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ORIGINAL ARTICLE

Four-year clinical evaluation of a self-adhesive luting agent for ceramic inlays

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Abstract
Objectives The aim of this randomized controlled clinical trial was to evaluate the 4-year clinical performance of a self-adhesive resin cement, RelyX Unicem (3M ESPE), used for cementation of ceramic inlays. In addition, the influence of selectively acid-etching enamel prior to luting on the clinical performance of the restorations was assessed.
Methods Sixty-two IPS Empress 2 inlays/onlays were placed in 31 patients by two experienced clinicians. The restorations were luted with RelyX Unicem with (=experimental group: E) or without (=control group: NE) prior enamel etching with phosphoric acid. At baseline, 6 months, and 1, 2, and 4 years after placement, the restorations were assessed by two calibrated investigators using modified USPHS criteria. Ten selected samples of each group were investigated under SEM regarding morphological changes at the cement–inlay interface.
Results The recall rate at 4 years was 97 %. Two restorations (1 E, 1 NE) were lost, and one (E) had to be replaced due to inlay and tooth fracture resulting in a survival rate of 95 %. No significant differences between the experimental and control group were noticed regarding all criteria (McNemar, $p<0.05$). An obvious deterioration in marginal integrity was observed after 4 years as only 5 % (E=7 %; NE= 3 %) of the restorations exhibited an excellent marginal adaptation. In 90 % of the restorations small, still clinically acceptable marginal deficiencies were observed. SEM of the luting gap showed an increased wear of the RelyX Unicem cement over the 4-year period.
Conclusions The self-adhesive luting cement RelyX Unicem can be recommended for bonding of ceramic inlays/onlays. Additional selective enamel etching does not improve the clinical performance of the restorations within the 4-year period.
Clinical relevance The self-adhesive resin composite RelyX Unicem showed acceptable clinical performance after 4 years of clinical service.

Keywords Glass ceramics · Adhesive inlays · Luting composite · Self-adhesive · Clinical trial

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Introduction

In the last decade, simplification of adhesive procedures has gained substantial importance. More specifically, for adhesive luting of inlays/onlays self-adhesive luting cements has been introduced. An important advantage of these luting cements is that they do not require pretreatment of the tooth surface, thereby reducing the technique sensitivity of the luting procedure. Self-adhesive luting resin cements are generally composed of phosphoric acid and/or carboxylic acid methacrylate monomers. These monomers are thought to bond chemically to tooth apatite and to the superficial oxides of the restoration. The resin cements are usually dual-cured resins that can be light-activated and can self-cure as well [1]. The different self-adhesive resin cements available on the dental market cannot be considered a homogenous group as they display disparate physico-chemical, physico-mechanical, and adhesive properties [2–7]. RelyX Unicem, the first introduced self-adhesive luting composite on the dental market, is the most

thoroughly investigated self-adhesive cement in the current literature. Several conclusions can be drawn from in vitro studies. First, the physico-mechanical properties of Unicem are in the range of those of conventional resin cements [3, 7–9]. Second, the dentin bonding efficiency in terms of bond strength, marginal adaptation, and microleakage is comparable to that of multi-step luting composites [4, 10–16], although the interaction of RelyX Unicem with dentin is superficial without the formation of a hybrid layer [5, 10, 17]. Some in vitro studies, however, showed less favorable results regarding dentin bonding efficiency [5, 18–23]. Regarding enamel bonding performance, all in vitro studies showed that RelyX Unicem cannot compete with cements that use etch-and-rinse adhesives [4, 10, 11, 24, 25]. However, a significant increase in bond strength and a better marginal adaptation can be obtained after etching the enamel with phosphoric acid [10, 11, 25, 26] and the use of a bonding agent [24, 27].

Regarding the clinical behavior of RelyX Unicem when it is used for cementation of inlays/onlays/partial crowns, only a few short-term (1–2 years) clinical trials are available in the literature, demonstrating that this cement shows good short-term clinical performance [28–32]. To date, no information is available from medium-term to long-term clinical trials. Therefore, the purpose of this study was to evaluate the 4-year clinical performance of RelyX Unicem used for cementation of ceramic inlays/onlays in a randomized controlled clinical trial. In addition, the influence of selective acid etching of enamel prior to luting on the clinical performance of the restored teeth was assessed. The hypothesis tested was that selective etching of enamel prior to luting has no influence on the clinical performance of the restorations.

Materials and methods

Clinical procedure

All patients were required to give written informed consent. The study was approved by the Commission for Medical Ethics of the Catholic University of Leuven. The patients agreed to a recall program of 4 years consisting of five appointments (baseline, 6 months, and 1, 2, and 4 years). Thirty-one healthy adult patients (22 female/9 male; 18–59 years), in need of two esthetic Class II posterior restorations, were selected for this study. They met the following criteria: vital teeth, absence of pain in the tooth to be restored, absence of any active and pulpal disease, no further restorations planned in other posterior teeth, possible application of rubberdam, inlay or onlay with maximum one cusp covered, high level of oral hygiene, contralateral side restorations (split mouth design).

These 31 patients received 62 IPS-Empress 2 (Ivoclar Vivadent; Schaan, Liechtenstein) inlays/onlays. In each patient, one restoration was luted with RelyX Unicem according to the instructions of the manufacturer (control group: non-etch; NE). In the tooth on the contra-lateral side, the enamel cavity margins were etched with 35 % phosphoric acid prior to cementation of the restoration with RelyX Unicem (experimental group: Etch; E).

Treatments were carried out by two experienced operators in the School of Dentistry, Department of Conservative Dentistry, Catholic University of Leuven. Forty-two inlays were MO/DO (E=22; NE=22), 12 MOD (E=4; NE=6), and 8 onlays (E=5; NE=3). The restorations were cemented in 32 premolars and 30 molars. Reasons for restoration were caries (n=10) and replacements (n=52).

Initial situations were recorded by X-rays. Five teeth required caries profunda treatment. In 4 cavities, the margin was located below the cemento-enamel junction and in 25 cavity preparations 0.5 mm of enamel was left at the proximo-cervical margin.

The preparations of the cavities were performed slightly divergently without beveling of the margins with 80-μm diamond burs and finished with 25-μm finishing diamonds (Inlay Preparation Set 4263, Komet; Lemgo, Germany). Minimum depth of the cavities was 1.5 mm with rounded occluso-axial angles. Minimum width at the isthmus was 2 mm. If an onlay preparation was made, the restoration was approximately 1.5 mm thick under the cusp tip and had at least a 1 mm wide or horizontally ending preparation. During cavity preparation, undercuts were avoided if possible. Small undercuts were blocked out with a resin-modified glass ionomer (Photac Fil, 3M ESPE; Seefeld, Germany). However, more than 50 % of the prepared tooth surface was required to consist of dentin.

