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A 2-year Randomized Clinical Trial of Three Bonding Techniques in Non-Carious Cervical Lesions

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Abstract: The aim of this randomized controlled clinical trial was to compare the 2-year clinical performance of resin composite restorations placed at non-caries cervical lesions (NCCL) with one-step self-etch, total-etch, and selective enamel etch & self-etch adhesive techniques. Thirty-two patients received three resin composite restorations each at NCCLs (Tetric EvoCeram/Ivoclar/Vivadent), bonded with a total-etch adhesive agent (ExciTE F/Ivoclar/Vivadent) and a self-etch (AdheSE One F/Ivoclar/Vivadent) without and with selective enamel etching. All restorations were evaluated by two examiners at baseline, 6-, 12-, 18- and 24-months post-operation regarding retention, caries occurrence, marginal adaptation, and marginal staining. A logistic regression analysis with generalized estimating equations was used. After 2 years, the retention rate was 86,8% for total-etch, 92.26% for self-etch, and 93.63% for selective enamel etching & self-etch. No caries was detected during all the restorations. Concerning marginal adaptation, the clinically perfect restorations were 26.9% for the total-etch technique, 16% for self-etch, and 25,9% for selective enamel etch & self-etch. All three adhesive strategies provided restorations with no significant differences in the retention rate and the marginal adaptation, whereas the total etch yielded better performance for marginal staining. All the restorations were assessed as clinically acceptable after 2 years.

Keywords: self-etch; total-etch; selective enamel etching; retention; caries; marginal adaptation; marginal staining; non-caries cervical lesions

1. Introduction

One-step self-etch adhesives are the latest evolution in adhesive systems for resin composite restorations. The rationale for introducing self-etch adhesives was to simplify and accelerate the application technique. By integrating the etching step into the bonding procedure, it was presumed that all the potential over-etching disadvantages [1] and humidity-related limitations [1] observed with the etch-and-rinse (total-etch) adhesives could be surpassed. Moreover, the retention of the smear layer could prevent tooth sensitivity [2].

Unfortunately, not all self-etch adhesives proved effective in etching enamel[3]. Thus, selective enamel etching with phosphoric acid was proposed in conjunction with the use of self-etch adhesives [3–6]. In addition, many studies showed inferior bonding performance and durability of one-step self-etch agents compared to etch-and-rinse and two-step self-etch adhesives [7,8].

Laboratory testing of bonding systems has already provided sufficient data about their features under vitro conditions [7]. Nevertheless, since the oral environment differs considerably,

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experimental testing cannot always project clinical performance in a predictable manner. Thus, clinical trials are needed to identify the behavior of the adhesive systems. As a function of time, further outcomes were achieved by more clinical studies conducted [1]. However, it is notable that remarkable differences regarding the findings are revealed among the investigations, even in trials that evaluate the same agents [9–13].

Non-caries cervical lesions (NCCL) have been extensively used in clinical testing of bonding systems due to the significant advantages they offer [9–14]. Firstly, a great number of NCCLs commonly exist in a mouth, providing sites for different restoration techniques, which can be subsequently evaluated under similar conditions. Secondly, their shape does not provide any undercuts, which could favor any mechanical retention of the restoration. Also, at NCCL, the enamel margins are usually limited in length and are thin compared to other types of restorations, so the adhesion reflects mostly the ability to adhere to dentine, which is considered the weak part regarding the bonding [15].

The aim of this randomized controlled clinical trial was to compare the 2-year clinical performance of resin composite restorations placed at NCCLs with one-step self-etch, total-etch, and selective enamel etch & self-etch adhesive techniques. The null hypothesis tested was that there is no difference among these three bonding techniques concerning retention, caries occurrence, marginal adaptation and marginal staining.

2. Materials and Methods

The clinical trial was a single-center, randomized, controlled, and parallel-designed study with patients' and clinical evaluators' blinding. Prior to patient enrollment, the Committee for Research and Ethics of the School of Dentistry, National and Kapodistrian University of Athens, Athens, Greece, approved the research protocol (Register No118). The clinical trial conforms to the guidance set by Clinical Trials.gov (NCT04565938).

