PCC with RelyX Unicem without selective enamel etching (RXU) was selected per patient that way. For insertion of the restorations, rubber dam was applied. In the control group (RXU), RelyX Unicem was used without any pre-

Fig. 1 Preparation design and manufacturing of PCC. **a** Preparation design of PCC. A modified cavity preparation was performed with slight modifications adapted to the given situation in the particular patient. **b** After impression taking, a cast was fabricated for indirect manufacturing of the CEREC III PCCs. **c** Marginal fit of the milled restorations must be controlled on the cast before placement. **d** Inserted restoration at Baseline. Note white margins along the buccal surface

treatment of the tooth tissues according to the recommendations of the manufacturer as described in the following section. In the experimental group (RXU+E), selective acid etching of the enamel for 30 s with a 37% phosphoric acid gel (Total Etch, Ivoclar Vivadent, Schaan, Liechtenstein) and consecutive rinsing with water spray for a minimum of 15 s was performed prior to the insertion of the restoration with RelyX Unicem. Thorough care was taken to limit acid etching to enamel margins and to prevent accidental etching of dentin. The internal surface of the ceramic was etched with 5% hydrofluoric acid gel (Vita Ceramics etch, Roeko/Coltene/Whaledent, Langenau, Germany) for 60 s and silanated with Monobond S (Ivoclar Vivadent, Schaan, Liechtenstein). After application of the silane coupling agent, the solvent was evaporated with compressed air.

Consecutively, the luting material (RelyX Unicem, 3M ESPE, Seefeld, Germany, nos. 251202, 269368 and 274219) was mixed and applied into the cavities, the restorations were inserted and excess luting material was removed. The restorations were held in place under light pressure by an instrument during light activated polymerization of the luting material. After light curing from each side for 20 s, examination of the luting areas for defects and removal of resin overhangs, the rubber dam was removed. The occlusion was adjusted, and the PCC restorations were polished with the Sof-Lex disc-system (3M ESPE, Seefeld, Germany) and diamond polishing paste (Vita Karat Diamantpolierpaste, Vita, Bad Säckingen, Germany).

One experienced dentist (FS), calibrated against a senior investigator (MF) before the start of the study (kappa=1) and not involved in the fabrication or insertion of the restorations evaluated the PCCs clinically at baseline (after placement and finishing/polishing procedures), and after 24 months according to the USPHS criteria [24] modified by Krejci et al. [25] and Mörmann et al. [26]. Clinical examination of the restorations was performed using a dental probe (EX 9), mirrors and magnifying eye glasses. Sensitivity to cold of the restored teeth was tested using Endo-Frost spray (Roeko/Coltene/Whaledent, Langenau, Germany). Postoperative hypersensitivities were determined by questioning the patients. According to the modified USPHS criteria, anatomic form, marginal adaptation, marginal discoloration, surface texture and recurrent caries were evaluated (Table 1). Furthermore, all restorations were documented by photographs within the respective recall intervals. The PBI according to Saxer and Mühlemann was employed for the assessment of the patients' oral hygiene [27].

Twenty-nine patients attended their appointment for the 2 years evaluation (±1 month). For USPHS evaluation, baseline data of these 29 patients and the 2 years recall data are reported, referring to all restorations still under risk at the 2 years recall (Fig. 2). Changes of clinical criteria between baseline and 24 months for all USPHS categories were compared for each luting procedure (RXU and RXU+E) separately.

Table 1 Modified USPHS criteria (representing the "modifications" from the original definitions by *Ryge [25])

	Modified USPHS Criteria	
Postoperative sensitivity	Alfa*	No postoperative sensitivity
	Bravo	Postoperative sensitivity
	Charlie	Postoperative sensitivity with treatment need
Anatomic form	Alfa	Correct contour
	Bravo	Slightly under- or overcontoured
	Charlie	Distinctly under- 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

