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Clinical Effectiveness of a Resin-modified Glass Ionomer Cement and a Mild One-step Self-etch Adhesive Applied Actively and Passively in Noncarious Cervical Lesions: An 18-Month Clinical Trial

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Clinical Relevance

Mild one-step self-etch adhesive can be an alternative to resin-modified glass ionomer cement with similar retention and improved esthetics in noncarious cervical lesions.

SUMMARY

Objectives: To evaluate the clinical effectiveness of two methods of application of a mild one-step self-etch adhesive and composite resin as compared with a resin-modified glass ionomer cement (RMGIC) control restoration in noncarious cervical lesions (NCCLs).

Methods: A total of 294 restorations were placed in 56 patients, 98 in each one of the following groups: 1) G-Bond active application combined with Solare-X composite resin (A-1SEA), 2) G-Bond passive application combined with Solare-X composite resin (P-1SEA), and 3) GC II LC RMGIC. The restorations were evaluated at baseline and after six, 12, and 18 months according to the FDI criteria for fractures/retention, marginal adaptation, marginal staining, postoperative sensitivity, and secondary caries. Cumulative failure rates were calculated for each criterion at each recall period. The effect of adhesive, method of application, and recall period were assessed. The Kruskal-Wallis test for intergroup comparison and Friedman and Wilcoxon signed ranks tests for intragroup comparison were used for each criterion (α=0.05).

Results: The retention rates at 18 months were 93.26% for the A-1SEA group, 86.21% for the P-

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1SEA group, and 90.91% for the RMGIC group. The active application improved the retention rates compared with the passive application of mild one-step self-etch adhesive; however, no statistically significant difference was observed between the groups. Marginal staining was observed in 13 restorations (1 in A-1SEA, 4 in P-1SEA, and 8 in RMGIC) with no significant difference between the groups. The RMGIC group showed a significant increase in marginal staining at 12 and 18 months from the baseline. There was no significant difference between the groups for marginal adaptation, secondary caries, or postoperative sensitivity.

Conclusion: Within the limitations of the study, we can conclude that mild one-step self-etch adhesive followed by a resin composite restoration can be an alternative to RMGIC with similar retention and improved esthetics in restoration of NCCLs. Agitation could possibly benefit the clinical performance of mild one-step self-etch adhesives, but this study did not confirm that the observed benefit was statistically significant.

INTRODUCTION

Noncarious cervical lesions (NCCLs) have become a well-known clinical entity presenting as noncarious loss of tooth substance with multifactorial etiology.[1] Restoration of such lesions becomes necessary in cases of sensitivity, esthetics, and plaque retention and where the tooth has to serve as an abutment for a removable partial denture. A variety of tooth-colored adhesives have been used in the past for restoration of NCCLs, such as glass ionomer cements (GICs), resin-based composite systems, and compomers.[2] With the development of resin-based adhesives, a number of materials have been tried from the conventional three-step etch-and-rinse to the most recent self-etch systems. The self-etch approach involves either a one-step or a two-step application procedure and can be further divided into "strong" with pH about 1 or below and "mild" with pH about 2 or greater.[3]

One-step self-etch adhesive systems have evolved as simplified adhesive systems with less technique sensitivity and shorter application time.[3,4] However, some studies have reported poor bond strength values, hydrolytic instability with time, and inferior marginal adaptation of one-step self-etch adhesives to enamel and dentin when compared with the two-step self-etch or etch-and-rinse systems.[4-9] On the other hand, some recent studies showed their satisfactory clinical performance.[10-16] This may be because of the development of new versions of one-step self-etch systems, especially the milder ones, which show bonding performance, almost comparable to the multistep gold standard approaches.[17]

In the past decade, some *in vitro* studies reported that by active application (agitation) of primer/adhesive, the bond strength of self-etch adhesives to enamel[18-20] and dentin[20-26] can be improved. This might be because of the active primer application that improves the smear layer dissolution, micromechanical interlocking, and chemical interaction with the dentin.[7,26,27]

In an *in vivo* study, Tewari and Goel[28] evaluated the effect of agitation and drying time of a mild two-step self-etch system on dentin bond strength. Agitation of primer along with adequate drying time improved the shear bond strength of adhesive to the dentin. However, clinical trials are necessary to verify the effectiveness of adhesive application methods in the oral environment over a period of time.