Inclusion criteria for patients to participate in the study were: (a) 19 years or older, (b) good general health, (c) available for follow-up visits, and (d) have at least 20 teeth. The exclusion criteria were: (a) rampant uncontrolled caries/high caries activity, (b) advanced untreated periodontal disease or receiving periodontal treatment, (c) >2 cigarette packs/day or equivalent chewing tobacco, (d) systemic or local disorders that contra-indicate dental procedures included in this study, (e) evidence of xerostomia and, (f) evidence of severe bruxism, clenching or TMD.

The selection pool consisted of patients receiving dental treatment in the postgraduate clinic of Restorative Dentistry. Two calibrated Operative Dentistry residents selected 32 participants who met the inclusion criteria. Before treatment, written informed consent was obtained from all participants.

Patients, irrespective of age and gender, had at least three NCCLs on incisors and/or canines and/or premolars of the upper or lower jaw. Each lesion was located at the cervical third of the buccal surface of the tooth, either at the same level or above the gums, with the cervical wall placed on dentin, not extending on adjacent surfaces and not exceeding 5mm in length, 3mm in height and 1.5mm in depth. A total of ninety-six lesions were eventually employed in thirty-two patients.

Each patient answered questions relative to his/her age, the frequency of tooth brushing and dental visits. In addition, the number of teeth with abraded non-carious cervical surfaces was recorded.

The restorations were performed by a single experienced dentist. All three lesions per patient were restored with Tetric EvoCeram (Ivoclar/Vivadent, AG, Shaan, Lichtenstein) (Table 1) following one of the subsequent three adhesive procedures for each tooth, in a statistical random order, using randomization tables. The first randomly selected method was used to restore the tooth with the lowest tooth number (according to the FDI system), and the second method was used for the tooth with the second lowest number, and the third one with the highest.

Table 1. Materials used.

Material	Company	Type	Composition	Instructions

 doi:10.20944/preprints202404.1636.v1

AdheSE One F	IvoclarVivadent, Schaan, Liechtenstein	One step, self-etch	Dimethacrylate, phosphonic acid acrylate, initiators and stabilizers in an aqueous solution HEMA, dimethacrylate, silicon dioxide, initiators and stabilizers	Brush onto the surface for >30s; disperse excess with a strong stream of air; light cure for 10s.
ExciTE F	IvoclarVivadent, Schaan, Liechtenstein	One step, total-etch	HEMA, dimethacrylates, phosphonic acid acrylate, highly dispersed silicon dioxide, initiators and stabilizers in an alcohol solution	Saturate enamel and dentine with a generous amount of the agent using the applicator; agitate the adhesive onto dentin surface for at least 10s with a gentle stream; light cure for 10s
Tetric EvoCeram	IvoclarVivadent, Schaan, Liechtenstein		75-76% w, Barium glass, ytterbium trifluoride, mixed oxide, prepolymer (82-83%) 17-18% w organic matrix	
N-etch	IvoclarVivadent, Schaan, Liechtenstein		37% phosphoric acid	

All the cavities restored required mechanical removal of sclerotic dentin with a round diamond bur and enamel beveling (0,5mm wide). Then, each of the three teeth per patient received one of the three adhesive procedures tested. The materials used and the application procedure per adhesive agent are presented in Table 1.

Method A: enamel was etched with 37% phosphoric acid for 30s and dentin for 15s, ExciTE F adhesive agent was applied and photocured with 800mW/cm² light intensity (Cure TC-01, Spring Health Products, Inc, Norristown, PA, USA), resin composite Tetric EvoCeram was placed, a transparent cervical matrix (Kerr-Hawe, Orange, CA, USA) covered its surface, the resin composite was photopolymerized for 40s and finishing/polishing was followed with diamond finishing burs, polishing disks and silicone polishers.

Method B: enamel etching was not performed, AdheSE One F adhesive agent was applied and the next clinical steps were the same as in method A.

Method C: enamel was etched with N-etch for 30s, then AdheSE One F adhesive agent was applied and the next clinical steps were the same as in method A.

Two experienced and calibrated examiners performed the evaluation. Before starting the evaluation, an intra-examiner and inter-examiner agreement of at least 85% was necessary. These examiners were not involved with the restoration placement, and therefore, they were blinded relative to the group assignment. All restorations were evaluated at baseline, 6-, 12-, 18—and 24—months post-operation, based on the criteria introduced by Hickel et al. 2010 [16].

