Clinical Evaluation of Indirect Composite Resin Restorations Cemented with Different Resin Cements

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Purpose: To clinically evaluate the performance of indirect composite resin restorations cemented with conventional and self-adhesive resin cements over a 12-month period.

Materials and Methods: Ten patients fulfilled all the inclusion criteria. Twenty-four composite resin restorations were performed using an indirect technique and cemented with a resin cement (RelyX ARC) or a self-adhesive resin cement (RelyX U100). Two independent evaluators analyzed the restorations using modified USPHS criteria after periods of two weeks and 6 and 12 months. Statistical significance between the cements at each timepoint was evaluated with the Wilcoxon test and between timepoints with the Mann-Whitney test, both at a significance level of 5%. Fisher's exact test was used to assess the occurrence of absolute failures.

Results: No statistically significant differences were found between the groups at the same timepoint nor between groups at different timepoints. The only significant difference was found for color match for both groups after 12 months.

Conclusion: After 12 months, indirect composite resin restorations cemented with self-adhesive resin cement performed similarly to those cemented with conventional resin cement.

Keywords: clinical trials, composite resin, resin cements, self-adhesive resin cements.

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Indirect restorations are preferred over direct restorations for the treatment of large cavities for many reasons: better marginal adaptation, improved anatomic form, better proximal contour and polishing ability, increased control of polymerization shrinkage compared to resin composite restorations,[18,20,22,32] as well as better monomer conversion rates via additional polymerization which improves physical properties, eg, hardness and water solubility.[21] Therefore, the luting agent plays a fundamental role in the longevity of these restorations as their long-term success is related to the stability, strength, and duration of the bond between the tooth structure, cement, and restoration.[22] Resin cements, associated with adhesive systems, bond to the tooth structure through a hybrid layer, while conventional cements, such as zinc phosphate cement and polycarboxylate cement, bond via micromechanical retention. Conventional cements have the disadvantage of having higher solubility, lower flexural strength, and a smaller range of available colors than resin cements.[6] As the conventional cements do not adhere to the teeth, the preparations are more invasive, and sometimes the use of a post is necessary to promote retention.

The adhesive luting technique can be classified according to the adhesive system utilized: a) etch-and-rinse; a multistep adhesive with one or two bottles, b) self-etch primer or adhesive, containing acidic monomers that demineralize enamel/dentin without rinsing; c) a self-adhesive resin cement that does not use a separate adhesive system.[26]

The instructions for use of self-adhesive resin cements do not include any pretreatment of the tooth surface, and their application procedure is extremely simple. They are characterized by having multifunctional acidic monomers that simultaneously demineralize and penetrate into the enamel and dentin. However, they do not form a hybrid layer.[9] Several

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Table 1 Inclusion criteria

❑ Healthy adult patients (between 18 and 70 years of age).
❑ Vital teeth with healthy opposing teeth or opposing teeth restored with resin composite.
❑ No pain or pulpal problems in the tooth to be restored.
❑ Needs at least two similarly designed preparations, ie, MO, OD, or MOD inlays, with a maximum isthmus of 2/3 the distance between the cusps, or onlays of similar size. The pair of restorations must be in premolars or molars, but not necessarily split-mouth design.
❑ Good oral hygiene.
❑ No bruxism or clenching.
❑ No orofacial pain.

studies[3,26] have indicated that this new category of cements does not represent a single entity, as the characteristics of their bond to the dental substrate differ by brand. The literature clearly demonstrates the superiority of RelyX U100, which, in addition to being the first product in this category, has also been the most studied and shows the most promising results.[1,17,26] This self-adhesive resin cement is dual curing, resulting in extensively cross-linked cement monomers and the creation of high molecular-weight polymers. The pH increases from 1 to 6 through the reaction of phosphoric acid groups with alkaline filler. Phosphoric acid groups also react with the tooth apatite, and the adhesion obtained relies on micromechanical retention and chemical interaction.[26]

Although in vitro studies have shown promising results in terms of the bond of self-adhesive resin cements to dentin[3,4,28] and to restorative materials such as composite resin and ceramic,[3,11] in vivo studies are essential to confirm the results of laboratory studies and to validate the quality of these new cements in a clinical setting. To date, only one clinical study[27] has compared the use of self-adhesive resin cement to conventional materials for the cementation of indirect restorations. It is thus imperative that further clinical trials be conducted to better assess the clinical efficacy of the self-adhesive resin cement RelyX U100 for the cementation of indirect restorations.

Hence, the aim of this study was to evaluate the clinical performance of two resin cements – one conventional (control group) and one self-adhesive (experimental group) – 2 weeks, and 6 and 12 months after the luting of indirect resin composite restorations. The null hypothesis tested was that there would be no difference between the experimental and control groups at any timepoint evaluated, as assessed according to the modified USPHS criteria.

MATERIALS AND METHODS

This study was approved by the Research Ethics Committee of the Pontifical Catholic University of Brazil (PUCRS; CAAE 0263.0.002.000-10). Ten patients (6 women, with an average age of 47 years, and 4 men, with an average age 46 years) were selected from the Operative Dentistry Clinic at the PUCRS Dental School. All patients were in need of at least two esthetic Class II posterior restorations and met the requirements of the inclusion criteria described in Table 1. All patients gave their consent by signing an informed consent form. Twenty-four restorations were performed: 8 patients received 2 restorations and 2 patients received 4 restorations, 12 in premolars and 12 in molars. These included 6 inlays (two pairs of three surfaces [MOD] and one pair of two surfaces [DO]) and 18 onlays all of similar size, as described in Table 2. A single experienced operator carried out all restorative procedures.