To our knowledge, there are only two studies that have evaluated the effect of active application of adhesive systems in a clinical scenario. Loguercio and others,[29] in a two-year clinical study showed that the application of a two-step etch-and-rinse system in a vigorously rubbing motion improved the retention of restorations in NCCLs. Similarly, in a recent clinical trial by Zander-Grande and others,[30] active application of two strong one-step self-etch adhesives improved the retention rates of cervical restorations compared with the passive application at a two year recall. However, no study has yet clinically evaluated the effect of agitation using mild one-step self-etch adhesives in restoration of NCCLs.

In a recent literature review of contemporary adhesives,[17] GICs showed the best clinical results in terms of retention in restoration of NCCLs when compared with the other adhesive categories. Despite this, glass ionomers commonly present with lower esthetic features (higher surface roughness, lower color stability, and lower wear resistance) and inferior mechanical properties when compared with the resin-based restorative materials.[31]

Besides micromechanical interlocking through hybridization, the chemical interaction between functional monomer and tooth substrate has an added advantage in improving the bonding potential of the adhesives.[32] The functional monomers in mild

self-etch systems result in superficial demineralization, keeping residual hydroxyapatite still attached to the collagen, and they have the potential to chemically interact with the hydroxyapatite.[3,17,27] Although the chemical bonding mechanism and one-step procedure of RMGIC is similar to mild one-step self-etch adhesives, there is a void in the literature as to the clinical comparison of these two materials. We could speculate that the new versions of mild one-step self-etch adhesives with a resin composite restoration would provide bonding performance comparable with GIC and with the esthetics of resin composites.

Thus, the aim of this randomized clinical study was to evaluate the influence of the application method of a mild one-step self-etch adhesive in restoration of NCCLs and also to compare it with a resin-modified GIC. The null hypothesis was that the clinical performance of both the materials is similar after 18 months of clinical service regardless of the method of application.

METHODS AND MATERIALS

Study Design and Participant Selection

The experimental design of our study followed the CONSORT statement. This randomized double-blind clinical trial was approved by the institutional ethical committee (PGIDS/IEC/2015/62). Written and informed consent was obtained from each patient after explaining the study procedure in his or her own language.

Inclusion and Exclusion Criteria

The study population included patients referred for the treatment of noncarious cervical lesions. These patients were screened by an experienced and calibrated examiner for noncarious cervical lesions to be included in the study as per specified inclusion and exclusion criteria. Healthy patients with an acceptable oral hygiene and age greater than 18 years who were willing to participate in the study and had at least 20 teeth in occlusion were included. Each patient had at least three noncarious cervical lesions to be restored in three different teeth. Lesions had to be noncarious, nonretentive, and $\geq$1 mm in depth and have a cavosurface margin not involving >50% of enamel. Lesions had to involve both enamel and dentin of vital teeth without mobility. Patients with extremely poor oral hygiene, severe periodontal disease, rampant caries, or a heavy bruxism habit were excluded.