The parameters evaluated were retention of the restoration, occurrence of caries, marginal adaptation and marginal staining. Retention and occurrence of caries along the restoration margins were scored as Yes or No. The criteria marginal adaptation and staining were graded from 1 to 5 according to the description suggested by Hickel et al [16].

Statistical Analysis

Absolute (number of observations) and relative (percentage ratios) frequencies were used to describe the qualitative characteristics of the present study. The description of the quantitative characteristics was based on the calculation of the interquartile range. It is stated that the statistical

 doi:10.20944/preprints202404.1636.v1

significance in the cases where there was more than one observation was based on the data of an observation of each individual, which was selected randomly[17]. This was done as there is expected to be a correlation between the repeated observations for the same person, and thus, the basic condition of the independence of the observations does not apply. However, the calculation of the other statistical significances was based on appropriate models which consider the correlation between the observations of the same individual.

A logistic regression analysis with generalized estimating equations was used to account for the clustered data (three restorations per patient). Cohen's kappa statistic was used to test inter-examiner agreement for each of the four evaluated parameters. Estimates from appropriate random effects and logistic regression models were used to capture the likelihood of course of clinical features assessed over time (random effects logistic regression). To calculate the respective 95% confidence intervals (95% CI), it was necessary to calculate the standard errors (SE) of the estimates based on the multivariate delta method.

Also, a multifactorial analysis was performed. The variables time, bonding technique, age, gender, frequency of brushing, visit to the dentist, and number of teeth with abraded cervical surfaces were included in the final models regardless of the degree of statistical significance. The level of significance was set at $P<0.05$. Based on the models mentioned, the effect of the restorative technique on the probability of the course of each clinical criterion over time was estimated, which was corrected for the possible effects of other potential confounders.

3. Results

The majority of thirty-two patients were women (59.4%) and the average age of the patients was 59.5 years. The recall rate at 6 months was 100% whereas after 24 months (overall recall rate) was 87.5%. The descriptive statistics of patient-related parameters are presented in Table 2. No statistically significant differences were detected for the characteristics of the patients in relation to their gender.

Table 2. Descriptive statistics of patient-related parameters.

	Male N(%)	Female N(%)	Total N (%)	p-value*
Brushing frequency				
> twice a day	9 (69.2)	16 (84.2)	25 (78.1)	0.386
Once a day	3 (23.1)	3 (15.8)	6 (18.8)	
2-3 times per week	1 (7.7)	0 (0.0)	1 (3.1)	
Frequency of dental visits				
1-2 times per year	2 (15.4)	7 (36.8)	9 (28.1)	0.185
Whenever a problem exists	11 (84.6)	12 (63.2)	23 (71.9)	
	Mean	Mean	Mean	p-value**
Age	57	60	59.5	0.577
Number of teeth with cervical abraded surfaces	11	11	11	0.513

* Chi square; ** Mann-Whitney.

No statistically significant differences were revealed among the three bonding techniques in terms of retention rates for all the recalls (Table 3).

Table 3. Retention rates at baseline, 6-, 12-, 18- and 24-months post-operation.

	Method A n (%)	Method B n (%)	Method C n(%)	p value*
baseline				

 doi:10.20944/preprints202404.1636.v1

Yes	32 (100)	32 (100)	32 (100)	
No	0 (0.0)	0 (0.0)	0 (0.0)	
6 months				
Yes	32 (100)	31 (100)	31 (96.9)	0.37
No	0 (0.0)	0 (0.0)	1 (3.1)	
12 months				
Yes	29 (96.7)	28 (100)	29 (100)	0.382
No	1 (3.3)	0 (0.0)	0 (0.0)	
18 months				
Yes	28 (96.6)	27 (96.4)	28 (100)	0.604
No	1 (3.4)	1 (3.6)	0 (0.0)	
24 months				
Yes	26 (96.3)	25 (96.2)	27 (100)	0.593
No	1 (3.7)	1 (3.8)	0 (0.0)	

*Chi-square.

No caries was observed at any restoration and evaluation time. Thus, the p-value column remains blank (Table 4).

Table 4. Caries occurrence at baseline, 6-, 12-, 18- and 24-months post-operation.

	Method A n(%)	**Method A n (%)**	**Method C n (%)**	**p value***
baseline				-
No	32 (100)	32 (100)	32 (100)	
6 months				-
No	32 (100.0)	31 (100.0)	31 (100.0)	
12 months				-
No	29 (100.0)	28 (100.0)	29 (100.0)	
18 months				-
No	28 (100.0)	27 (100.0)	28 (100.0)	
24 months				-
No	26 (100.0)	25 (100.0)	27 (100.0)	

*Chi-square.