At the first appointment, local anesthesia was administered and all carious tissue and/or existing restoration material were removed. Preparations were finishing using diamond burs (Kit inlay/onlay KG Sorensen; Cotia, SP, Brazil), and no lining materials were used. Impressions were taken using a polysiloxane vinyl putty and regular body (Express XT, 3M ESPE; St Paul, MN, USA) in a partial plastic tray (Moldex, Angelus, Londrina, PR, Brazil). Provisional restorations were fabricated using a light-cured temporary restorative material (Bioplic, Biodinamica; Ibiporã, PR, Brazil). The color of the restoration was selected using the Vitapan Classical color scale (Vita Zahnfabrik; Bad Säckingen, Germany).

The impressions were sent to a commercial dental laboratory. There, the restorations were built from a composite resin (Filtek Supreme XT, 3M ESPE; St Paul, MN, USA) in increments on the stone cast. Adoro pigments (Ivoclar Vivadent; Schaan, Liechtenstein) were used to add characterization to the resulting restorations. Each increment was light cured for 10 s using an LED device (Ivoclar Targis Quick, Ivoclar Vivadent). After completing the restoration, its marginal adaptation, proximal contacts, and occlusion were checked on models positioned in a semi-adjustable articulator. Finishing and polishing were completed with fine cross-cut tungsten carbide burs and rubber silicon carbide. Afterwards, an additional polymerization step was performed in an external photoactivator unit (Ivoclar Targis Power Oven, Ivoclar Vivadent) in which the pieces were coated in glycerol and placed in the oven under vacuum for 22 min. The restoration was then polished with a goat-hair polisher, a rouge polishing bar (Shofu; San Marcos, CA, EUA), and a cotton wheel.

The patients attended a second appointment two weeks later, during which the prepared restorations were cemented as follows: 1. Teeth were randomly assigned to receive the conventional resin cement RelyX ARC (3M ESPE; Seefeld, Germany), shade A3, or the self-adhesive resin cement RelyU100 (3M ESPE; Seefeld, Germany), shade A2 (Table 3); 2. either absolute or relative isolation was achieved, depending on the clinical case; 3. the provisional restoration was removed and the preparation was cleaned with pumice and water;

Table 2 Pairs of teeth, kinds of resin cement, and preparation design

Patients	U100		ARC	
	Tooth	Cavity design	Tooth	Cavity design
1	Mandibular right first molar	MOD inlay	Mandibular left second molar	MOD inlay
2	Maxillary right first molar	DO onlay, reduction of the DB and DL cusps	Mandibular left first molar	MOD onlay, reduction of the B cusps
3	Maxillary right first premolar	DO onlay, reduction of the B and L cusps	Mandibular left second premolar	MOD onlay, reduction of the B and L cusps
4	Maxillary left first premolar	DO onlay, reduction of the L cusp	Maxillary left second premolar	MOD onlay, reduction of the L cusp
5	Maxillary right first premolar	DO inlay	Maxillary right second premolar	MO inlay
6	Maxillary left first premolar	MOD onlay reduction of the L cusp	Maxillary left second premolar	MOD onlay, reduction of the L cusp
7	Mandibular left second molar	MOD onlay reduction of the B cusp	Maxillary left first molar	DO onlay reduction of the B cusp
8*	Maxillary left first molar	MOD onlay reduction of the B and L cusps	Maxillary right first molar	MOD onlay reduction of the B and L cusps
8*	Mandibular right second premolar	MO inlay	Mandibular left first premolar	MOD inlay
9*	Maxillary left second molar	MOD onlay reduction of the B and L cusps	Maxillary right first molar	MOD onlay reduction of the MB and ML cusps
9*	Maxillary left second premolar	DO onlay, reduction of the B cusp	Maxillary left first premolar	MOD onlay reduction of the B cusp
10	Mandibular right first molar	MO onlay, reduction of the B cusp	Maxillary right first molar	MO onlay, reduction of the B cusp

ARC: resin cement RelyX ARC; U100: self-adhesive resin cement RelyX U100; MOD: mesio-occluso-distal; MO: mesio-occlusal; DO: disto-occlusal; B: buccal; L: lingual; DB: disto-buccal; DL: disto-lingual. *Patients 8 and 9 received two pairs of restorations. Data on pair of restorations were included in the statistical analyses instead of the number of patients.