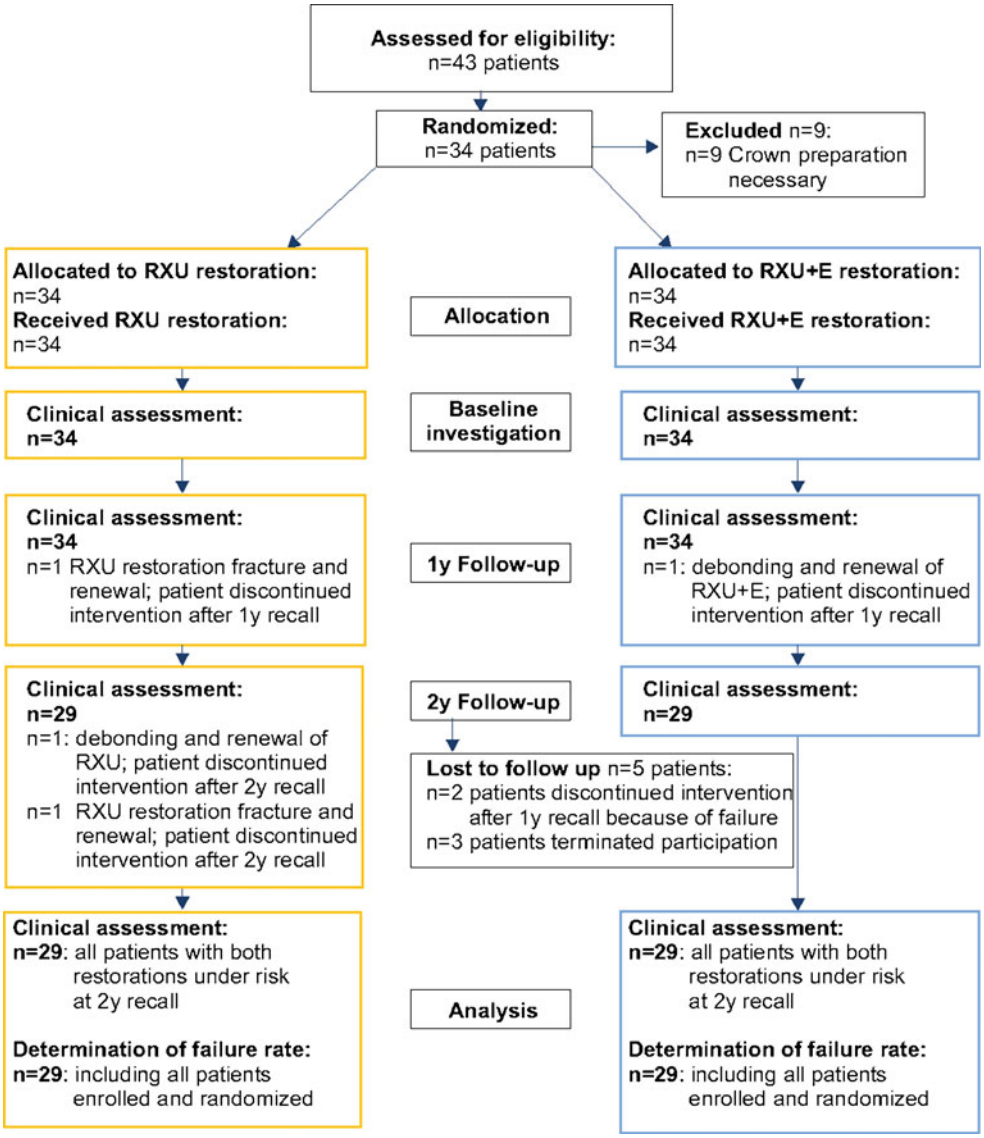

Fig. 2 Flow of participants through each stage

The "percentage failure" within the 2-year recall period was calculated as defined in the ADA Program Guidelines [19] (percentage failure = (previous failures + current failures/previous failures + number of restorations at current recall) × 100). Any restoration that was mobile, fractured or missing or needed renewal for reasons determined by USPHS ratings was considered a failure. ADA Guidelines require a minimum of 95% restorations to be acceptable after 2 years [19]. For statistical analysis of the data, the chi-square test was applied (α=0.05).

Results

The flow of participants through each stage of the study is shown in Fig. 2. Thirty-four patients received the intended treatment and were recalled within the first year (baseline/1-year; recall rate: 100%). For the 2 years evaluation, recall rate was 85.3%. Two restorations (1RXU, 1RXU+E) had failed within the first year and were not evaluated at the 2 years recall. Two patients refused to attend any further recall appointments. One further patient refused to attend any further recall appointment, but assured by telephone interview that both restorations were still in situ.

