

1-Year Clinical Study of Indirect Resin Composite Restorations Luted with a Self-Adhesive Resin Cement: Effect of Enamel Etching

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In vitro studies have recommended enamel-etching before luting indirect restorations with self-adhesive resin cement. However, there is no scientific proof that this procedure has any clinical relevance. Thus, the aim of this study was to evaluate the effect of enamel-etching on the marginal quality of indirect composite resin restorations (inlay/onlay) using the self-adhesive cement RelyX Unicem clicker. Forty-two posterior teeth were selected from 25 patients that presented one or two teeth with large restorations in need of replacement. All teeth were prepared by the same operator and impressed with polyvinylsiloxane material. The composite resin restorations were built over plaster casts using the incremental technique with a LED device for light-curing the increments. The inlays/onlays were cemented according to one of the following protocols: 1. Etched group (ETR) - selective enamel phosphoric-acid etching + RelyX Unicem clicker; 2. Non-etched group (NER) - RelyX Unicem clicker alone. Each surface was light-cured for 60 s. Recalls occurred after 1 week (baseline), 6 and 12 months when the teeth were evaluated according to previously established scores (modified USPHS criteria). The clinical analysis showed little or no visible changes in the marginal quality after 1 year, even though a probe could detect all the restorations margins. Statistical analysis (Fisher's exact test, $p < 0.05$) detected no differences between the groups after 12 months. No restorations failed and no secondary caries were found. Enamel acid etching had no clinical relevance on the marginal quality of indirect composite resin restorations luted with RelyX Unicem clicker after 1 year of follow up.

Key Words: clinical study, indirect restorations, luting cement, marginal quality, self-adhesive.

INTRODUCTION

Contemporary cementation technique using high-flow composite resins (so-called resin cements) is a time-consuming and technique-sensitive procedure. During resin cement polymerization, high internal stresses can be developed causing disruption between the restoration and cavity walls that also can lead to marginal leakage, especially when margins are located in dentin. In the case of inlay/onlay preparations, the presence of peripheral enamel is critical to successful bonding (1).

The clinical success of indirect composite resin restorations has been evaluated by measuring marginal fit and leakage, and correlating these parameters with loss of integrity of the bond to peripheral tooth structure (2).

Loss of this integrity has been associated with formation of secondary caries, post-operative-sensitivity and staining of the tooth/restoration interface (3,4). In spite of this, there is no restoration/luting material combination capable of achieving a complete marginal seal (5).

The newly developed self-adhesive resin cements have been advocated to be applied to freshly prepared tooth surface that has received no surface pre-treatment for luting metal, ceramic or resin composite indirect restorations. One of these cements, RelyX Unicem (3M ESPE, St. Paul, MN, USA), has been shown to provide good marginal sealing of pressed ceramic veneers as well as all-ceramic crowns. This self-adhesive cementing agent has also been shown to achieve *in vitro* dentin adhesion at levels comparable

to those obtained when using conventional resin luting cements and dentin adhesive systems (6-8) although it interacts only superficially with dentin, resulting in lack of hybrid layer or resin tags (9-12). In addition, the *in vitro* tensile bond strength of RelyX Unicem to enamel has been shown to increase significantly when the enamel is acid etched prior to cementation (9-13). However, self-etching systems leave more small marginal defects compared with phosphoric-acid etched enamel (14). This situation has led to the recommendation to etch enamel surfaces with phosphoric acid before cementation with self-adhesive cement. Notwithstanding, tensile bond strength is not correlated to marginal quality, but to the ability of a material to be held in place when mechanical retention is weak or missing (15). In addition, about 82% of prognosis based on laboratory tests did not match the clinical outcome, so *in vitro* studies are unable to predict the performance of the same materials *in vivo* (15).

The literature is scarce on the clinical performance of RelyX Unicem clicker for insertion of composite resin inlay/onlay restorations. Thus, the aim of this present study was to evaluate if the selective enamel phosphoric-acid etching beforehand on placement of indirect resin composite restorations with a self-adhesive resin cement (RelyX Unicem clicker) has any effect on clinical performance after 12 months.

MATERIAL AND METHODS

Approval was granted from the local Ethics Committee (protocol #109/2007) and the study was performed in accordance with the 'Recommendations for conducting controlled clinical studies of dental restorative materials' (16). All selected subjects were properly informed and gave written consent.