Table 3 Materials, compositions, and manufacturers

Material	Composition	Manufacturer
RelyX U100 (self-adhesive resin cement)	Base paste (white): methacrylate monomers containing phosphoric, acid groups, methacrylate monomers, silanated fillers, initiator components, stabilizers Catalyst paste (yellow): methacrylate monomers, alkaline (basic) fillers, silanated fillers, initiator components, stabilizers, pigments	3M ESPE; Seefeld, Germany
RelyX ARC (resin cement)	Paste A: bis-GMA, TEG-DMA, silane treated silica, functionalized dimethacrylate polymer, 2-benzotriazolyl-4-methylphenol, 4-(dimethylamino)-benzeneethanol Paste B: silane treated ceramic, TEG-DMA, bis-GMA, silane treated silica, functionalized dimethacrylate polymer, 2-benzotriazolyl-4-methylphenol, benzoyl peroxide (72 wt%)	3M ESPE; Seefeld, Germany
Primer (Scotchbond Multi-Purpose)	HEMA, polyalkenoic adic polymer, water	3M ESPE; St Paul, MN, USA
Bond (Scotchbond Multi-Purpose)	Bis-GMA, HEMA, tertiary amines (both for light-curing and self-curing initiators), photo-initiator	3M ESPE; St Paul, MN, USA
Silane	Silane	Dentsply; York, PA, USA
Filtek Supreme XT (composite resin)	Type of filler: ZrO_2/SiO_2 (clusters of 0.6–1.4 µm, individual particle size of 5–20 nm) 78 wt% Resin matrix: bis-EMA, UDMA, bis-GMA, TEG-DMA	3M ESPE; St Paul, MN, USA

4. the internal surface of the restorations was treated with airborne particle abrasion using 50-µm aluminum oxide at 4-bar pressure and a distance of 10 mm for 5 s, washed with air and water for 30 s, and coated with a silane layer (Dentsply; York, PA, USA); 5. the restorations were cemented with either RelyX ARC or RelyXU100. For RelyX ARC cementation, the Scotchbond Multi-Purpose adhesive system (3M ESPE) was applied. The tooth cavity was conditioned with 37% phosphoric acid for 15 s, rinsed with water for 10 s, and the excess water was removed with cotton buds. A layer of primer was applied, followed by gentle air drying for 5 s. Then, the bond was applied and light cured with a quartz-tungsten halogen light-curing unit (Optilight Plus, Gnatus; Ribeirão Preto, SP, Brazil) for 10 s. Irradiance levels of the light were monitored periodically with a radiometer (Demetron Model 100, Kerr; Orange, CA, USA) to ensure that the range was between 500 and 550 mW/cm^2. RelyX ARC's base and catalyst pastes were hand mixed for 20 s according to the manufacturer's instructions, and were immediately placed in the cavity, and held in place with strong finger pressure for 3 min. Excess cement was removed, and the restoration was light cured for 60 s on each side (occlusal, buccal, and lingual). Occlusal adjustments were made prior to finishing and polishing with Soflex disks (3M ESPE), and a #12 scalpel blade was used to remove excess cement from the proximal areas. For RelyX U100 cementation, the base and catalyst pastes of the self-adhesive resin cement were mixed for 20 s according to the manufacturer's instructions, and placed on the internal side of the indirect restoration; the restoration was immediately positioned in the tooth and held in place with strong finger pressure for 3 min. Excess cement was removed and light cured for 60 s on each side (occlusal, buccal, and lingual). Occlusal adjustments were made, the completed restoration was finished and polished using Soflex disks, and a #12 scalpel blade was used to remove the excess cement from the proximal areas.

At recall visits performed at 2 weeks (baseline), 6 and 12 months after the cementation, follow-up examinations were performed. The patients received oral hygiene instruction and periodontal cleaning (supragingival scaling and root planing for all teeth) when they entered the study and at 6 and 12 months. Two calibrated, blinded, independent examiners with mirrors, probes, and dental floss evaluated the restorations and completed a questionnaire according to modified USPHS (United States Public Health Service) criteria[22] (Table 4). When there was disagreement on any criterion, the investigators reached a consensus. At the baseline and 12-month appointments, periapical radiographs were taken with standardized positioning and irradiation parameters for each restored tooth. These radiographs were also analyzed by the evaluators.

Statistical Analysis

The twelve pairs of restorations were considered the sample size of the study to increase the power analysis. The ordinal classifications of USPHS for the comparison between groups at the same timepoint were analyzed using the Wilcoxon Signed-Ranks test. The Mann-Whitney test was used for evaluations between different timepoints (baseline, 6 months, and 12 months). Fisher's Exact Test was used to assess the occurrence of absolute failures between the groups. All tests were performed at a significance level of $\alpha = 0.05$.

RESULTS

A total of 12 pairs of restorations were evaluated (n = 12), and one patient failed to attend the 6-month recall appointment (n = 11). A predominance of Alpha 1 scores was noted for all categories (Table 5) except Color Match, for which Alpha 2 was more common (Fig 1). This finding represented a significant difference ($p < 0.05$) from baseline to 12 months for the 2 groups (Table 6). Although no significant difference was observed in any criteria when comparing the experimental and control groups at different timepoints ($\alpha = 0.05$; Mann-Whitney test), a tendency for Alpha 1 to become Alpha 2 was observed in the categories of surface roughness and marginal integrity (Table 5). All failures that appeared over the 12-month period occurred in the restorations cemented with RelyX U100; however, no significant difference was found between the groups in terms of the frequency of absolute failure occurrences ($p = 0.109$; Fisher's exact test). At baseline, one patient who had constant, unbearable pain was referred for endodontic treatment. The restoration was preserved and the pulp chamber was restored with composite resin Filtek Supreme XT after endodontic treatment. However, this restoration was considered to be an absolute failure, ie, there was a loss of restoration. At the 6-month follow-up, another absolute failure occurred. This patient also had constant, unbearable pain and required endodontic treatment, during which the onlay was lost. At the 12-month recall, there was one relative failure (a small fracture of the enamel that was repaired with Filtek Supreme XT composite resin) and one absolute failure (radiography revealed secondary caries in the proximal gingival floor via radiography).