Full-arch impressions were taken with high-viscosity addition-silicon impression material (Dimension Penta, 3M ESPE) and low-viscosity, syringeable material was used (Dimension Garant, 3M ESPE) to record preparation details.

For all preparations, provisional restorations were made with Pro-Temp (3M ESPE) and cemented with an eugenol-free temporary luting cement (RelyX Temp NE, 3M ESPE). One dental ceramist produced all the inlays and onlays with IPS Empress 2 (Ivoclar Vivadent), according to manufacturer's instructions within 1 or 2 weeks after impression taking.

To ease the placement of the inlays/onlays, isolation took place with rubberdam. This also prevented that phosphoric acid gel came into contact with the gingiva while etching the cervical enamel margins in the Etch group. After isolation, the intraoral fit of the restoration was evaluated. The approximal contacts were measured using dental floss and standardized metal blades. The thickness of these blades varied from 0.05 to 0.25 mm (0.05, 0.10, 0.15, 0.20, and 0.25 mm).

Prior to insertion, the thickness of the inlays and onlays (deepest fissure, isthmus, cusp) was recorded using a pair of tactile compasses, with an accuracy of 0.01 mm (ODI D calliper gauge, Kroeplin; Schluechtern, Germany).

The internal surface of the inlays was etched with 4.5 % hydrofluoric acid (4.5 %; IPS Ceramic etching gel, Ivoclar Vivadent, 60 s), rinsed for 60 s, and neutralized (IPS Neutralizer, Ivoclar Vivadent). After application of the silane coupling agent (Monobond S, Ivoclar Vivadent), the solvent was evaporated with compressed air.

Allocation to the cavity-pretreatment group with (experimental group; Etch) or without enamel etching (control group; Non-etch) occurred strictly at random just before cementation [28].

In the experimental group, the enamel margins were etched with 35 % phosphoric acid gel (Ultra-Etch, Ultradent Products; Salt Lake City, UT, USA; 1 mm outside the cavity, 1.5 mm inside the cavity at the occlusal and proximal part of the cavity) for 15 s, followed by thorough rinsing and drying. Next, the RelyX Unicem Maxicapsule (3M ESPE) was mixed in the Rotomix (3M ESPE) for 10 s and the cavity was filled with cement. The restoration was seated and held in place under light finger pressure. After tack curing with the polymerization light for 2–3 s, excess cement was removed and each surface was light-cured for 20 s. The curing light used was Elipar FreeLight 2 (3M ESPE) with an intensity of 1,250 mW/cm^2.

After light-curing and examination of the luting areas for defects, the rubberdam was removed. Centric and eccentric occlusal contacts were adjusted with diamond finishing burs (Esthetic Trimming Set, Komet) prior to Soflex disks (3M ESPE; St Paul, MN, USA). Overhangs were removed and polished in the same way, proximally with interdental diamond strips (GC; Tokyo, Japan) and interdental polishing strips (GC Epitex strips; GC). Final polishing was conducted using felt disks (Dia-Finish E Filzscheiben, Renfert; Hilzingen, Germany) with polishing gel (Brinell, Renfert).

At baseline (1 month after placement) and after 6 months and 1, 2, and 4 years, all available restorations were assessed according to the modified United States Public Health Service (USPHS) criteria by two independent investigators using mirrors, probes, dental tape, bitewing radiographs, and intraoral photographs [28]. The scores for each parameter were divided into clinically acceptable scores alpha 1 (excellent), alpha 2 (good), and bravo (sufficient) and clinically unacceptable scores charlie and delta. If an alpha 2 score is present, correction is still posssible without damaging the tooth or restoration. This is not the case when the restoration has a bravo score. With a charlie score, repair of the restoration is still possible. With a delta score, replacement of the restoration is needed. The two evaluators were different from the two clinicians who had placed the restorations. Both examiners were used to assess adhesive restoration in clinical trials for more than 20 years. In case of disagreement, a consensus was reached by discussion.

Statistical analysis

Statistical analysis compared the ratings of marginal integrity, inlay integrity, tooth integrity, sensitivity, complications, and X-ray examination between the experimental group and the control group on a pair-wise basis using the McNemar test at a significance level of 5 % ($p>0.05$). Survival statistics were determined using the Kaplan–Meier algorithm and the difference between the two groups was determined with the Log Rank test ($p>0.05$).

Scanning electron microscopic analysis

Impressions of the restorations were taken at baseline, 1 year, and 4 years (Dimension Penta, 3M ESPE) and epoxy replicas were manufactured (Epofix Resin, Struers, Ballerup, Denmark). Twenty casts of 10 randomly selected patients were prepared for SEM evaluation to illustrate morphological changes at the cement–inlay interface over time. The replicas were then mounted on aluminium stubs, sputter-coated with gold, and examined under SEM at different magnifications (XL30 FEG SEM, Philips). SEM examination was performed by a third evaluator who was blinded to the restorative procedures.

Results

The results of the baseline, 1, 2, and 4-year evaluation are presented in Table 1. Figures 1 and 2 show clinical photographs of two Empress 2 inlays (E, NE) in the same patient at baseline, 1 year and 4 years. SEM photographs of the same restorations at the same recalls are shown in Figs. 3, 4, 5, and 6.

One patient (who received 2 restorations) did not attend the 2 and 4-year recall examinations (drop-out rate: 3 %) as she had moved to another place. After 4 years of clinical service, 2 restorations of the NE group in 2 different patients had to be replaced due to loss of retention, and 1 restoration of the E group in another patient showed a clinically unacceptable tooth and inlay fracture. Fifty-seven inlays were in good condition (survival rate computed with the Kaplan–Meier algorithm, 95 %). The survival rate was 97 % for the E group and 93 % for the NE group. There was no significant difference between both groups (Log Rank test; $p=0.5$).

Over the whole observation period, the restorations of the E and NE group showed no statistically significant differences regarding marginal integrity, inlay integrity, tooth integrity, sensitivity, complications, and radiographic assessment (McNemar; $p>0.05$).