Forty-two indirect composite resin restorations (17 mandibular molars, 10 maxillary molars, 4 mandibular premolars, 11 maxillary premolars; two-face inlays = 7, three-face inlays = 12, onlays = 23) were placed in 25 patients (19 female, 6 male; age 22 to 72 years; mean age = 43 years). All of them had to be in good health, have at least 70% full dentition and functional occlusion, have no periodontal disease and keep moderate level of oral hygiene. The teeth were vital (n=39) or not (n=3) with effective antagonist. Seventeen patients received two restorations as follows: one tooth with selective enamel phosphoric-acid etching and one without any pretreatment. The remaining 8 patients received only one restoration in a split-mouth design

(2 conditioned, 6 not conditioned). All subjects were examined by one experienced clinician.

The 3 non-vital teeth were previous filled with composite resin in order to behave biomechanically as vital ones. The cavities were prepared with slightly occlusal divergent walls (5° to 15°), round internal angles and without beveling of the margins. Some weak walls were previously filled as above to avoid excessive wearing of tooth structure during preparation. The cavities did not have any standardized size or geometry since the purpose was only to replace the old or damaged last restorations. All the occlusal, axial, buccal, lingual or palatal margins were in enamel. Regular diamond burs were used for preparation (2135, 3131, 4138; KG Sorensen, Barueri, SP, Brazil) and carbide burs (H375R 012, H375R 018, H379 018; Komet Brasseler, Schaumburg, IL, USA) were used for finishing the cavities. All superficial margins were finished with ultrasonic tips (ref. 6.1107; CVD Vale, São José dos Campos, SP, Brazil). No lining material was applied. Triple-tray impressions were taken with a polyvinylsiloxane material (Express; 3M ESPE) in a single-step technique. The teeth were protected with temporary eugenol-free restorations for 1 week.

The composite resin restorations (Filtek Supreme XT; 3M ESPE) were built over stone dies by the incremental technique using a LED device with power density of 1000 mW/cm² (Flashlite 1401; Discus, Culver City, CA, USA) for light curing the increments (40 s for dentin opacity shades and 20 s for all other shades - manufacturer's instructions). The fitting accuracy of the restorations was visually inspected on a second plaster cast set in a semi-adjustable articulator. Proximal and occlusal contact points were checked. Finishing and polishing were done with SofLex discs (3M ESPE), finishing resin brushes (Jiffy Brushes; Ultradent, South Jordan, UT, USA) and felt discs with diamond pastes (Poli I, Poli II; Kota Imports, São Paulo, SP, Brazil). The internal surface of the restorations was abraded with 50 µm aluminum oxide (60 psi, 10 s) cleaned with 35% phosphoric acid (15 s), washed with copious water (15 s) and cleaned in ultrasonic device (2 min).

After removing the temporary restorations, the cavities were cleaned with pumice slurry and inlay/onlay fitting accuracy was checked with dental mirror, clinical probe, dental floss and a 12-µm-thick carbon paper (ref. BK 1028; Bausch, Koln, Germany). Under rubber dam isolation, the indirect restorations were cemented according to one of the following protocols: 1. Etched

group (ETR) - selective enamel phosphoric-acid etching + RelyX Unicem clicker; 2. Non-etched group (NER) - RelyX Unicem clicker alone (Fig. 1).

Two or three clicks of cement were dispensed over a paper pad and hand mixed for 20 s with a plastic spatula. The cement was immediately applied at the internal surface of the restoration and inserted into the prepared cavity. The restorations were kept under strong finger-pressure for 2 min while removing excess cement. Each surface was light-cured for 60 s (60-240 s total). If necessary, occlusal contacts were adjusted and polished again. The overall restoration fitting was checked and the marginal cement layer was finished with diamond strips (Cosmedent, Chicago, IL, USA) and SofLex discs (3M ESPE).

Recalls were done at 1 week (baseline - not shown), 6 months (not shown) and 12 months after insertion. All the restorations were evaluated according to the modified USPHS (United States Public Health Service) criteria (16) (Table 1), following the 'Recommendations for conducting controlled clinical studies of dental restorative materials' (16). Eight parameters were asserted and each one was previously detailed and classified into 3 categories for assessment: *Aesthetic*: Marginal staining (MS) and Subjective satisfaction (SS); *Functional*: Marginal adaptation (MA), Marginal wear in occlusal contact area (WOC) and Marginal wear in free contact area (WFC); *Biological*: Sensitivity (SE), Tooth integrity (TI) and Secondary caries (SC).