DISCUSSION

Study Design

The USPHS[7] clinical criteria for assessing restorations are the instruments of choice of most researchers because they are simple and build on the quality parameters (acceptable or not acceptable) of restorative materials and/or treatments. However, with the evolution of restorative materials, modifications of these criteria have been proposed. In 2007, Hickel et al[16] made recommendations for conducting controlled clinical studies of dental restorative materials based on Ryge modified criteria in order to improve and standardize them. Incorporating these guidelines, Peumans et al[22] proposed modified USPHS criteria to evaluate the cementation of indirect ceramic restorations. These were the criteria used in the present study.

Table 4 Modifited USPHS criteria investigated (according to Peumans et al[22])

USPHS criteria	Alpha 1	Alpha 2	Bravo	Charlie	Delta
Modified criteria	Clinically excellent/ very good	Clinically good (slight deviations from ideal performance, correction possible without damage of tooth or restoration)	Clinically sufficient/ satisfactory (few defects, correction impossible without damage of tooth or restoration. No negative effects expected.)	Clinically unsatisfactory (severe defects, prophylactic removal for failures)	Clinically poor (immediate replacement necessary)
Surface roughness	Smooth	Rough (polishable)	Rough (not polishable without causing damage)	N/a, see marginal integrity	N/a, see marginal integrity
Color match	Matching	Clinically good (minor color deviation)	Clinically satisfactory	Clinically unsatisfactory	N/a
Marginal integrity	Harmonious outline	Marginal gap (max. > 100 µm) Filling excess Discoloration (removable)	Marginal gap (> 100 µm) Discoloration (not removable)	Marginal gap (> 200 µm) Filling excess Discoloration (removable)	Loss of restoration Secondary caries
Inlay integrity	No splits, cracks, roughness, fractures	Minor split (max. 100 µm) Crack formation (not probable) Roughness	Noncorrectable split Crack (> 100 µm) Abrasion (> 100 µm) Roughness	Non-correctable split Crack (> 200 µm) Serious abrasion (> 200 µm)	Fracture with loss of restoration
Tooth integrity	Complete integrity	Minor enamel split (max. 100 µm) Hairline crack (max.100 µm)	Enamel split (> 100 µm) Crack (> 100 µm)	Major enamel split (dentin/base exposure) Crack (> 200 µm)	Cusp/tooth fracture
Proximal contact	Physiological	Too weak Too strong	Far too weak (no indication of damage to tooth, gingival or periodontium (> 100 µm)	Gingival trauma (food impaction)	N/a
Sensitivity	Not hypersensitive	N/a	Premature/strong (no subjective complaints, no treatment) Delayed/weak (no subjective complaints, no treatment)	Premature/strong (treatment is priority) Delayed/weak (treatment is priority)	Negative
Complications	No complications	Treatment-related post-operative complications (no treatment)	Continuing or recurring complications in the medium term (months), no treatment	Complications of permanent pain, treatment is necessary	Permanent and unbearable complications, immediate endodontic treatment
Patient satisfaction	Satisfied	N/a	Criticism of esthetic shortcomings, dissatisfaction with chewing comfort, time-consuming procedure	N/a	Completely dissatisfied
Radiographic examination	Harmonious transition	Cement excess Positive and negative steps (max. 100 µm)	Marginal gap (> 100 µm) Negative steps (> 100 µm)	Marginal gap (> 200 µm) Cement excess (intraradicular or non-removable, replacement) Negative step (> 200 µm)	Secondary caries Apical changes Tooth or inlay fractures

Hickel et al[16] suggested several criteria that should be adopted in clinical studies. Some of them were followed in this study, eg, the sample had to include one test and one control group, the patients had to be from the general community rather than dental students, the study had to include paired restorations, both groups – test and control materials – had to be placed in the same type of tooth with a comparable cavity size, and whenever possible, the restorations had to be placed during the same appointment. It was not easy to recruit patients who fulfilled all these inclusion criteria; thus, the number of available patients was limited. However, the comparison of very similar restorations in the

Table 5 Results from frequency distribution for all tested restorations at different timepoints

	Baseline (n = 12 / 12)					6 months (n = 11 / 11)					12 months (n = 12 / 12)				
	Alpha 1	Alpha 2	Bravo	Charlie	Delta	Alpha 1	Alpha 2	Bravo	Charlie	Delta	Alpha 1	Alpha 2	Bravo	Charlie	Delta
	ARC/ U100	ARC/ U100	ARC/ U100	ARC/ U100	ARC/ U100	ARC/ U100	ARC/ U100	ARC/ U100	ARC/ U100	ARC/ U100	ARC/ U100	ARC/ U100	ARC/ U100	ARC/ U100	ARC/ U100
Surface roughness	11/12	1/0	0/0	N/a	N/a	10/9	1/0	0/0	N/a	N/a	7/5	5/4	0/0	N/a	N/a
Color match	9/9	3/3	0/0	0/0	N/a	2/4	9/5	0/0	0/0	N/a	1/1	11/8	0/0	0/0	N/a
Marginal integrity	11/11	1/1	0/0	0/0[b]	0/0[a]	10/7	1/2	0/0	0/0[b]	0/0[a]	8/7	4/2	0/0	0/0[b]	0/1[a]
Inlay integrity	12/10	0/2	0/0	0/0[b]	0/0[a]	11/8	0/1	0/0	0/0[b]	0/1[a]	12/9	0/0	0/0	0/0[b]	0/1[a]
Tooth integrity	12/12	0/0	0/0	0/0[b]	0/0[a]	11/9	0/0	0/0	0/0[b]	0/0[a]	12/8	0/0	0/0	0/1[b]	0/0[a]
Proximal contact	12/11	0/1	0/0	0/0	N/a	10/8	0/0	0/0	0/0	N/a	12/8	0/1	0/0	0/0	N/a
Sensitivity	12/11	N/a	0/0	0/0	0/1	11/9	N/a	0/0	0/0	0/0	12/9	N/a	0/0	0/0	0/0
Complications	12/11	0/0	0/0	0/0	0/1[a]	11/9	0/0	0/0	0/0	0/2[a]	12/9	0/0	0/0	0/0	0/2a
Patient satisfaction	12/12	0/0	0/0	N/a	0/0	11/9	0/0	0/0	N/a	0/0	12/9	0/0	0/0	N/a	N/a
Radio-graphic examination	12/10	0/2	0/0	0/0	0/0[a]	N/a	N/a	N/a	N/a	N/a	10/8	1/0	0/0	0/0	0/1[a]