Sample Size Calculation

The retention rate of a mild one-step self-etch adhesive, G-Bond, was reported to be 98%[13] after 1 year of clinical service. With an α of 0.05, a power of 80%, and a two-sided test, the minimal sample size of 98 restorations per group was calculated to detect a difference of 10% among the tested groups.[33]

Randomization

Randomization was carried out to balance the distribution of restorative treatment among the groups. The lesions were randomly, but consecutively, restored with each of the materials until 294 restorations were placed. When a patient presented, the teeth were restored starting from the upper right quadrant followed by upper left, lower left, and finally lower right quadrant using FDI notation for tooth identification. For a new patient, the material used to restore the first tooth was taken from the list for the next restoration. Each patient received at least three restorations, one from each of the three study groups. In some cases, more lesions were restored but not always in equal numbers.[34]

Restorative Procedure

All patients were given oral hygiene instructions before starting the operative treatment. Preoperative photograph of the lesions were taken. Before starting the treatment, some features of NCCLs were recorded as described in Table 1. The cavity dimensions in millimeters (cervicoincisal height and buccolingual depth), the geometry of the cavity (evaluated by adapting a wire along the inner walls of the cavity and then measuring the angle as <90°, 90-135°, and >135°) and presence of antagonist were recorded. The preoperative sensitivity was also evaluated by applying air from a dental syringe placed 2 cm from the tooth surface. Degree of sclerotic dentin of the lesions was measured according to the criteria described by Swift and others.[34] Lesions were then cleaned with a slurry of pumice and water on a slow rotating rubber cup in a slow-speed hand piece, rinsed, and dried. The appropriate shade of the resin composite was determined. Isolation was performed with cotton rolls and gingival retraction cord. No additional retention or bevel was given as per the guidelines recommended by the American Dental Association (ADA).[36] A mild one-step self-etch adhesive (G Bond, GC, Tokyo, Japan) with a resin composite (Solare-X, GC, Tokyo, Japan) or a resin-modified GIC (GC II LC Gold Label, GC, Tokyo, Japan) was used for restoration of the lesions. Teeth were then

Table 1: *Demographic Characteristics of Research Subjects and Characteristics and Distribution of Noncarious Cervical Lesions*

Characteristic	No. of Patients		
Gender distribution			
Male	44		
Female	12		
Age distribution, y			
30-39	4		
40-49	12		
50-59	14		
60-69	21		
70-79	5		
	Characteristics and Distribution of Noncarious Cervical Lesions		
	Group 1 (A-1SEA)	Group 2 (P-1SEA)	Group 3 (RMGIC)
Tooth distribution			
Incisors	15	13	14
Canines	20	10	10
Premolars	48	58	60
Molars	15	17	14
Shape/degree of angle			
<90	87	92	93
90-135	11	6	5
>135	0	0	0
Cervicoincisal height			
<1.5	10	11	7
1.5-2.5	51	47	47
>2.5	37	40	44
Degree of sclerotic dentin			
1	35	30	32
2	47	46	41
3	12	21	21
4	4	1	4
Buccolingual depth, mm			
1-2	86	89	95
2.1-3	12	9	3
Preoperative sensitivity			
Yes	7	5	6
No	91	93	92
Arch distribution			
Maxillary	64	57	57
Mandibular	34	41	41
Presence of antagonist			
Yes	95	96	94
No	3	2	4

randomly allocated to any of the three groups, namely, resin-modified GIC (RMGIC), mild one-step self-etch adhesive passive application (P-1SEA), and mild one-step self-etch adhesive active application (A-1SEA). The procedure for restoration placement was as per the manufacturer's instructions as follows (Table 2):

1. RMGIC group: A dentin conditioner (GC) was applied to the bonding surface for 10 seconds with a cotton pellet, washed, and dried. The RMGIC was then applied and light cured for 40 seconds. The cured restoration was then coated with a bonding agent (Tetric N-bond, Ivoclar Vivadent AG, Schaan, Liechtenstein) and light cured before and after polishing to prevent desiccation.
2. P-1SEA group: The adhesive was spread over the entire lesion surface and left undisturbed for 5-10 seconds, air dried for five seconds, and then light cured for 10 seconds.
3. A-1SEA group: The adhesive was applied rigorously for five seconds using a microbrush and left undisturbed for 5-10 seconds, air dried for five seconds, and light cured for 10 seconds.