Statistical analysis proved no significant differences between the bonding methods for all follow-up times and grades regarding marginal adaptation (Table 5).

Table 5. Marginal adaptation at baseline, 6-, 12-, 18- and 24-months post-operation.

	Method A n (%)	**Method B n (%)**	**Method C n (%)**	**p value***
(grades 1-5) **baseline**				0.77
(1) Perfect	31 (96.9)	31 (96.9)	30 (93.8)	
(2) Marginal gap < 150 µm	1 (3.1)	1 (3.1)	2 (6.3)	
6 months				0.448
(1) Perfect	22 (68.8)	16 (51.6)	20 (64.5)	
(2) Marginal gap < 150 µm	10 (31.3)	14 (45.2)	11 (35.5)	

 doi:10.20944/preprints202404.1636.v1

(3) Marginal gap < 250 μm	0 (0.0)	1 (3.2)	0 (0.0)	
12 months				
(1) Perfect	13 (44.8)	11 (39.3)	13 (44.8)	0.695
(2) Marginal gap < 150 μm	16 (55.2)	16 (57.1)	16 (55.2)	
(3) Marginal gap < 250 μm	0 (0.0)	1 (3.6)	0 (0.0)	
18 months				
(1) Perfect	9 (32.1)	6 (22.2)	10 (35.7)	0.532
(2) Marginal gap < 150 μm	19 (67.9)	20 (74.1)	18 (64.3)	
(3) Marginal gap < 250 μm	0 (0.0)	1 (3.7)	0 (0.0)	
24 months				
(1) Perfect	7 (26.9)	4 (16.0)	7 (25.9)	0.528
(2) Marginal gap < 150 μm	18 (69.2)	20 (80.0)	20 (74.1)	
(3) Marginal gap < 250 μm	0 (3.8)	1 (4.0)	0 (0.0)	

*Chi-square.

No statistically significant differences were detected among the bonding methods for all follow-up times and grades concerning the marginal staining (Table 6).

Table 6. Marginal adaptation at baseline, 6-, 12-, 18- and 24-months post-operation.

	Method A n (%)	**Method B n (%)**	**Method C n(%)**	**p value***
(grades 1-5) baseline				
(1) No	32 (100.0)	32 (100.0)	32 (100.0)	-
6 months				
(1) No	31 (96.9)	29 (93.5)	31 (100.0)	0.352
(2) Minor	1 (3.1)	2 (6.5)	0 (0.0)	
12 months				
(1) No	29 (100.0)	25 (89.3)	28 (96.6)	0.147
(2) Minor	0 (0.0)	3 (10.7)	1 (3.4)	
18 months				
(1) No	28 (100.0)	24 (88.9)	24 (85.7)	0.252
(2) Minor	0 (0.0)	3 (11.1)	3 (10.7)	
(3) Moderate	0 (0.0)	0 (0.0)	1 (3.6)	
24 months				
(1) No	26 (100.0)	19 (76.0)	21 (77.8)	0.067
(2) Minor	0 (0.0)	6 (24.0)	5 (18.5)	
(3) Moderate	0 (0.0)	0 (0.0)	1 (3.7)	

*Chi-square.

Regarding the probability of correlation of the perfect marginal adaptation, in all observation times, with the parameters of time, age, gender, bonding method, frequency of brushing, visit to the dentist, number of teeth with abraded cervical surfaces, as independents, only time had a statistically significant effect. The probability of a perfect marginal adaptation decreased, and the relative decrease was estimated to 17.9% per month (p-value <0.001).

 doi:10.20944/preprints202404.1636.v1

As far as marginal staining, over time, the probability of absence of marginal staining decreased and the relative decrease was estimated to 11.8% per month (p-value <0.001). Reduced probability of absence of marginal staining by 88.9% (relative difference) compared to the total-etch one (p-value <0.001) was calculated with self-etch method. Accordingly, the technique with selective enamel etch&self-etch had a reduced chance of no straining by 84.5% (relative difference) compared to the total-etch one (p-value <0.001).