The distribution of restorations between molars and premolars is outlined in Table 2. Median patient age was 41 years (24–59 years). Fourteen male and 15 female patients participated in the study. The PBI indicating the quality of oral hygiene of the patients was less than 20% in the 29 patients (24 months). Median PBI was 8% (5–10%).

Clinical assessment

The results of the clinical assessment are summarized in Table 3 for the 58 restorations under risk. In the following,

Table 2 Distribution of PCC in the RXU and in the RXU+E group

	RXU (n=29)	RXU+E (n=29)
Molars	n=22	n=21
Premolars	n=7	n=8

n number of restorations

the major outcomes with respect to categories of USPHS criteria are reported.

During the observation period of 2 years, one endodontic treatment (postoperative hypersensitivity at 24 months: 1 (3.6%) charlie) had to be performed (RXU). The restoration did not have to be removed and is still under risk. No further changes in pulp vitality occurred during the observation period.

Regarding clinical changes over time separately within each group, RXU and RXU+E, statistically significant differences were determined between baseline and 24 months for criteria marginal adaptation and marginal discoloration: marginal adaptation and marginal discoloration both revealed a statistically significant increase in bravo ratings after 2 years as compared to baseline for both luting procedures ($p \leq 0.05$), RXU and RXU+E, along with a statistically significant decrease of alfa ratings ($p \leq 0.05$; Table 3 and Figs. 3, 4, 5).

Regarding the comparison between the two luting procedures RXU vs. RXU+E at BL and 24 months, no statistically significant differences could be found between the luting procedures at baseline and after 2 years for criteria marginal adaptation and marginal discoloration. Marginal deterioration was generally less pronounced with RXU+E than with RXU, but this difference was statistically not significant (Table 3 and Fig. 5).

For USPHS criteria postoperative hypersensitivity, anatomic form, recurrent caries and surface texture, no statistically significant differences could be determined between RXU and RXU+E or between the two recalls (BL/24 months).

Percentage failure

One PCC of the RXU group debonded after 11 months in situ. One PCC of the RXU+E group showed an infracture after 12 months. Both restorations were replaced and excluded from the study. Furthermore, one PCC (RXU) debonded after 23 months in situ and one PCC (RXU) fractured after 24 months in situ and had to be renewed. Thus, a total of four restorations (n=3 RXU, n=1 RXU+E) of originally 68 PCCs failed within 24 months (overall percentage failure=6.7%). RXU revealed 5.1% percentage failure within 24 months, whereas RXU+E group showed

Table 3 Results at baseline and 24 months after placement in relation to modified USPHS criteria

Time			Postoperative hypersensitivity			Anatomic form			Marginal adaptation			Marginal discoloration			Surface texture			Recurrent caries		
			Alfa	Bravo	Charlie	Alfa	Bravo	Charlie	Alfa	Bravo	Charlie	Alfa	Bravo	Charlie	Delta	Alfa	Bravo	Charlie	Alfa	Bravo	Charlie
RXU	BL	n	25	4	0	28	1	0	28[a]	1[a]	0	28[a]	1[a]	0	0	29	0	0	29	0	0
		%	86.2	13.8	0	96.6	3.4	0	96.6	3.4	0	96.6	3.4	0	0	100	0	0	100	0	0
RXU	24mo	n	25	2	1	25	1	1	4[a]	23[a]	0	14[a]	10[a]	4[a]	0	28	0	0	28	0	0
		%	89.3	7.1	3.6	86.2	3.4	3.4	13.8	79.3	0	50	35.7	14.3	0	100	0	0	100	0	0
RXU+E	BL	n	21	8	0	29	0	0	29[a]	0	0	28[a]	1[a]	0	0	29	0	0	29	0	0
		%	72.4	27.6	0	100	0	0	100	0	0	96.6	3.4	0	0	100	0	0	100	0	0
RXU+E	24mo	n	27	2	0	28	0	1	8[a]	21[a]	0	17[a]	8[a]	4[a]	0	29	0	0	29	0	0
		%	93.1	6.9	0	96.6	0	3.4	27.6	72.4	0	58.6	27.6	13.8	0	100	0	0	100	0	0