N/a: not applicable; a: absolute failure; b: relative failure.

same patient decreases the risk of including confounding variables.

Prospective studies that have control and test in the same patient have been reported to be highly appropriate for comparing treatment modalities,[27] because patient factors that influence the longevity of restorations, such as oral hygiene and diet, are the same for the test and control groups. The sample size of this study was reduced due to the strict inclusion criteria adopted, which were much more demanding than the inclusion criteria of clinical studies.[2,8,19,31] Despite the sample size, the design, observations, and analysis of the present study followed the standards of good practice.

Clinical Evaluation

The null hypothesis tested in this clinical study was partially rejected because the control and experimental groups, as evaluated by modified USPHS criteria, exhibited no significant differences either among themselves or at different timepoints (baseline, 6 and 12 months), except in the color match category.

The predominance of Alpha 1 (clinically excellent) results observed at baseline for the color match criterion gave way to Alpha 2 (clinically good) at 12 months for both groups. The observed change after 12 months was small enough not to compromise patient satisfaction with the restorations. This small color change may be due to several factors related to the mechanical properties and color stability of composite restorations, including the chemical reactions of the organic resin matrix, its interaction with the fillers, the filler size, the water sorption and the degree of conversion from monomers to polymers.[25] A pigment system for resin was used (Adoro, Ivoclar) to characterize the inlay and onlay restorations. These pigments were used when opacification was necessary or between layers of resin to give an occlusal characterization effect; they were never used as the final layer.

No significant differences for the proximal contact and roughness criteria were observed at 12 months. Although the roughness results showed a tendency for the score to decrease from Alpha 1 to Alpha 2, this finding was predicted by other clinical studies on indirect resin composite restorations.[1,8,18,20,31] A polymerization protocol with LED was used, followed by a further polymerization with heat and pressure (Ivoclar Targis Power). The additional polymerization increases the degree of conversion of composite resins,[24] and improves the composite properties such as diametral tensile strength, microhardness,[29] flexural strength, and wear resistence.[24] Although a slight instability was observed in the behavior of the resin shade, satisfactory results for the roughness and proximal contact criteria were obtained, highlighting the overall quality of the restorative material.

In the current study, no significant differences in the integrity of the indirect restorations were observed after 12 months, which demonstrated the good mechanical properties of Filtek Supreme XT for indirect restorations. This result is consistent with the findings of Azevedo et al[2] who assessed indirect restorations of Filtek Supreme XT cemented with RelyX U100 and observed no failures after a period of one year. Filtek Supreme XT is a nanoparticle