All teeth were identified as a number by one independent examiner. The recall assessments were performed by the same clinician in a blind examination. Data were subjected to statistical analysis. As non-

normal data distribution, was observed in both groups, the non-parametric Fisher's exact test was used with $p < 0.05$ as level of significance.

RESULTS

Twenty-five subjects (100%) attended the 12-month recall. Twenty-three restorations from NER group and 19 restorations from ETR group could be reassessed. The overall clinical performance is shown in Table 2. All subjects were satisfied with their restorations and all restorations were in the range of clinically acceptable rating. More than 99% of the scores were considered clinically excellent (Alpha 1) or good (Alpha 2) (Fig. 2). Only 3 scores (0.9%) were classified as clinically sufficient (Bravo): 2 from ETR group (MS=1, Fig. 3; SE=1) and 1 from NER group (SE) (Table 2).

No failure or secondary caries was recorded. There was no statistically significant difference between the groups for any parameter after 12 months.

DISCUSSION

In this small-scale *in vivo* study, the clinical performance of 42 indirect composite resin restorations luted with the self-adhesive resin cement RelyX Unicem clicker were assessed after 12 months of clinical service. Though it is a short period of time for evaluating indirect

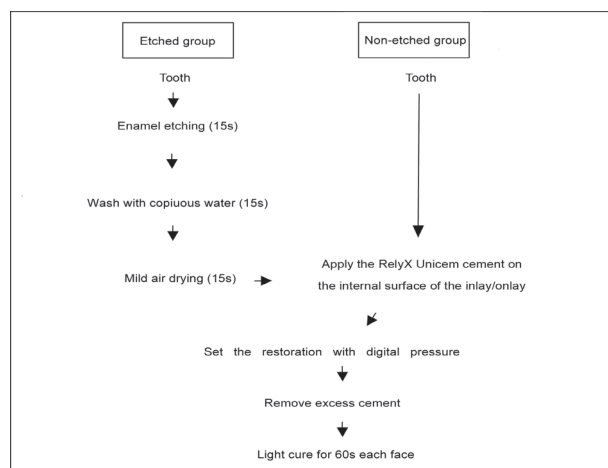


Figure 1. Treatment procedures.

Table 1. Modified USPHS criteria.

Modified criteria	Description	Original criteria
Clinically excellent (Alpha 1)	Very good, perfect	Alpha
Clinically good (Alpha 2)	Slight deviations from ideal performance, possible correction without damage	Alpha
Clinically sufficient (Bravo)	Minor shortcomings, no unacceptable effects, but not adjustable without damage	Bravo
Clinically unsatisfactory (Charlie*)	Insufficient, failure	Charlie/Delta

*The procedure had failed, irrespective of being repairable or not.

restorations, it was set strict parameters to rank each restoration change. In unison with the USPHS criteria and 'Recommendations for conducting controlled clinical studies of dental restorative materials' (16), the best score - Alpha - was divided in two scores: 1- clinically excellent (Alpha 1) and 2- clinically good (Alpha 2), so that every minimal change could be pointed out. Bravo (3) was kept as original criterion (clinically satisfactory) and the scores Charlie and Delta (4) were attached meaning failure (Table 1).

Clinical analysis recorded little or no visible changes in the marginal quality after 12 months, even though all the restorations margins could be detected by a probe, resembling small cement wear. Long-term marginal deterioration is a real and universal fact, which

the most frequent characteristics are underfilling and marginal staining (17-19). The longitudinal marginal deterioration presents three sequential stages patterns: 1st: the initial rapid progress, with wear of resin cement (6 to 21 months); 2nd: the marginal deterioration continues but in a slow down speed (21 to 72 months), and 3rd: rapid deterioration again, with damages in both structures (tooth and restoration) (19). The wide variation among the results reflects the variety of conditions by individual restorations: the amount of excess resin composite cement, marginal widths of resin cement and occlusal forces that might differ in each restoration. In a previous study (20), the substance loss within the luting gap over a six-year period *in vivo* was evaluated. Replicas from 39 ceramic inlays/onlays restored teeth

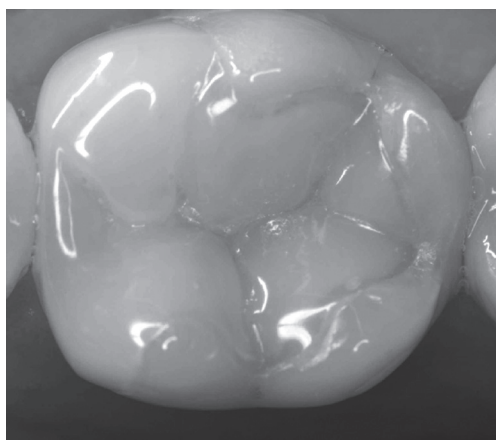


Figure 2. Tooth/restoration scored 100% Alpha 1 (clinically excellent).