Table 1 Clinical results in % for IPS Empress 2 inlays according to modified USPHS-criteria on baseline, 1, 2, and 4 years

		Baseline (n=62)			12 months (n=62)			24 months (n=60)			48 months (n=60)		
		Etch	Non-etch	Total	Etch	Non-etch	Total	Etch	Non-etch	Total	Etch	Non-etch	Total
Surface roughness	Alpha 1	100	93.3	96.7	83.8	71	77.4	73.3	56.7	65	70	53.3	61.7
	Alpha 2	0	6.4	3.2	16.2	22.6	19.4	26.7	36.7	31.7	30	40	35
	Bravo	0	0	0	0	0	0	0	0	0	0	0	0
	No info	0	0	0	0	6.4	3.2	0	6.6	3.3	0	6.7	3.3
Color match	Alpha 1	87.5	73.3	80.4	80.6	67.8	74.2	66.7	46.7	56.7	66.7	40	53.3
	Alpha 2	12.5	26.7	19.6	19.4	25.8	22.6	33.3	46.7	40	33.3	50	41.7
	Bravo	0	0	0	0	0	0	0	0	0	0	3.3	1.7
	No info	0	0	0	0	6.4	3.2	0	6.6	3.3	0	6.7	3.3
Marginal integrity	Alpha 1	75	66.7	70.7	41.9	38.7	40.3	23.4	20	21.7	6.7	3.3	5
	Alpha 2	25	30	27.5	54.8	51.6	53.2	70	66.6	68.3	76.7	66.7	71.7
	Bravo	0	3.2	1.6	3.2	3.2	3.2	6.6	6.6	6.6	13.3	23.3	18.3
	Charlie	0	0	0	0	0	0	0	0	0	3.3	0	1.7
	Delta	0	0	0	0	6.4	3.2	0	6.6	3.3	0	6.7	3.3
Inlay integrity	Alpha 1	96.8	96.8	96.8	87.1	93.5	90.3	86.7	93.3	90	83.4	80	81.6
	Alpha 2	0	3.2	1.6	3.2	6.4	4.8	0	3.3	1.7	3.3	6.7	5
	Bravo	3.2	0	1.6	9.6	0	4.8	13.3	3.3	8.3	10	10	10
	Charlie	0	0	0	0	0	0	0	0	0	3.3	0	1.7
	No info	0	0	0	0	0	0	0	0	0	0	3.3	1.7
Tooth integrity	Alpha 1	78.1	83.3	80.7	87.1	90.3	88.7	90	86.6	88.3	76.7	86.7	81.6
	Alpha 2	21.9	16.7	19.3	12.9	9.7	11.3	10	13.4	11.7	20	10	15
	Bravo	0	0	0	0	0	0	0	0	0	0	0	0
	Delta	0	0	0	0	0	0	0	0	0	3.3	0	1.7
	No info	0	0	0	0	0	0	0	0	0	0	3.3	1.7
Sensitivity	Alpha 1	100	96.7	98.4	100	100	100	100	100	100	100	96,7	98.3
	Alpha 2	0	3.2	1.6	0	0	0	0	0	0	0	0	0
	Bravo	0	0	0	0	0	0	0	0	0	0	0	0
	No info	0	0	0	0	0	0	0	0	0	0	3.3	1.7
Complications	Alpha 1	96.8	100	98.4	96.8	96.8	96.8	96.7	93.3	95	100	93.4	96.6
	Alpha 2	3.2	0	1.6	3.2	3.2	3.2	0	0	0	0	3.3	1.7
	Bravo	0	0	0	0	0	0	3.3	6.7	5	0	0	0
	No info	0	0	0	0	0	0	0	0	0	0	3.3	1.7
X-ray examination	Alpha 1	93.8	90	91.9	/	/	/	/	/	/	86.7	83.3	85
	Alpha 2	6.3	10	8.1	/	/	/	/	/	/	13.3	10	11.7
	Bravo	0	0	0	/	/	/	/	/	/	0	0	0
	No info	0	0	0	/	/	/	/	/	/	0	6.7	3.3

Obvious marginal deterioration was observed during the 4-year study period. The percentage of restorations with an excellent marginal adaptation (alpha 1) decreased from 70.7 % at BL (E=75 %; NE=66.7 %) to 5 % after 4 years (E=6.7 %; NE=3.3 %). Unacceptable scores (1 charlie and 2 delta scores) were noted for the 3 failed restorations described above. All other restorations showed a clinically acceptable marginal adaptation: an alpha 2 (E=76.7 %; NE=66.7 %) or a bravo score (E=13.3 %; NE=23.3 %).

Regarding inlay integrity, 81.6 % of the restorations were intact at the 4-year recall (E=83.4 %; NE=80 %). Only one restoration of the etch group (1.7 %) showed an unacceptable porcelain fracture in combination with a cusp fracture. About 18 % of the restorations (n=9) showed a clinically acceptable fracture of the porcelain (alpha 2 score or fracture <100 μm—E=3.3 %; NE=6.7 %; bravo score or fracture >100 μm—E=10 %; NE=10 %). Seven of the 9 fractures presented as half-moon fractures at the marginal ridge. Five of these fractures were already present at the 2-year recall.

The percentage of restored teeth with complete tooth integrity or an alpha 1 score at 4 years (E=76.7 %; NE=86.7 %) was approximately the same as that at baseline (E=