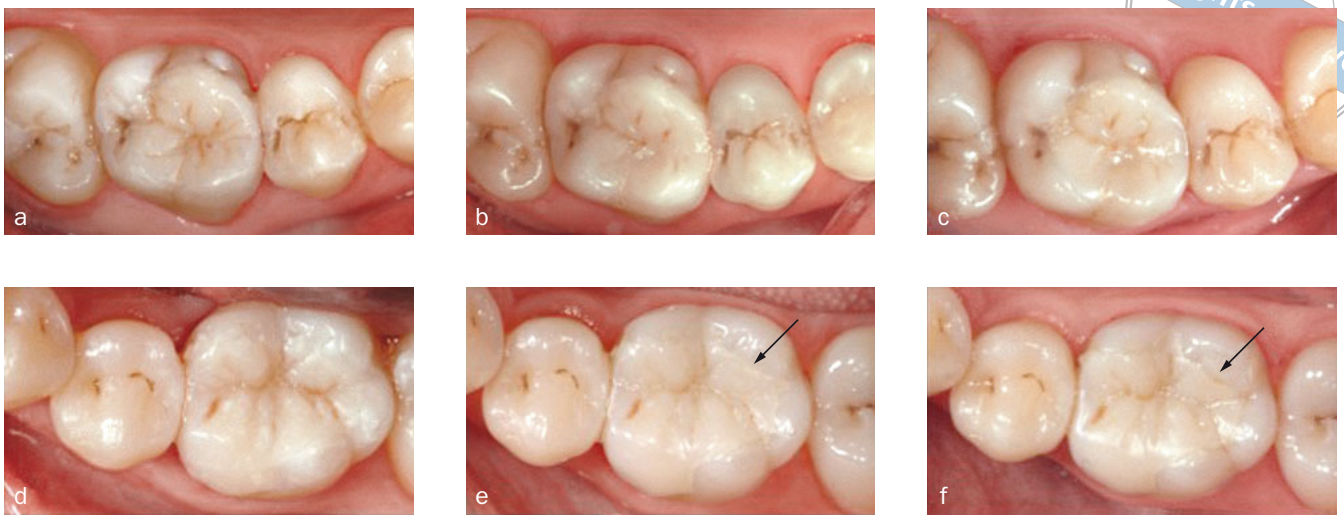

Fig 1 Images of restorations evaluated at three periods of time. In this patient, old amalgam restorations in the right maxillary first molar and the right mandibular first molar were replaced by indirect resin composite restorations. In a, b, and c, the onlay was luted with RelyX ARC. a) Baseline: Alpha 1 for color match and marginal integrity. b) 6 months: Alpha 1 for marginal integrity, and Alpha 2 for color match. c) 12 months: Alpha 1 for marginal integrity, Alpha 2 for color match. In d, e, and f, the onlay was luted with RelyX U100. d) Baseline: Alpha 1 for color match and marginal integrity. e) 6 months: Alpha 2 for color match and marginal integrity (arrow). f) 12 months: Alpha 2 for color match and marginal integrity (arrow).

Table 6 p-values of the Wilcoxon signed-rank test for comparison between times

Time	Cement	Surface roughness	Color match	Marginal integrity	Inlay integrity	Tooth integrity	Proximal contact	Sensitivity	Complications	Patient satisfaction	Radiograph
Baseline and 12 months	ARC	0.125	0.008*	0.250	1.000	1.000	1.000	1.000	1.000	1.000	1.000
	U100	0.125	0.031*	0.250	1.000	1.000	1.000	1.000	1.000	1.000	1.000
Baseline and 6 months	ARC	1.000	0.031*	1.000	1.000	1.000	1.000	1.000	1.000	1.000	N/a
	U100	1.000	0.625	1.000	1.000	1.000	1.000	1.000	1.000	1.000	N/a
6 and 12 months	ARC	0.125	0.500	0.250	1.000	1.000	1.000	1.000	1.000	1.000	1.000
	U100	0.125	0.250	0.500	1.000	0.500	1.000	1.000	1.000	1.000	1.000

*Wilcoxon signed-rank test, significant at $p < 0.05$.

composite resin with spherical particles that are responsible for its polishing quality and increased fracture resistance, because the mechanical stresses, which tend to focus on the angles and protuberances of the filler particles, are minimized in this material.[25] It must be mentioned that one loss of a restoration in the experimental group at 6 months occurred as a result of endodontic treatment, necessitating the partial removal of the restoration, resulting in its weakening and fracture.

In order to standardize the wear of the restorations, only teeth with sound or composite-restored opposing teeth were selected, because the marginal integrity of indirect restorations is influenced by the material of the opposing dentition. Generally, excellent (Alpha 1) or very good (Alpha 2) scores were achieved for the marginal integrity criterion, and no significant differences were observed between groups at any of the evaluation times. This also indicates that removable or deep pigmentation was not observed. This finding is in accordance with the considerations of failure in the intermediate time frame (6 to 18 or 24 months) proposed by Hickel et al.[16] However, there was a Delta score at 12 months related to an absolute failure caused by the development of secondary caries in the experimental group. Interestingly, for this particular restoration, the baseline score for marginal integrity was recorded as Alpha 2 by radiographic examination (ie, negative step < 100 µm). A possible explanation is that an increase in the size of the marginal gap results in the degradation of the bonding system, allowing microleakage and secondary caries.[19] It is therefore interesting to consider the study of Peumans et al,[23] who used SEM to evaluate replicas of indirect ceramic restorations cemented with RelyX U100 with and without prior acid etching on the

enamel. They noted that although the marginal integrity was clinically acceptable, microscopic analysis showed that the harmonious outline decreased from 70% at baseline to 5% after four years. However, when the marginal integrity is evaluated clinically and by SEM, most studies have not shown a clear correlation between the results.[16] Another possible explanation is given in a review[15] which suggested that a gap of up to or over 400 µm in easy to clean areas is necessary for the development of secondary caries. However, in difficult to access areas, such as the proximal gingival floor of Class II restorations, the presence of cariogenic plaque is enough to enable the development of caries, regardless of the size of the gap. To date, there is no evidence that the size of the marginal discrepancy and the development of caries is correlated.[15] However, while a discolored margin is not itself indicative of secondary caries, the deterioration and discoloration of the marginal seal can be predictive of future failures.[14] Thus, any marginal changes deserve the attention of dentists, as these may affect the prognosis of the restoration, and radiographic examinations are essential for assessment of the marginal adaptation of interproximal areas.