Number of restorations for the RXU group at the 2-year recall were slightly lower than the total due to an adjustment for failures. Statistical test—chi-square test

BL baseline investigation, *24mo* investigation 24 months after placement, n number of restorations evaluated at the 2-year recall, % percentage of restorations

[a] Significant difference between baseline and 2 years investigation ($p \leq 0.05$)

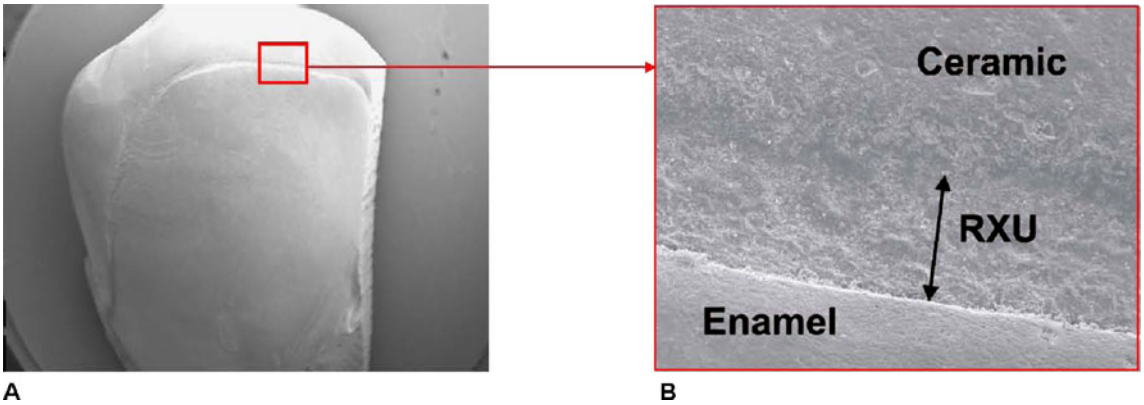

Fig. 3 SEM images of a PCC (RXU) after 24 months observation period. **a** Overview, premolar 45, buccal aspect. **b** Magnification, premolar 45, buccal aspect. Note the rough surface and the wear of the luting cement (RXU) representing marginal deterioration

1.7% percentage failure. This difference was, however, statistically not significant.

Discussion

Study design

The basic study design followed the ADA Acceptance Program Guidelines suggested for application in clinical trials [28]. These were the guidelines available when the study was launched in 2006. Today, clinical criteria for evaluation of direct and indirect restorations as revised by the World Dental Federation (FDI) in 2007 should be applied [29], including the requirement of two independent evaluators. In the present study, all restorations were evaluated by one experienced dentist who had been calibrated against an experienced senior investigator [17, 21]. The reporting of the study complies with the CONSORT Statement [20].

Two methods for clinical evaluation were applied in the present study: (1) the modified USPHS criteria were used to evaluate those restorations that were in situ (under risk) after 2 years and (2) failure calculation according to ADA guidelines [19] was performed for all restorations that had been originally placed and included in the study. The modified USPHS criteria allow for evaluating the clinical performance and changes within the restorations over time including failures (delta ratings). However, with these criteria, no passed/failed limit is defined. For calculation of percentage of failure, ADA guidelines for restorative materials were applied additionally, in which a passed/failed limit is defined (<5% failure) for the observation period of 2 years. Furthermore, failure of restorations within the observation period and prior to the 2 years recall can be more readily evaluated by using the ADA method. On the other hand, failure is a rather coarse criterion. Therefore, failure data are complemented by clinical data recorded with modified USPHS criteria.