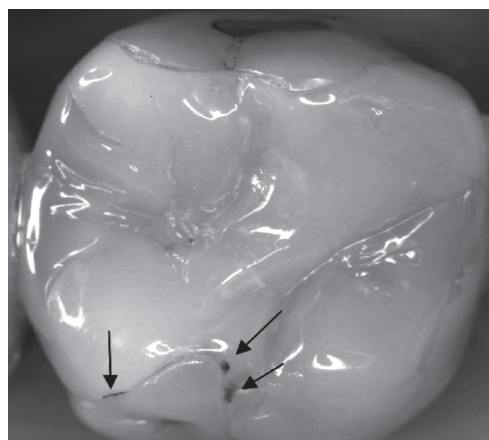


Figure 3. Tooth/restoration scored Bravo (clinically sufficient) for marginal staining parameter.

Table 2. Results of the clinical evaluation (%) at 12-month recall.

Clinical evaluation	ETR			NER			Fisher's exact test
	%Alpha 1	%Alpha 2	%Bravo	%Alpha 1	%Alpha 2	%Bravo	
MS	73.7	21.0	5.3	87.0	13.0	0.0	p=0.4269
SS	100.0	0.0	0.0	100.0	0.0	0.0	p=1.0000
MA	84.2	15.8	0.0	69.6	30.4	0.0	p=0.3049
WOC	84.2	15.8	0.0	91.3	8.7	0.0	p=0.6440
WFC	94.8	5.2	0.0	100.0	0.0	0.0	p=0.4524
SE	87.5	6.25	6.25	87.0	8.7	4.3	p=1.0000
TI	84.2	15.8	0.0	91.3	8.7	0.0	p=0.6440
SC	100.0	0.0	0.0	100.0	0.0	0.0	p=1.0000

ETR: etched group; NER: non-etched group; MS: marginal staining; SS: subjective satisfaction; MA: marginal adaptation; WOC: marginal wear in occlusion contact area; WFC: marginal wear in free contact area; SE: sensitivity; TI: tooth integrity; SC: secondary caries.

were analyzed by scanning electron microscopy. They found that after 6 months, all the restorations had shown marginal erosion, which had increased over time, but it was more pronounced at the first 12 months. Another research (21) also found that marginal underfilling had been the most frequent event in 32 ceramic inlays *in vivo*. Moreover, those authors showed that, for cements with large particle size and great superficial roughness, this wear was higher (RelyX Unicem has average particle size of 9 μm - 90% < 9.5 μm). Actually, this study also found that marginal occlusal contact areas had slightly worst appearance than free contact ones, since the rate of Alpha 1 score was higher for WFC than that for WOC for both groups (ETR group: 94.8% for WFC, 84.2% for WOC; and NER group = 100.0% for WFC, 91.3% for WOC) (Table 2). Occlusal loads can accelerate marginal deterioration (19). In fact, the cement layer is a weak link at indirect restorations and, if possible, the cavosurface angle should be out of occlusal contact areas. However, in this study, it was desirable to preserve dental structure; thus, sometimes marginal layers were under occlusal contact areas. Meanwhile, even though in free contact areas, the wear of the cement is a regular find (17-19). This event is thought to be due to lower wear resistance of the luting composite resin than that of the inlay/onlay material, as proven by *in vitro* tests too (17). On the other hand, in the present study, the underfilled margins had no influence on the performance and the longevity of the restorations, as reported elsewhere (17,20,21).

Although without statistical relevance, marginal staining was the second more frequent find for both groups among the overall analyzed clinical parameters (Table 2). This event corroborates other reports in the literature (17-19). The increased wear of resin cements, when compared to restorative composite resins and the higher inorganic particles' size enhance the superficial roughness of the cement layer (22). It is supposed that rougher surfaces might catch more residual substances and, depending on how colored is the subject diet or habits, they can rapidly stain these areas. It can be also be assumed that some stained areas (Fig. 3) could result from pigments gathered into porosity due to entrapped voids into the cement material. Voids are also observed in cements that use automatic mixing, but air bubble inclusion is more likely to appear during hand mixing the cement. Capsulated delivery may improve the homogeneity and reduce the inclusion of voids. However, it must be emphasize that self-adhesive cements need some seating pressure during the initial

self-cure period (11). This procedure has been related to enhance interfacial strength and adaptation besides reducing the cement thickness and porosity. In this study, the indirect restorations were kept under strong finger pressure during the initial 2 min of self-cure. It can be speculated that the width of the cement layer could also influence this finding: large widths > less local pressure > less cement flow > less bubble air eject.