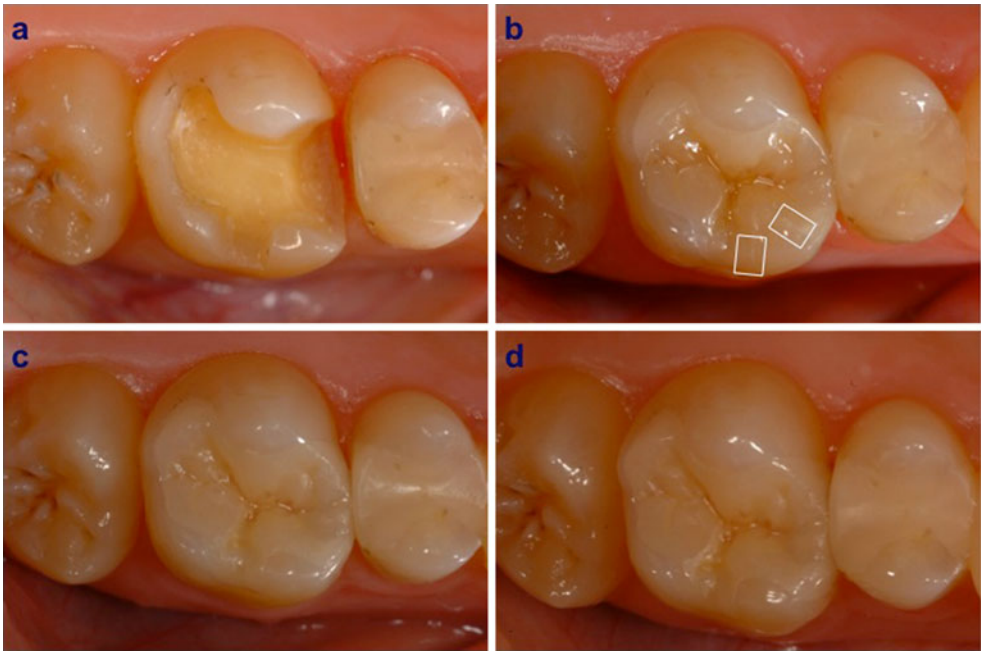

Fig. 1 In this patient, an old amalgam restoration on the left upper first molar was replaced by a ceramic inlay. The inlay was luted with Relyx Unicem without etching the enamel (NE). **a** Cavity preparation. **b** Baseline: slight cement excess was recorded at the margins resulting in an alpha 2 score. **c** A harmonious outline or an alpha 1 score was noticed at the margins at the 1-year recall. **d** After 4 years of clinical service, a marginal gap <100 μm (alpha 2 score) was observed. The mesio-buccal margin and the margin at the buccal extension indicated by the *white rectangles* were analysed by SEM (Figs. 3 and 4). Both areas were contact-free during occlusion and articulation

78.1 %; NE=83.3 %). All alpha 2 scores (E=20 %; NE=10 %; n=9) were observed as unprobable hairline cracks. Six of the 9 crack lines were not caused by the cementation procedure, as they were already present before cavity preparation.

Sensitivity, which already rarely occurred at baseline, was not present at the next recalls. One patient complained that her restored first upper premolar (NE group) was still sensitive during biting and flossing. This complication was also present at the 2-year recall, but was less pronounced at the 4-year recall.

During radiographic examination at the 4-year recall, wearing out of the luting composite was also recorded at proximo-cervical margins. The percentage of restorations with a harmonious transition (alpha 1 score—baseline, 92 %; 4 years, 85 %) or slight cement excess (alpha 2 score—baseline, 8 %; 4 years, 3.3 %) decreased, while the percentage of restorations with a small positive or negative step (<100 μm) at the cervical margin increased slightly (alpha 2 score—baseline, 0 %; 4 years, 8.3 %).

No esthetic failures, such as clinically unacceptable surface roughness and color mismatch, were present at the 4-year recall. For both parameters, a decrease in the percentage of restorations with an alpha 1 score was noticed (surface roughness, 61.7 %; color match, 53.3 %), and an increase in alpha 2 scores (surface roughness, 35 %; color match, 41.7 %).

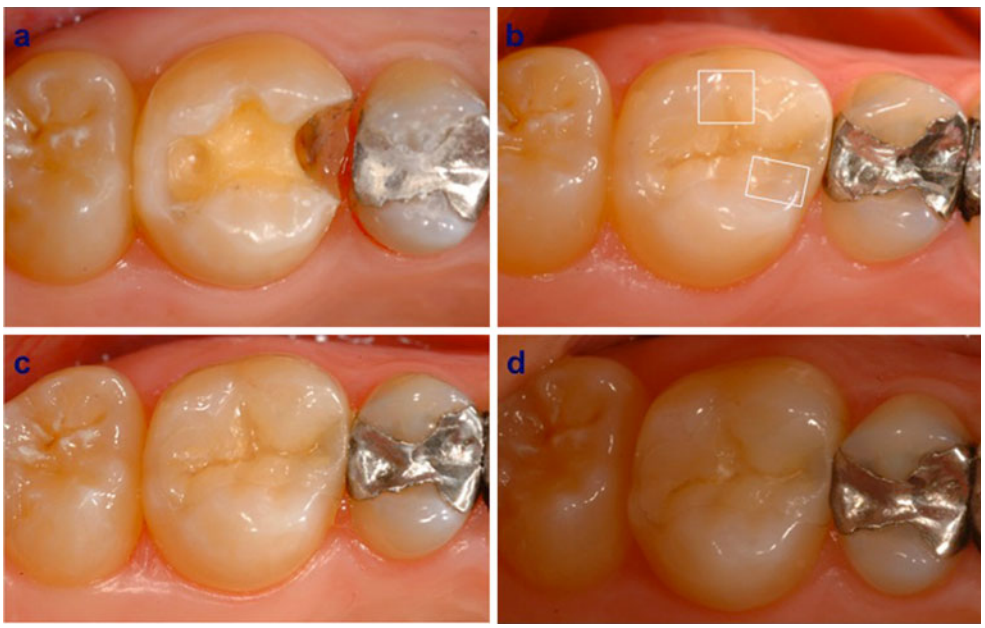

Fig. 2 In the same patient as in Fig. 1, an old amalgam restoration on the right upper first molar was replaced by a ceramic inlay. The inlay was luted with Relyx Unicem with prior selective etching of enamel (E). **a** Cavity preparation. **b** Baseline: The margins showed a harmonious outline or an alpha 1 score. **c** The same observation was done at the 1-year recall. **d** After 4 years of clinical service, a marginal gap <100 μm (alpha 2 score) was observed. The mid-buccal margin and the mesio-palatal margin indicated by the *white rectangles* were analysed by SEM (Figs. 5 and 6). Both areas were contact-free during occlusion and articulation

Average ceramic dimensions measured prior to insertion were 1.9 mm below the deepest fissure, 3.3 mm buccolingually at the isthmus, and 3.5 mm below reconstructed onlay cusps. SEM evaluation showed distinct changes at the luting gap with time, namely wearing out of the luting composite (Figs. 3, 4, 5, and 6). This was observed both on the occlusal contact areas and on the contact-free areas. The wear seems to be more pronounced in regions where the luting space was wider (Fig. 4). Sometimes, air bubbles were noticed in the luting composite, which can contribute to increased wear (Fig. 4). In some restorations (14.5 %), a marginal gap was already present at baseline (Fig. 6). In some restorations, minor fractures (not visible during clinical evaluation) of the porcelain margin were observed after 4 years of clinical functioning (Fig. 7).