Another important factor related to marginal integrity is the ability of the cement to bond both the tooth and the restorative material. In relation to the dental substrate, the mechanism of bonding between RelyX U100 and the tooth structure appears to be more chemical than micromechanical in nature.[10] This chemical bond is established by the specific multifunctional phosphoric-acid methacrylate, which is ionized at the time of mixing and reacts with the hydroxyapatite of the mineral tissues of the tooth.[12] Self-adhesive resin cements superficially interact with dentin and enamel, without forming a true hybrid layer,[9,33] which is observed when an adhesive system is applied previously to the resin cement.[9] Studies on the marginal adaptation of ceramic restorations luted with RelyX U100 showed similar results in dentin and worse results in enamel.[3,4,11] In vitro studies[9,10] have evaluated the use of acid etching enamel with bond strength tests prior to cementation with RelyX U100. The results of such studies suggest a better prognosis for restorations cemented with RelyX U100 with prior acid etching. However, when clinical studies on this issue were performed using indirect resin[2] and ceramic[23,30] restorations, the authors concluded that there were no significant differences between the treatments. Therefore, in this study, it was decided not to etch the enamel before the application of RelyX U100, as the current evidence is inconclusive regarding the effectiveness of this procedure.

No restorations were lost due to a loss of retention during the period of the study. This finding suggests that both resin cements produced an adequate bond to the dental substrate. The retention of inlays and onlays depends on the ability of the resin cements to bond effectively with the surrounding enamel and dentin. In the case of RelyX ARC, this union is promoted by the formation of a hybrid layer caused by the adhesive system, whereas for RelyX U100, the resin cement promotes its own retention. Due to the thixotropic behavior of RelyX U100, both in vitro[9,13] and in vivo[30] studies have shown that a constant pressure (20 to 40 g/mm^2) should be applied at the time of cementation to reduce the viscosity of the cement. In addition to reducing any air bubbles, this pressure promotes the adaptation of the cement to the walls of the cavity by optimizing physical interactions, such as van der Waals forces, hydrogen bridges, and charge transfers.[13] It is therefore believed that applying pressure contributes to the retention of restorations cemented with RelyX U100.

Many cases of post-operative sensitivity resolve a few weeks after the placement of the restoration. However, some teeth require endodontic treatment to address hypersensitivity symptoms that are unrelated to simple sensitivity, but instead to irreversible pulp inflammation. These complications are related to premature failures that occur within six months, as described by Hickel et al.[16] Two such failures were observed in this study: one at baseline and another at the 6-month recall. Both failures occurred in the experimental group. These two teeth did not show any signs or symptoms of pulp inflammation during the treatment procedures. Many factors could have contributed to the irreversible pulp inflammation, such as the depth of the cavities, dental procedures, and the inherent immune reaction of the pulp to attack.[5] Finally, a small enamel fracture near a restoration in the experimental group occurred after one year. This relative failure, related to the integrity of the tooth, may have happened due to patient characteristics (chewing force, intrinsic properties of the enamel), the material used (adhesive cement failure), or some combination of both. Therefore, as there was no significant difference for any criterion when comparing the two groups at different times ($\alpha = 0.05$; Mann-Whitney test), this failure is believed to have occurred by chance.

It is important to emphasize that a follow-up of 12 months is a short period of time. Little or no differences are expected in short evaluations such as this, when materials are considered to be of good quality. However, it is an initial evaluation and more differences can be expected after a longer follow-up. Therefore, future evaluations are needed to elucidate the long-term performance and determine possible differences between the materials.

CONCLUSION

It can be concluded that indirect composite resin restorations cemented with the self-adhesive resin cement RelyX U100 had an acceptable clinical performance similar to that of restorations cemented with resin cement RelyX ARC after one year.