Clinically, only 1 tooth from ETR group received Bravo score (3 - clinically satisfactory = "moderate surface staining, also present on other teeth, not aesthetically unacceptable"), whereas all others achieved Alpha 1 and Alpha 2 ratings. Stained areas have been frequently associated with secondary caries. Notwithstanding, marginal staining is not directly related with bacterial presence (3,17,19) and only gaps greater than 400 μm at the margins resulted in bacterial growing on the subjacent dentin (4). Moreover, secondary caries rarely appears at occlusal areas and its developing is more related to subject bacterial flora and hygiene habits than marginal defects (3). Thus, although just one tooth showed slightly marginal staining, no secondary caries were found, in line with another studies (3,4).

Even though without statistical difference, the rates of Alpha 1 score for WOC in ETR group was slightly lower than NER (84.2% *versus* 91.3%) (Table 2). It can be speculated that the enamel-etching procedure could have weakened the enamel periphery since the high viscosity of the cement could not have infiltrated the enamel microporosity created, leading to unfilled spaces. It was found that the rate of Alpha 1 ("complete integrity") for 'tooth integrity' clinical parameter (TI) for NER group was further higher. Thus, it can be proposed that the self-adhesive cement was able to bond and to bear the marginal enamel even without acid etching, avoiding failure under repeated stress as well as growing enamel cracks. This fact can also be correlated with those of a previous study (23) in which enamel conditioning with phosphoric acid before a self-etching system negatively affected the marginal integrity from indirect restorations after loading. It was found more microscopic enamel cracks when the non-beveled enamel was phosphoric acid etched before the cementation. The authors suggested that it depends on how enamel prisms are cut, i.e., transversally or longitudinally, shearing off of the subsurface enamel prisms together with cohesive fractures within enamel. This means that polymerization shrinkage of the resin cement is still a critical property and could be responsible for this event.

Conversely, the score percentage of Alpha 2 (“small marginal fractures/defects removable by polishing”) for the ‘marginal adaptation’ clinical parameter in NER group was almost twice than that of ETR group, 30.4% and 15.8% respectively (Table 2). This finding can be compared with the self-etching systems performance where enamel margins without phosphoric-acid conditioning might show more small defects than etched ones (14). These marginal imperfections range from dull surface, minor staining, hairline cracks to wear of the cement. Polishing or no required treatment could remove all marginal imperfections. According to several *in vitro* studies that evaluated enamel bond strength of self-adhesive cements (9-13), their values are significantly lower than those of resin luting cements in enamel. In addition, it has been asserted that etch-and-rinse adhesive systems are still being the most reliable to maintain a durable bond in enamel, even after mechanical and thermal cycling (14). It was found that when enamel was phosphoric-acid etched prior to the luting procedure with RelyX Unicem, the bond strength values were similar to those from other resin cements (9,13).

According to Heitze et al. (15), bond strength is important when mechanical retention is weak or missing. Thus, it was supposed that marginal ending of the composite resin restorations could be thinner, weakening these areas of the restorations and consequently making them totally dependent on the underlying cement for bearing loads. Perhaps the excess of cement that flowed over the ungrounded and non-etched enamel placed immediately out of the cavosurface angle of the cavity could not be strongly held there. As it leached, this fragile part of the restoration could have fractured, leaving more imperfections at margins. Moreover, it can be speculated that if the non-etched enamel allowed more dislodgement of cement in the meanwhile it could also result in more evident tooth margins. Thus, this study partially supports those studies that showed higher enamel bond strengths for self-adhesive cements when the enamel was previously etched (9,12,13). This event might be clearer when epoxy resin replicas could be analyzed by scanning electron microscopy. Otherwise, these marginal small defects did not interfere the clinical acceptance of the restorations. This finding is in accordance with other *in vivo* reports (24,25) with results after 2 years that also showed that these marginal changes had no influence at the restorative clinical longevity (2). Perhaps, longer experimental time could enlighten this outcome.