Discussion

Due to the less favorable bonding efficiency of RelyX Unicem to enamel, some authors have questioned if this self-adhesive luting cement can be used for cementation of restorations with preparation margins located almost completely in enamel, e.g. inlays/onlays/partial crowns [1, 33]. The results of this study confirm that RelyX Unicem is indicated for cementation of these restorations, as the survival rate after 4 years was 95 %. In addition, the survival rate is quite similar compared to the 4-year survival rate of inlays/onlays cemented with a conventional etch-and-rinse luting composite [34–40], which is considered as the golden standard of luting cements for inlays/onlays. In the control group (NE) 2 restorations failed due to debonding, 1 at 6 months and the other at 12 months. The failure rate in the NE group (7 %) was not significantly different from the E group, where enamel was selectively etched with phosphoric acid prior to cementation (3 %; Log Rank test $p=0.5$). In this latter group one restored tooth failed at the 4-year recall due to the occurrence of a cusp fracture in combination with a porcelain fracture. The porcelain fracture was already observed after 3 years and was repaired with composite. At that moment, a visible crack line was noticed on the adjacent cusp which fractured 1 year later. Bruxism was considered to be associated with the fracture [41].

Only two 2-year clinical trials are available in the literature evaluating the clinical performance of RelyX Unicem used for cementation of ceramic inlays/onlays/partial crowns. In the study of Taschner et al. [29], no failures were observed in the group where inlays/onlays were cemented with RelyX Unicem compared to 1 fracture in the Syntac/Variolink (Ivoclar Vivadent) group. In the study of Schenke et al. [32] with a similar study design as that of the present study, 3 failures were recorded in the RelyX Unicem group (2 debondings and 1 inlay fracture) and 1 unacceptable inlay fracture in the group where RelyX Unicem was used with prior selective etching of enamel. Similarly as in the present study, additional selective enamel etching did not considerably improve the clinical performance of restorations.

Regarding the parameters of marginal integrity, tooth integrity, inlay integrity, post-operative sensitivity, and radiographic

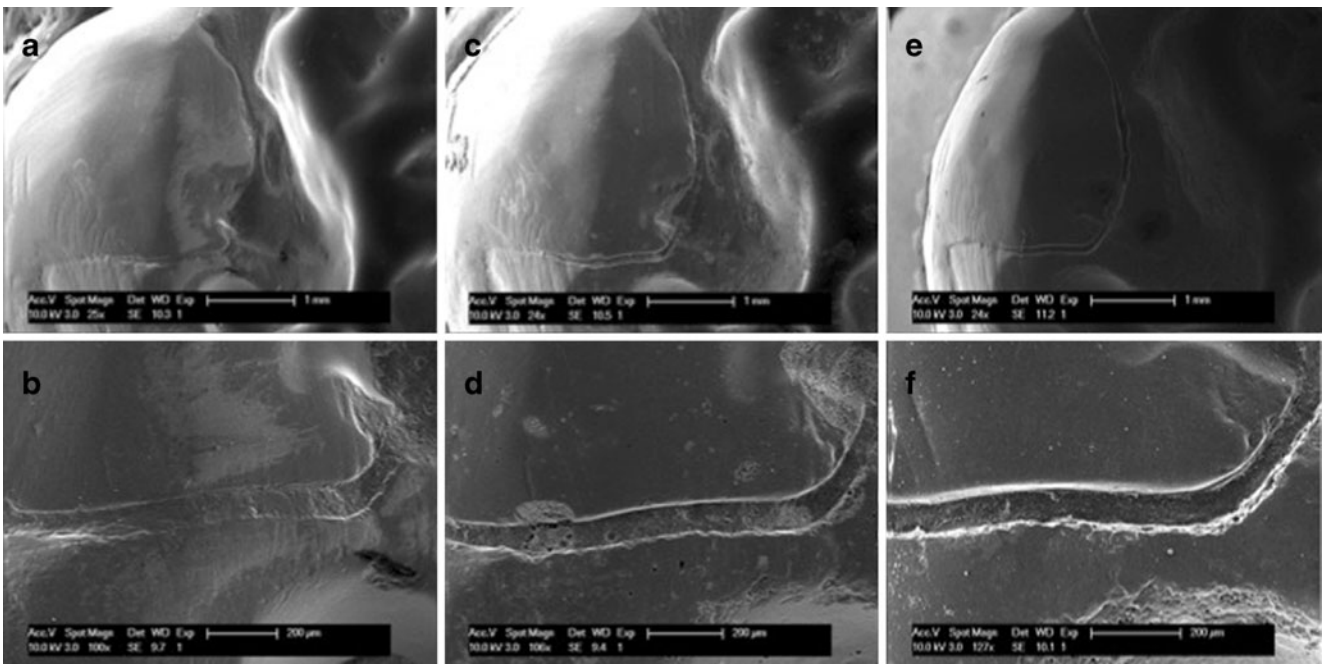

Fig. 3 SEM pictures of the margin at the buccal extension of the ceramic inlay belonging to the NE group shown in Fig. 1. Baseline (**a**, **b**), 1 year (**c**, **d**), and 4 year (**e**, **f**) at different magnifications. The SEM pictures clearly show the wearing out of the luting composite. The marginal gap was smaller than 100 μm