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REFERENCES

1. Abo-hamar SE, Hiller KA, Jung H, Federlin M, Friedl KH, Schmalz, G. Bond strength of a new universal self-adhesive resin luting cement to dentin and enamel. Clin Oral Investig 2005;9:161-167.
2. Azevedo CGS, De Goes MF, Ambrosano GMB, Chan DCN. 1-Year clinical study of indirect resin composite restorations luted with a self-adhesive resin cement: effect of enamel etching. Braz Dent J 2012;23:97-103.
3. Behr M, Hansmann M, Rosentritt M, Handel G. Marginal adaptation of three self-adhesive resin cements vs. a well-tried adhesive luting agent. Clin Oral Investig 2009;13:459-464.
4. Behr M, Rosentritt M, Regnet T, Lang R, Handel G. Marginal adaptation in dentin of a self-adhesive universal resin cement compared with well-tried systems. Dent Mater 2004;20:191-197.
5. Bjørndal L, Demant S, Dabelsteen S. Depth and activity of carious lesions as indicators for the regenerative potential of dental pulp after intervention. J Endod 2014;40(4 suppl):S76-81.
6. Burke FJ, Crisp RJ, Richter B. A practice-bases evaluation of the handling of a new self-adhesive universal resin luting material. Int Dent J 2006;56: 142-146.
7. Cvar JF, Ryge G. Reprint of criteria for the clinical evaluation of dental restorative materials. 1971. Clin Oral Investig 2005;9:215-232.
8. D'Arcangelo C, Zarow M, De Angelis F, Vadini M, Paolantonio M, Giannoni M, D'Amario M. Five-year retrospective clinical study of indirect composite restorations luted with a light-cured composite in posterior teeth. Clin Oral Investig 2013 May 22. [Epub ahead of print].
9. De Munck J, Vargas M, Van Landuyt K, Hikita K, Lambrechts P, Van Meerbeek B. Bonding of auto-adhesive luting material to enamel and dentin. Dent Mater 2004;20:963-971.
10. Duarte S Jr, Botta AC, Meire M, Sadan A. Microtensile bond strengths and scanning electron microscopic evaluation of self-adhesive and self-etch resin cements to intact and etched enamel. J Prosthet Dent 2008;100:203-210.
11. Frankenberger R, Lohbauer U, Schaible RB, Nikolaenko SA, Naumann M. Luting of ceramic inlay in vitro: Marginal quality of self-etch and etch-and-rinse adhesive versus self-etch cements. Dent Mater 2008;24:185-191.
12. Gerth HUV, Dammaschke T, Züchner H, Schäfer E. Chemical analysis and bonding reaction of RelyX Unicem and Bifix composites: a comparative study. Dent Mater 2006;22:934-941.
13. Goracci C, Cury AH, Cantoro A, Papacchini F, Tay FR, Ferrari M. Microtensile bond strength and interfacial properties of self-etching and self-adhesive resin cements used to lute composite onlays under different seating forces. J Adhes Dent 2006;8:327-335.
14. Hayashi M, Tsuchitani Y, Kawamura Y, Miura M, Takeshige F, Ebisu S. Eight-year clinical evaluation of fired ceramic inlays. Oper Dent 2000;25: 473-481.
15. Heintze SD. Systematic reviews: I. The correlation between laboratory tests on marginal quality and bond strength. II. The correlation between marginal quality and clinical outcome. J Adhes Dent 2007;9(suppl 1): 77-106.
16. Hickel R, Roulet J-F, Bayne S, Heintze SD, Mjör IA,Peter M, Rousson V, Randall R, Schmalz G, Tyas M, Vanherle G. Recommendations for conducting controlled clinical studies of dental restorative materials. J Adhes Dent 2007;9(suppl 1):121-147.
17. Hikita K, Van Meerbeek B, De Munck J, Ikeda T, Van Landuyt K, Maida T, Lambrechts P, Peumans M. Bonding effectiveness of adhesive luting agents to enamel and dentin. Dent Mater 2007;23:71-80.
18. Lange RT, Pfeiffer P. Clinical evaluation of ceramic inlays compared to composite restorations. Oper Dent 2009;34:263-272.
19. Manhart J, Chen HY, Mehl A, Hickel R. Clinical study of indirect composite resin inlays in posterior stress-bearing preparations placed by dental students: results after 6 months and 1, 2, and 3 years. Quintessence Int 2010;41:399-410.
20. Ozakar-Ilday N, Zorba Y ,Yildiz M , Erdem V, Seven N, Demirbuga S. Three-year clinical performance of two indirect composite inlays compared to direct composite restorations. Med Oral Patol Oral Cir Bucal 2013;18:e521-528.
21. Park SH. Comparison of degree of conversion for light-cured and additionally heat-cured composites.J Prosthet Dent 1996;76:613-618.
22. Peumans M, De Munck J, Landuyt K, Poitevin A, Lambrechts P, Van Meerbeek B. Two-year clinical evaluation of a self-adhesive luting agent for ceramic inlay. J Adhes Dent 2010;12:151-161.
23. Peumans M, Voet M, De Munck J, Landuyt KV, Ende AV, Meerbeek BV. Four-year clinical evaluation of a self-adhesive luting agent for ceramic inlays. Clin Oral Investig 2013;17:739-750.
24. Peutzfeldt A, Asmussen E. The effect of postcuring on quantity of remaining double bonds, mechanical properties, and in vitro of two resin composites. J Dent 2000;28:447-452.
25. Pires-de-Souza FC, Garcia LF, Hamida HM, Casemiro LA. Color stability of composites subjected to accelerated aging after curing using either a halogen or a light emitting diode source. Braz Dent J 2007;18:119-123.
26. Radovic I, Monticelli F, Goracci C, Vulicevic ZR, Ferrari M. Self-adhesive resin cements: A literature Review. J Adhes Dent 2008;10:251-258.
27. Schenke F, Federlin M, Hiller K, Moder D, Schmalz G. Controlled, prospective, randomized, clinical evaluation of partial ceramic crowns inserted with RelyX Unicem with or without selective enamel etching. Results after 2 years. Clin Oral Investig 2012;16:451-461.
28. Schenke F, Holler KA, Schmalz G, Federlin M. Marginal integrity of parcial ceramic crowns within dentin with different luting techniques and materials. Oper Dent 2008;33:516-525.
29. Silva GR, Simamoto-Júnior PC, Mota AS, Soares CJ. Mechanical properties of light-curing composites polymerized with different laboratory photocuring units. Dent Mater J 2007;26:217-223.
30. Taschner M, Krämer N, Lohbauer U, Pelka M, Breschi L, Petschelt A, Frankenberger R. Leucite-reinforced glass ceramic inlays luted with self-adhesive resin cement: a 2-year in vivo study. Dent Mater 2012;28: 535-540.
31. Thordrup M, Isidor F, Hörsted-Bindslev P. A 5-year clinical study of indirect and direct resin composite and ceramic inlays. Quintessence Int 2001;32:199-205.
32. Touati B, Aidan N. Second generation laboratory composite resins for indirect restorations. J Esthet Dent 1997;9:108-118.
33. Yang B, Ludwig K, Adelung R, Kern M. Micro-tensile bond strenght of three luting resins to human regional dentin. Dent Mater 2006;22:45-56.

Clinical relevance: After a one-year period of clinical function, the self-adhesive resin cement RelyX U100 showed acceptable clinical behavior when used for the cementation of composite resin inlays and onlays.