Limitations of prospective studies are generally a selected patient population, a limited observation period and a comparatively small number of treatments [18, 30–32]. Another disadvantage of the present study was that the preparation and restoration of selected teeth was not performed by one operator. “Operator” or “clinical experience” may influence the clinical success rate of the restorations [33]. The group of patients, however, was very homogenous, and the restorations placed in each patient had the same age. A main advantage of split-mouth

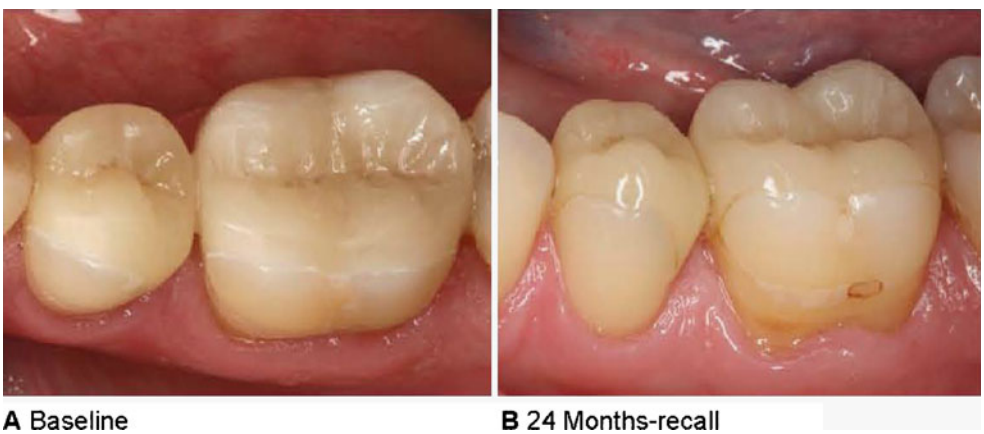

Fig. 4 Overview of changes within USPHS categories marginal discoloration and marginal adaptation over time. Clinical situation at **a** baseline and **b** after 24 months in situ. Premolar 35 (RXU+E), molar 36 (RXU). During the examination periods (**a** and **b**), an increase in marginal discoloration as well as in marginal deterioration were observed. *White margins* along luting space at *baseline* are attributed to desiccation of the luting material during luting procedure

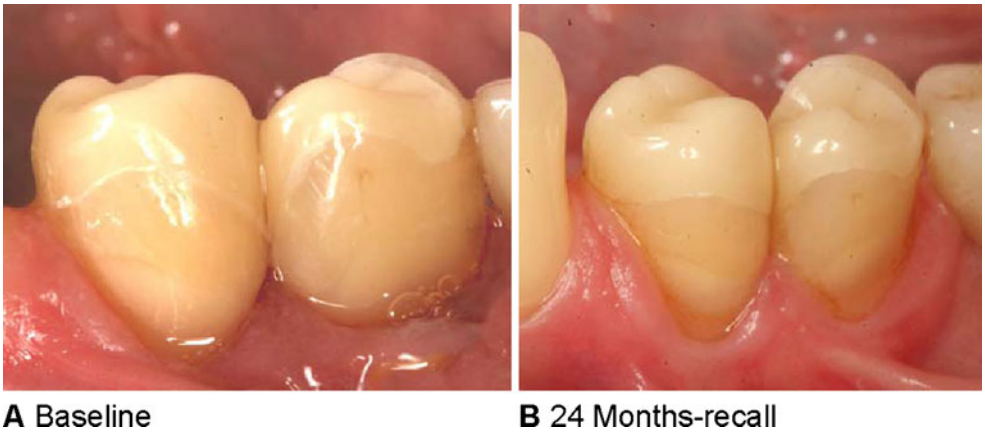

Fig. 5 Overview of clinical performance of different luting techniques over time: clinical situation at **a** baseline and **b** after 24 months in situ. *Left to right* First premolar 34 (RXU), second premolar 35 (RXU+E). During the examination periods (**a** and **b**), no differences in clinical performance between the two luting techniques were observed. White margins along luting space at *baseline* are attributed to desiccation of the luting material during luting procedure

trials is that test and control restorations are placed in the same patient. Patient factors influencing longevity of partial crowns like oral hygiene and diet are the same for the test and the control group. Therefore, prospective split-mouth studies are reported as highly suitable for comparing treatment modalities [34].

The CEREC III system was used for fabricating the partial ceramic crowns. In the present study, the CEREC restorations were machined indirectly using a cast to make it more convenient for the supervising operator to additionally control the preparation and the marginal fit of the milled restorations on the cast before placement. CAD/CAM fabrication of ceramic inlays and PCC restorations is a scientifically accepted and well-documented treatment procedure [21, 35, 36].