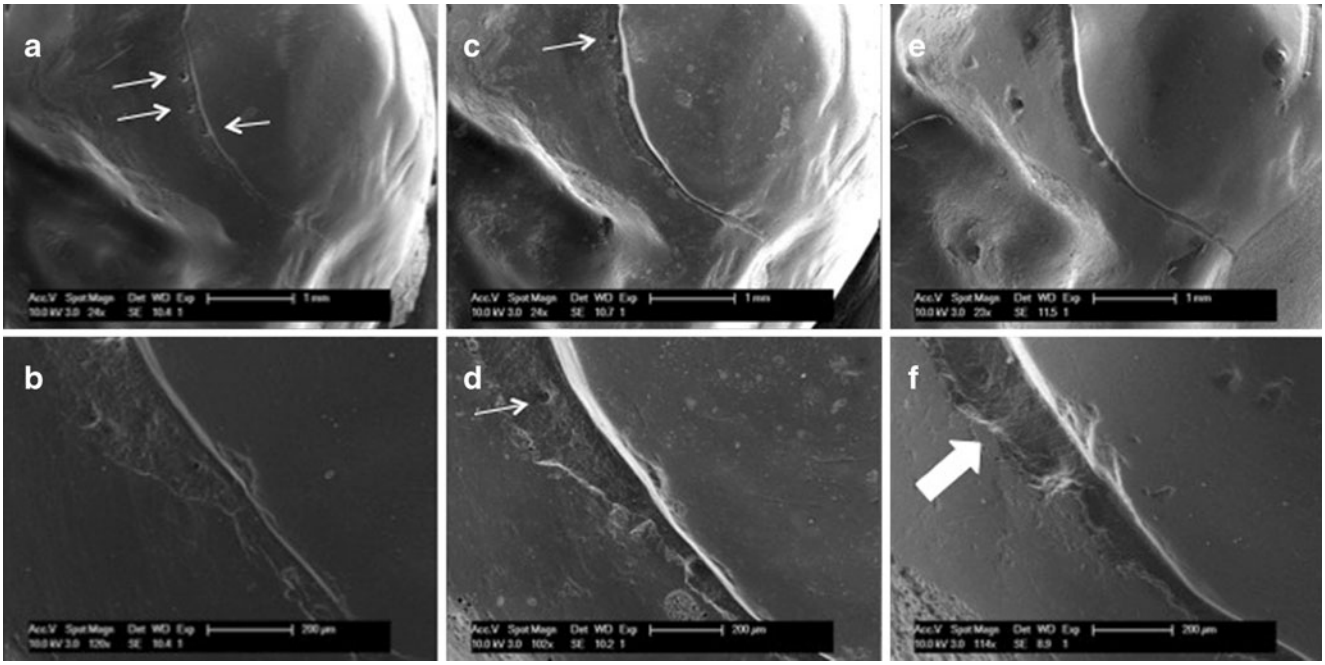

Fig. 4 SEM pictures of the mesio-buccal margin of the ceramic inlay belonging to the NE group shown in Fig. 1. Baseline (**a**, **b**), 1 year (**c**, **d**), and 4 year (**e**, **f**) at different magnifications. An increased wear of the luting composite was observed in the region where marginal gap was wider (*large arrow*). The air bubbles present in the luting cement may have contributed to increased wear of the luting composite

examination, no significant difference was noticed between both groups. This is in line with the hypothesis of the study.

The parameter that changed most clearly after 4 years was marginal integrity. The percentage of restorations with a harmonious outline decreased considerably from 70.7 % at BL to 5 % at the 4-year recall. However, marginal integrity remained clinically acceptable in all restorations except for the 3 failures. Similarly, all clinical investigations of ceramic inlays/onlays/partial crowns show appreciable changes in the marginal areas of the restorations after 4 years of clinical functioning [34–39]. In the different clinical trials at University of Erlangen [29, 34, 35, 38, 39], where the same

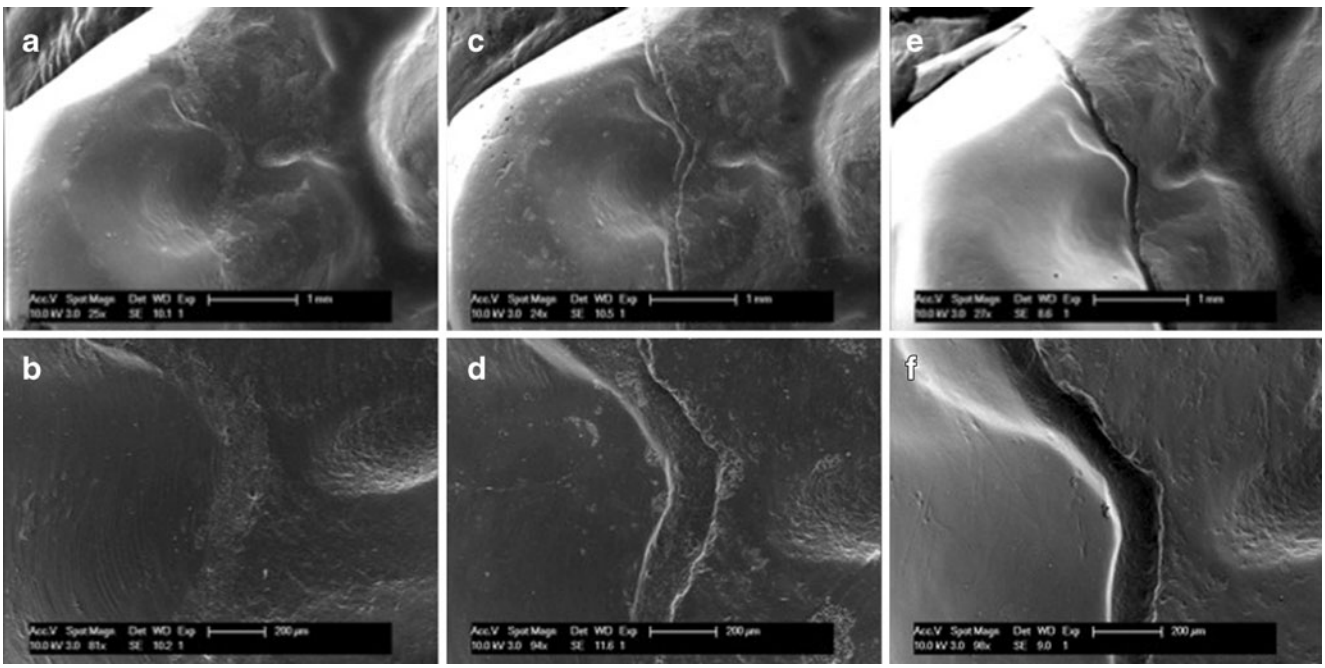

Fig. 5 SEM pictures of the mesio-palatal margin of the ceramic inlay belonging to the E group shown in Fig. 2. Baseline (**a**, **b**), 1 year (**c**, **d**), and 4 year (**e**, **f**) at different magnifications. Similarly as in the NE group, the luting composite visibly wears out of the luting gap with time