4. Discussion

The research and development of dental adhesives has mostly focused on making the clinical procedure more user-friendly by reducing the number of bottles and/or steps of application. Clinicians certainly prefer less complicated and more versatile adhesive materials. However, there is a trade-off between the simplification of dental adhesives and clinical outcomes [7]. The current study investigated the clinical performance of a self-etch, a total-etch, and a selective enamel etch bonding technique employed for restoration of non-caries cervical cavities after 24 months of oral function.

32 patients enrolled in the trial with a mean age of 59.5 years and the majority of whom were women. At 6 months, the re-examination rate was 100%, and at 24-month reached 87.5%. The reasons for drop-off were the inability of two patients to participate in the 12-, 18- and 24-month reviews for serious health reasons, of one patient at 18- and 24-month due to immigration and of one patient at 24-month due to personal problems.

Apart from the favorable sample size and hence power of the study, this clinical trial was adequately randomized and exhibited a double-blinded evaluation. A single resin composite material was used with all bonding procedures to rule out the composite-related influence of the adhesives on the performance of the restorations.

Until 2007, the most widely used system for clinical evaluation of restorations was the USPHS (United States Public Health Service) [18,19]. In 2007, the FDI World Dental Federation approved a new system of clinical criteria due to the low sensitivity of USPHS criteria in short-term clinical trials. From 2007 until today, this system has undergone changes and improvements, and the last one, published in 2010, has been used in the present clinical study [16,20].

The null hypothesis of the study was partially rejected. According to our findings, the three bonding techniques provided high retention rates, ranging between 96,6% to 100% at the 18-month assessment. These values fall into the American Dental Association (ADA) requirement for full acceptance in clinical use, which must be higher than 90% [21]. Concerning the retention rates after 24 months of oral service, an average of 9.1% for the three bonding methods was achieved. The value is close to 10%, which has been reported in a meta-analysis study for 3 years of observation time [22].

Over the last two decades, many randomized clinical studies, systematic reviews and meta-analysis investigations have been conducted, to determine the percentage of loss of resin composite restorations performed on non-caries cervical substrates [15,24–26]. However, the absence of standardization in clinical trial design leads to an extremely wide range of reported rates. Therefore, the outcomes related to the comparative assessment of different categories of adhesive systems tested under the same study may be considered as a more reliable evaluation approach.

The results of the present clinical study did not show any statistically difference in terms of retention among the restorations placed with the self-etch, total-etch, and selective enamel etch & self-etch bonding methods (86.8%, 92.26% and 93.63%, respectively). Under this consideration, we can state that the type of the bonding system does not influence the retention performance of the restorations in a mid-term period of 24 months.

Notably, the conclusions of systematic reviews that examined the risk of restoration loss with the use of adhesives that belong to different adhesive strategies are controversial. Some studies revealed comparable outcomes among different types of bonding types/techniques for long-lasting post-operation periods [27–30] whereas some others did not confirm such an effect [22,31–33]. Multiple variables of the adhesive systems related to the composition, the application steps, the acidity, and the placement process cause the heterogeneity of the results received. However, we should highlight that the studies which revealed the association of the adhesive type with the retention values state that the total-etch technique leads to a lower risk of restoration loss relative to the self-etch [31–33].

 doi:10.20944/preprints202404.1636.v1

The obvious disagreement between these studies and our outcomes seems reasoned because meta-analysis studies include a wide range of adhesive types, commercial brands, and techniques, whereas, in our study, the used agents are produced by the same manufacturer and have a very similar composition. Concerning the impact of selective enamel etching, the literature certifies that it does not offer an advantage over self-etch [3,31].

Regarding the occurrence of caries at the margins of restorations, no statistical comparison was carried out among the three techniques because no case of caries incidence was detected during the 2-year evaluation period. The absence of caries is a repeated finding in most of the relevant clinical trials [6,11,34,35]. Even after 8 eight years, Mahn et al (2015) reported that the prevalence was close to zero [32]. It is interesting to point out that in our study, perfect agreement (kappa=1) was obtained between the two evaluators for the criteria retention and caries.