Clinical assessment

In the present study, results indicate that ageing of the restorations during the 2-year observation period revealed a significant decrease of marginal integrity associated with a significant increase in marginal discoloration for the RXU group as well as for the RXU+E group from BL to 24 months. RXU+E shows a trend for lower deterioration over time as compared to RXU; however, this difference is not statistically significant.

Marginal deterioration of ceramic restorations over time in general is attributed to degradation of the luting material in the luting space due to wear and fatigue and to insufficient bonding to the hard tooth tissues [37, 38]. Taschner et al. investigated the clinical performance of ceramic inlays luted with RXU (n=43) and Syntac/Variolink II (SV; n=40), but they did not employ selective enamel etching with RXU. They reported marginal deterioration of the restorations after 1 year for both luting materials [14]. Bravo ratings for marginal integrity increased from 9% at BL to 23% after 1 year for RXU and from 5% to 13% for SV. However, this difference was statistically not significant. After 2 years of clinical service, criteria, marginal integrity and integrity tooth revealed statistically significant better results for the control cement (SV) than for RXU [13].

Peumans et al. investigated the 2-year clinical performance of ceramic inlays (n=62 in 31 patients) luted with either RXU or RXU+E [12]. Overall marginal adaptation of both groups, RXU and RXU+E, revealed obvious deterioration during the 24 months observation period (excellent margin BL: 70.7%; 24 months, 21.7%). Inlays luted with RXU+E revealed slightly better marginal adaptation (BL: 75%; 24 months, 23.4%) than inlays luted with RXU alone (BL: 66.7%; 24 months, 20%); however, this difference was statistically not significant [12]. Data accessible to date refer only to ceramic inlay restorations [12–14], but they are in accordance with the findings of the present study on PCCs revealing deterioration of marginal adaptation of RXU and RXU+E over time and an overall acceptable clinical performance of the restorations after 2 years. It remains to be shown whether the marginal deterioration observed for RXU and RXU+E within the first 2 years will continue over time or eventually stabilize as reported for adhesively luted ceramic restorations [35, 37, 38].

Based on in vitro findings [9, 11], selective acid etching of enamel prior to luting with RXU was advocated for in the literature. However, the advantages of selective etching of enamel upon marginal adaptation in the clinical situation could neither be confirmed in the present study nor in the investigation of Peumans et al. [12]. In the in vitro investigations, RelyX Unicem was bonded to an enamel surface only, generated by flattening the lingual or buccal enamel [9, 11].

In vivo, Taschner et al. [14] indicated that the residual amount of enamel along the cavity margins (10% of the cavities without enamel left at the proximal margins, 51% of the restorations with less than 0.5 mm enamel) did not have any influence upon the marginal performance of ceramic inlays and onlays luted with RXU or SV. Peumans et al. [12] reported that 29 out of 62 restorations had 0.5 mm or less enamel left at the cervical margin, 33

restorations had 1 mm or more enamel left. The limited amount of selectively etched enamel along the restoration margins may account for the fact that up to 2 years, no significant beneficial impact of selective enamel etching could be shown in the clinical situation.

The criterion marginal adaptation is closely correlated to the criterion marginal discoloration. Here, too, a statistically significant difference was found for RXU and RXU+E between baseline (RXU 96.6% alfa; RXU+E 96.6% alfa) and the 2-year recall (RXU 50% alfa; RXU+E 58.6% alfa) in the present study. Marginal discoloration along with marginal deterioration is attributed to the capacity for staining of the exposed luting material and its roughness owing to porosity [9]. Kashiwada et al. [39] reported that the resin matrix of RelyX Unicem wore markedly after toothbrush abrasion in acidic environment (1.30 μRA) as compared to an experimental material (1.16μRA) and fillers were cropped out from the resin matrix. Clinically, this process may account for increased marginal discoloration observed after 24 months. Also, individual diet (e.g. red wine, green tea, coffee etc.), smoking and bad oral hygiene may have a slight influence on appearance of marginal discoloration. However, the latter was ruled out due to the quality of oral hygiene of the patients enrolled in the present study: PBI was less than 20% in 29 patients after 2 years.