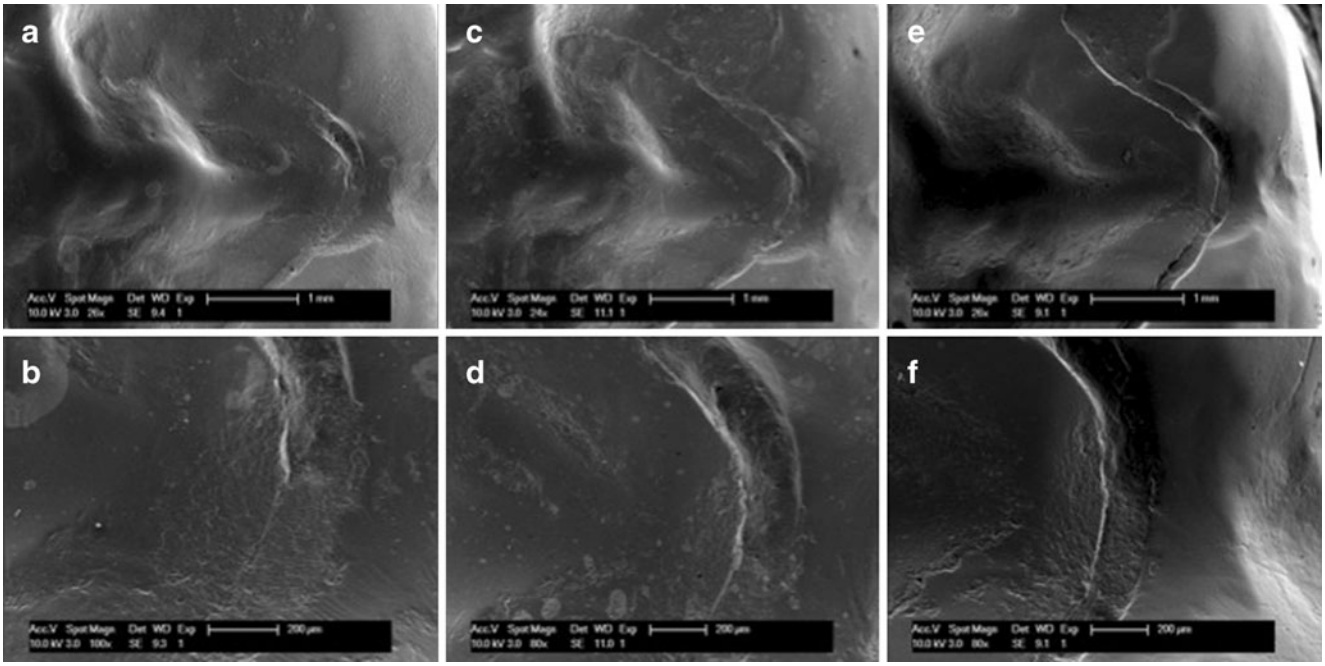

Fig. 6 SEM pictures of the mid-buccal margin of the ceramic inlay belonging to the E group shown in Fig. 2. Baseline (**a**, **b**), 1 year (**c**, **d**), and 4 year (**e**, **f**) at different magnifications. The luting composite was torn out of the luting space by the cementation method, i.e. removal of excess luting composite after 2–3 s of tack curing. This marginal gap at baseline, which was not observed during clinical evaluation, became deeper with time

evaluation system was used as that of the present study, the percentage of restorations with an alpha 1 score at baseline was much lower than in our study. An explanation for this low percentage of alpha 1 scores was the presence of a slight excess of luting composite, which corresponds to an alpha 2 score. Due to wear or degradation of the luting composite with time, this score changed into alpha 1 and finally into marginal ditching (alpha 2 or bravo score). In the present

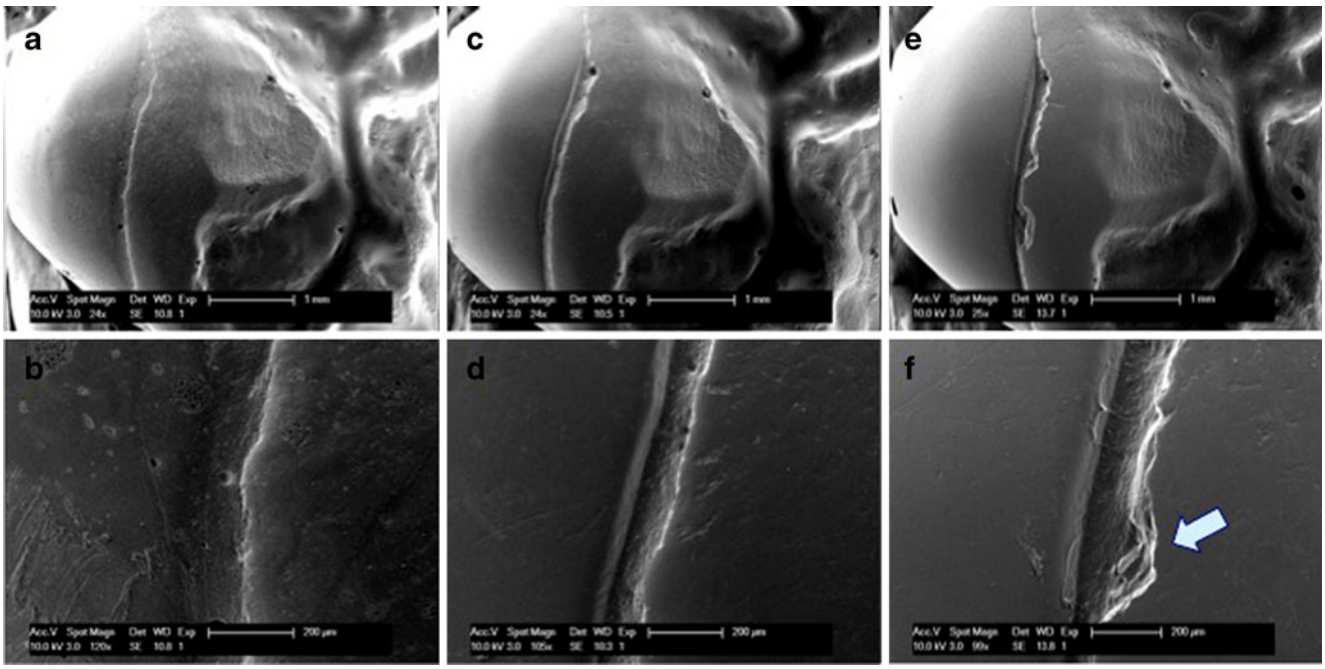

Fig. 7 SEM pictures of an MOD inlay on an upper right second premolar belonging to the E group. Baseline (**a**, **b**), 1 year (**c**, **d**), and 4 year (**e**, **f**) at different magnifications. Due to wearing out of the luting composite, very small fractures of the porcelain margin were noticed at the 4-year recall (*large arrow*). These small porcelain chippings were not recorded during clinical evaluation

study, excess of cement was observed in only a limited number of restorations (12.9 %) at baseline. Some restorations (14.5 %) even showed a slight marginal gap (<150 μm) at the baseline evaluation (Fig. 6). This could have been caused by the cementation method, e.g. by the removal of excess luting composite after 2–3 s of tack curing.