As a function of time, the restorations shifted gradually from the clinically perfect to an acceptable situation in terms of marginal adaptation. The relative decrease in the number of restorations with perfect marginal integrity was estimated to be 17.9% per month. Imperfections along their margins were present in most of the restorations, regardless of the three bonding procedures applied. Specifically, after 24 months post-operation, the clinically perfect restorations were 26.9% for the total-etch technique, 16% for self-etch, and 25,9% for selective enamel etch & self-etch. Although the performance of self-etch adhesion was recorded as inferior compared to the two techniques employed with enamel etching, these differences were not statistically significant. However, it may be an indication of enhanced interlocking of resin composite to etched enamel tissue. Indeed, in vitro studies have shown that higher bond strengths are provided with universal adhesives when the application of the bonding follows the enamel etching [36].

All the non-perfect restorations were assigned as clinically acceptable because only small local defects (less than 150μm and 250μm) were present. In addition, according to the outcomes of the current trial, we can state that the three adhesive techniques are able to yield equal quality of marginal adaptation, providing 100% satisfied marginal sites (perfect and acceptable grades 2 and 3).

In general, marginal defects are usually detected beyond the beveled margins onto uncut enamel. According to in vitro studies, the inability of the self-adhesive systems to sufficiently etch the enamel, especially the uncut parts, leads to the creation of a bond that is more prone to degradation [37,40].

Nevertheless, under the conditions of the recent trial, such a different performance between total-etch and self-etch bonding procedures was not observed. A possible explanation may be that the less favorable adhesion is expressed as very small marginal defects, which are not easily noticeable under clinical examination in the post-treatment period of the study. This finding is in agreement with the conclusion of Josic et al (2021) that self-etch and total-etch bonding strategies provide restorations with comparable marginal outcomes up to 3 years follow-up [33], but it is in contrast with two other systematic reviews/meta-analyses, which showed worse marginal performance in restorations with the use of self-etch relative to total-etch techniques [30,32]. Furthermore, Szesz et al (2016) found that selective enamel etching provided better marginal quality to self-etch [3].

The patient-related parameters (gender, oral health attitudes, number of cervical abraded lesions), as single factors, did not interact with the changes in marginal adaptation in all groups of aged restorations.

According to the clinical evaluation, 3.12% of the restorations applied with the total-etch method, 26.11% with self-etch, and 21.64% with selective enamel etch &self-etch presented marginal staining, which was judged as mild. So, all the restorations are characterized as clinically acceptable for up to 2-year oral function. Although the discoloration values assigned fall into the range of mean values reported in systematic studies [22,32], direct comparison may be not reliable because different categories of restorative materials - resin composites and glass-ionomers - were analyzed all together in these studies.

The single-factor analysis revealed that when the self-etch agent is used even prior to enamel etching (methods B and C), the probability of marginal discoloration through time will be statically higher than with the total-etch technique. Under the consideration that a similar correlation was not determined for marginal adaptation, we can claim that the marginal imperfections may not be the strong contributor to the marginal discoloration phenomenon [39,40]. The different enamel etching

 doi:10.20944/preprints202404.1636.v1

patterns produced by the self-etch adhesive compared to total-etch techniques might be attributed to the marginal discoloration outcomes. Irrespective of the etching pattern produced by the various self-etch systems, all their sub-categories provide a very shallow enamel etching, with fewer micro-porosities for resin infiltration and weaker bond strength [6,41,42]. The certain quality of interface/bond may favor the infiltration of stains and/or bacterial biofilm, causing margin pigmentation.

An in vitro study reported some moderate correlation between marginal staining and bond strength values after 6 months of water aging [43]. However, it is notable that according to the findings of the current study, neither the selective enamel etching, which aims to improve the interface, reduced the possibility for marginal discoloration relative to the total-etch system. To ensure this hypothesis, we should record the discoloration separately along the enamel and dentin margins during the examination. Because if the stains are mainly absorbed at the dentin margins, the selective enamel etching may not have a remarkable impact on the total marginal discoloration even in case of reduced discoloration at the enamel part.

The superiority of total-etch technique to the self-etch has been mentioned in most of the systematic studies [22,27,30,32] whereas only Josic et al (2021) concluded no difference [33].

5. Conclusions

Upon 2 years of oral service, the three adhesive strategies provided restorations with no significant differences on the retention rate and the marginal adaptation, whereas the total-etch yielded better performance for marginal staining. Through time, marginal adaptation and staining were becoming worse although all the restorations assessed as clinically acceptable after 2 years. The three adhesive methods completely protected all the restorations against caries occurrence.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Conflicts of Interest: The authors declare no conflicts of interest.

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