The low rate of hypersensitivity observed in

this study can be attributed to the absence of dentin phosphoric acid etching step during the self-adhesive luting procedure and the high capacity of RelyX Unicem to wet the dentin surface, providing a good dentinal seal (6,11). It was speculated that this outcome could be due to: 1) the superficial chemical interaction of RelyX Unicem with dental hard tissues upon maintenance of smear layer and avoiding long resin tags (9,13), so that no uncured monomers or leached resin components could get in contact with the pulp; 2) the low solubility of RelyX Unicem; 3) the self neutralizing mechanism during the setting reaction, as claimed by the manufacturer.

It has been reported that, for tooth-colored inlays, postoperative hypersensitivity was due to incompletely sealed dentin or detachment from restoration/luting composite. Thus, it might be speculated that, besides all these characteristics, RelyX Unicem was able to seal dentin tissue and keep internal and external restorations margins sealed avoiding leakage and fluid movement through dentin tubules. We believe that all of these factors do contribute to the low hypersensitivity rate found in this study, but the dentin sealing ability of RelyX Unicem is the key factor. As shown in Table 2, one tooth from ETR group and one from NER group received Bravo score (3 - clinically satisfactory = “hypersensitivity for extreme temperatures - hot/freeze”) for the ‘sensitivity’ clinical parameter. Actually, all subjects reported no sensitivity at baseline. At the time of the 12-month evaluation, one subject was pregnant (5.5 months) and she reported that the sensitivity had appeared recently. She was instructed to clean her teeth more frequently and the sensitivity disappeared and after 3 weeks. The other tooth, from a middle-aged male, exhibited some gingival recession. The patient reported that the sensitivity was cyclical and after a cold/hot pulp sensitivity test, it was concluded that the pain was from the exposed cervical dentin. He was instructed to gently brush his teeth.

In vitro and *in vivo* studies have shown that up to now, no restorative procedures and materials are able to achieve perfectly sealed margins (5,23), and that the majority of direct and indirect restorations have been in service for long time without clinical complications (2). In addition, the percentage of ‘continuous margins’ as the only parameter for clinical success is too rigid and is not supported by clinical studies (1). In the present study, all indirect composite resin restorations luted with the self-adhesive resin cement RelyX Unicem were clinically acceptable after 12 months of clinical service irrespective of previous enamel phosphoric acid etching.

RESUMO

Estudos *in vitro* têm recomendado condicionamento ácido do esmalte antes da cimentação de restaurações indiretas com cimento resinoso autoadesivo. Entretanto, não há nenhuma prova científica de que este procedimento tenha relevância clínica. Assim, o objetivo deste estudo foi avaliar o efeito do condicionamento ácido do esmalte na qualidade marginal de restaurações indiretas de resina composta (*inlay/onlay*) usando o cimento autoadesivo RelyX Unicem *clicker*. Quarenta e dois dentes posteriores foram selecionados de 25 pacientes com 1 ou 2 restaurações amplas com necessidade de substituição. Todos os dentes foram preparados pelo mesmo operador e impressos com material à base de polivilsiloxano. As restaurações de resina composta foram construídas sobre troquel de gesso usando a técnica de colocação em camadas e polimerizadas usando aparelho de luz emitida por diodo (LED). Os *inlays/onlays* foram cimentados de acordo com um dos protocolos: 1. Grupo condicionado (ETR)- condicionamento seletivo do esmalte com ácido fosfórico + cimentação com RelyX Unicem *clicker*; 2. Grupo não condicionado (NER)- cimentação com RelyX Unicem *clicker* somente. Cada superfície foi fotoativada por 60 s. Os retornos para acompanhamento foram feitos após 1 semana (*baseline*), 6 e 12 meses onde os dentes foram avaliados de acordo com critérios previamente estabelecidos (USPHS Modificado). A análise clínica mostrou pouca ou nenhuma alteração visível na qualidade marginal após 1 ano, porém uma sonda clínica pode detectar todas as margens restauradoras. A análise estatística (Teste exato de Fisher, $p < 0,05$) não detectou diferença entre os grupos após 12 meses. Nenhuma restauração falhou e nenhuma cárie secundária foi encontrada. O condicionamento ácido do esmalte não teve relevância clínica na qualidade marginal de restaurações indiretas de resina composta cimentadas com RelyX Unicem *clicker* após 1 ano de acompanhamento.

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