In this clinical trial, the cervical margins of only four restorations were located below the cemento-enamel junction, which means that almost all preparation margins ended in enamel. In an in vitro study of Frankenberger et al. [25], the marginal enamel quality of ceramic inlays after thermomechanical loading was significantly better when an etch-and-rinse adhesive (Syntac/Variolink) was used compared to RelyX Unicem. At the dentin side, no difference was noted in marginal quality. Marginal adaptation of the ceramic inlays/onlays at the enamel side improved significantly when the enamel was selectively etched with phosphoric acid prior to cementation with RelyX Unicem. This observation, however, was not clinically visible after 4 years of clinical functioning. There might be a small indication in this clinical trial that the marginal integrity was slightly superior in the E group, as a higher percentage of bravo scores was noted in the NE group compared to the E group (23 % vs. 13 %). In addition, marginal discoloration (included in the criterion of marginal integrity) occurred more frequently in the NE group than in the E group (13.3 % vs. 6.7 %). Nevertheless, these differences were not statistically significant. The same observation has been reported in a 2-year clinical trial of Schenke et al. [32] with similar study set-up.

SEM analysis of replicas provided a clearer view of the degradation process. In both groups an increasing wear of the luting composite was noticed from baseline to 4 years. The wear was more pronounced when the luting gap was wider. This correlation between depth and width of the luting gap was also observed in vitro [42] and in other clinical trials [43–45]. Regarding wear resistance of RelyX Unicem, an in vitro study of Belli et al. [46] found that the wear resistance of RelyX Unicem to toothbrush abrasion was similar to conventional resin cements and flowable composites. However, with the ACTA abrasive test under higher loads, RelyX Unicem wore more rapidly when compared to conventional resin cements and flowable composites. Although increased wear was clearly observed after 4 years of clinical functioning, this increased wear and marginal deterioration had no negative influence on the clinical functioning of the restorations. Longer-term evaluation should demonstrate if this marginal deterioration will become detrimental for the clinical performance of the restorations.

Regarding inlay integrity, only one restoration showed a clinically unacceptable porcelain fracture in combination with a cusp fracture. In the present clinical trial lithium disilicate ceramic Empress 2 (Ivoclar Vivadent) was used, which has enhanced mechanical properties compared to leucite reinforced ceramic and feldspatic ceramic [47, 48]. In three clinical trials evaluating Empress 2 inlays/onlays/partial crowns, no unacceptable fractures occurred after 2–3 years [37, 49, 50]. Nevertheless, a very low percentage of unacceptable fractures was also recorded in medium-term clinical trials where inlays/onlays were fabricated from leucite reinforced ceramic [34, 35, 37, 51, 52] or feldspatic ceramic [36, 53, 54]. The total number of fractures (19 %; n=10) in this study was also comparable to other 4-year studies with leucite-reinforced ceramic IPS Empress inlays/onlays using the same modified USPHS criteria as in the present study [34, 35]. The clinically acceptable chip fractures that occurred at the marginal ridge of 7 restorations were probably caused by microcracks created by grinding during correction of occlusion and articulation. Indeed, the clinical pictures at baseline showed a rougher surface in this area. An accurate polish of occlusally adjusted areas should involve considerable attention to prevent this problem, as was emphasized in the clinical trials carried out at the University of Erlangen [35, 38, 55, 56]. In a 12-year clinical trial, Frankenberger et al. [57] observed that inlay fractures occurred in two phases. In a first phase, fatigue fractures induced by adjustments with rotary instruments occurred between 3 and 4 years of clinical service. A second phase of fractures occurred after 10 years, due to the fact that the antagonistic enamel was significantly abraded more than the ceramic resulting in positive ceramic steps [45]. If these step formations are not adjusted, initial cracks are initiated at exactly these points of unsupported ceramic. In the present clinical trial, some restorations showed ditching of the porcelain at the margins due to wearing out of the luting composite over the 4-year study period. However, this porcelain ditching was only observed during SEM evaluation (Fig. 7). It is advisable to carefully monitor the ceramic-enamel interface with time to prevent the occurrence of fractures [56, 57].

Postoperative sensitivity did not occur at the 4-year recall. In fact, there was only one restored tooth with increased sensitivity at baseline (NE), and one tooth that was slightly sensitive during flossing at the 4-year recall (NE). Similarly, Taschner et al. [29] recorded no postoperative sensitivity at teeth restored with inlays/onlays cemented with RelyX Unicem and Syntac/Variolink in a 2-year clinical trial. However, in the clinical trial of Schenke et al. [31, 32] evaluating partial ceramic crowns cemented with RelyX Unicem with and without selective enamel etching, a high percentage of postoperative sensitivity was recorded at baseline (NE= 13.8 %; E=27.6 %). At the 2-year recall, postoperative sensitivity occurred less frequently (NE=10.7 %; E= 6.9 %). Saad et al. [58] investigated post-cementation

sensitivity associated with RelyX Unicem used with fixed partial dentures. In this clinical trial postoperative sensitivity with an etch-and-rinse luting cement was significantly higher than that associated with RelyX Unicem at all test intervals (24 h and 2, 6, and 12 weeks after cementation). Possible explanations for the very low frequency of postoperative sensitivity in these clinical trials are: (1) low shrinkage strain and shrinkage stress recorded in vitro for RelyX Unicem [59]. (2) RelyX Unicem's unique pH profile characterized by a more rapid rise in pH to neutrality [2, 3]. Together with the low solubility of the cement [60], this may prevent hydrolysis and release of components for diffusion through the dentinal tubules. (3) RelyX Unicem's reaction with the smear layer, which takes the form of alteration rather than total removal [10, 17]. This helps in preventing any migration of cement components towards the pulp, and hence, reduces the risk of pulpal reaction with subsequent post-cementation hypersensitivity as was demonstrated in vitro [61, 62].

Finally, the esthetic quality of the restorations decreased slightly during the 4-year study period. This was recorded as an increase in alpha 2 scores in color match (41.7 %) and surface roughness (35 %). Deterioration of the surface could be the result of occlusal contact wear, extrinsic mechanical wear, and chemical degradation of the glazing material and was also observed in other clinical trials evaluating IPS Empress [37, 51, 52] and Vita Mark II [63] partial coverage restorations. This rougher surface may lead to a slight color mismatch. Indeed, the percentage of restorations with a perfect color match decreased from 80.65 % at BL to 53.3 % at 4 years. The darkening of the natural tooth could also have been contributed to this clinically acceptable color mismatch [64]. The increase of surface roughness as well as the slight color deviation and alteration over time were not deemed to be a significant clinical problem in this investigation and were only evaluated by the examiners. The same observation has also been reported in clinical trials evaluating IPS Empress I, II, Procad, and CEREC/Vita Mark II restorations [52, 63–65].

Conclusion

In summary, the self-adhesive luting cement RelyX Unicem can be recommended for bonding of ceramic inlays. A clinically acceptable marginal deterioration was noticed in almost all restorations after 4 years of clinical functioning. Finally, selective etching of enamel did not improve the clinical performance of the restorations within the 4-year study period.

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

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