With respect to postoperative hypersensitivity, the RXU as well as the RXU+E group reveal postoperative hypersensitivities in the same order of magnitude (RXU, 89.3% alfa; RXU+E, 93.3% alfa at 24 months). This seems to be of special interest because each patient could compare the reaction to the two different luting procedures [34]. These results indicate that additional selective enamel etching does not lead to an increase of postoperative hypersensitivity if carefully applied.

Percentage failure

In the present investigation, percentage failure for RXU+E was 1.7% (one failure within 24 months) and percentage failure for RXU was 5.1% (three failures within 24 months). Reasons for failure were fracture (1RXU+E, 1RXU) and debonding (2RXU) of the restorations.

Debonding may be related to the nature of the interaction of RelyX Unicem with the tooth tissues. DeMunck et al. [9] demonstrated in an in vitro study that interaction of RXU with dentin and enamel occurred only superficially: no resin tags or hybrid layer formation could be identified within the dentin despite intimate adaptation of the material to the cavity walls. However, smear layer removal by etching of the dentin prior to luting with RXU significantly reduced bond strengths to dentin (15.9 MPa RXU; 5.9 MPa RXU+E) as the viscous cement could not penetrate the demineralized collagen mesh. Therefore, inadvertent etching of dentin in the process of selective acid etching of enamel may be detrimental to the retention of the restoration. Placement and light curing of the restorations under pressure as applied in the present study, however, has been advocated for in the literature as it enhances adaptation of the luting material to the tooth structure and minimizes voids along the interface [9, 12, 40].

Regarding percentage of failure of all-ceramic restorations, Hickel and Manhart [36] investigated the longevity of restorations in posterior teeth and reasons for failure. They reported an annual failure rate for ceramic restorations in general of 0–7.5% and 0–4.4% for CAD/CAM restorations. For self-adhesive luting materials, Taschner et al. reported one failure in the SV group due to marginal enamel chipping after 6 months of clinical service [14]. No further failures were recorded up to 2 years within the SV and the RXU group [13]. Peumans et al. [12] reported that two restorations (6.7%) of the RXU group failed due to loss of retention within the first year, whereas all restorations in the RXU+E group were rated clinically acceptable after 2 years. The differences between survival functions of RXU and RXU+E (93.3% vs. 100%) were statistically not significant. The authors conclude that RXU+E had no significant influence on marginal integrity or complications of the restored teeth after 24 months [12].

In that, the results reported in the literature for RXU [12–14] and RXU+E [12] covering an observation period of 2 years are in line with the findings of the present investigation. However, ADA guidelines require that there cannot be more than 5% unacceptable restorations as the minimum standard for acceptance of the quality of the restorations at 2 years [19]. In the present study, RXU+E meets this criterion (1.7%), RXU does not (5.1%), although the difference between the two luting techniques regarding failure is statistically not significant.

In summary, it has to be stated that the results are ambivalent. Statistical evaluation of the data implies that the null hypothesis cannot be rejected, but RXU does not meet the limit of <5% failure after 2 years as outlined by ADA guidelines [19]. Although the results of the present study imply that there is a tendency for more favourable results if selective enamel etching is applied prior to insertion of ceramic PCCs with a self-adhesive luting material, longer-term evaluation is needed to confirm this.

Conclusions

Within the limitations of the present study, the following could be concluded:

1. The clinical evaluation using modified USPHS criteria revealed that after 2 years marginal adaptation and

marginal discoloration are subject to significant changes over time ($p \leq 0.05$) for both luting procedures, RXU and RXU+E. Selective enamel etching prior to luting had no significant influence on modified USPHS criteria.

2. Percentage of failure calculation showed that additional selective etching of enamel (RXU+E) fulfils ADA guidelines (<5% failure at 2 years), but RXU does not. However, the differences are not statistically significant.

Acknowledgements The authors would like to express their thanks and appreciation to Prof. Dr. L. J. Nunez, Memphis, Tennessee, for reviewing the manuscript and for his advice as a native English speaker in terms of grammar and style.

Conflict of interest The authors declare that they have no conflict of interest.

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