After adhesive application in groups 2 and 3, the lesions were incrementally restored with appropriate shade of the resin composite and cured using light-emitting diode (LUX V curing light, Guilin Woodpecker Medical Instruments Co Ltd, China).

All restorations were finished and polished using abrasive discs (Super-Snap, SHOFU Inc, Kyoto, Japan) a week after placing the restorations. At this visit, baseline records of the restorations were also recorded. Clinical examination records and photographs at 1:1 magnification were taken at baseline and at every follow-up visit.[34]

Restoration Evaluation

Clinical evaluation was done by two experienced examiners who were familiar with the evaluation criteria and who were not involved in the placement of the restorations and thus were blinded to the group assignment. For training purposes, the examiners observed 10 photographs that were representative of each score for each criterion. They evaluated 10 to 15 teeth in two different clinical appointments. The intraexaminer and interexaminer agreement of at least 85% was necessary before beginning the evaluation. The restorations were evaluated at baseline and after 6, 12, and 18 months of clinical service. At each recall visit, the restorations were assessed using a dental operating microscope at 1× magnification (OPMI Pico, Carl Zeiss Surgical GmbH, Germany) according to the FDI World Dental Federation criteria described by Hickel and others.[37] The primary outcome variable evaluated was fractures/retention of the restoration. The

Table 2: *Materials, Manufacturers, Lot Number, and Application Techniques*

Material	Category	Mode of Application
G-Bond (GC, Tokyo, Japan), Lot no. 1411121	One-step self-etch adhesive with pH=2	Passive application: Apply adhesive gently over bonding surface and leave undisturbed for 5-10 s, air dry for 5 s, and light cure for 10 s
		Active application: Apply adhesive rigorously for 5 s using microbrush and leave undisturbed for 5-10 s, air dry for 5 s, and light cure for 10 s
Solare-X (GC, Tokyo, Japan), Lot no. 1309041	Light-cured resin composite	After adhesive application, resin composite was placed in 1-mm increments and cured for 20 s
GC Dentin Conditioner (GC, Tokyo, Japan), Lot no. 1401161	Polyacrylic acid conditioner	Apply to bonding surface for 10 s with a cotton pellet, wash/dry but do not desiccate, then apply light-cured GIC
GC 2 LC Gold Label Light-Cured Glass Ionomer Universal Restorative (GC, Tokyo, Japan), Lot no. 1405201	Light-cured GIC	Place dentin conditioner for 10 s, wash/dry, place RMGIC, light cure for 40 s

secondary outcome variables such as marginal staining, marginal adaptation, postoperative sensitivity, and secondary caries were also evaluated. For each evaluated criteria, scoring ranges from 1 (very good), 2 (good, after correction very good), 3 (sufficient/satisfactory, minor shortcomings), 4 (unsatisfactory, but repairable) to 5 (poor, replacement necessary). Restorations with scores 1 to 3 in each evaluated criteria were considered acceptable (success). Restorations rated 4 or 5 were classified as clinically unacceptable (failure), excluded from further assessment, and were repaired or replaced.

Statistical Analysis

Statistical analysis was performed for each criterion in IBM SPSS Statistics version 20 software. Descriptive statistics were used to describe the distributions of the evaluated criteria. The statistical analysis followed the intention-to-treat protocol, which included all teeth in their originally randomized groups, even those that were not able to be analyzed during the scheduled recall visits. In this case, the missing data are filled by carrying the last observed value of such teeth.[38] This approach is more conservative and less open to bias.

The Kruskal Wallis test was used for intergroup comparison among the three groups for each criterion, and the p-value <0.05 was considered to be statistically significant. The difference in the performance of each group at baseline and after each recall visit (6, 12, and 18 months) was assessed by Friedman and Wilcoxon signed ranks tests (α=0.05). To determine the strength of patient factors such as tooth type, location, size and shape of the lesion, and dentinal sclerosis, the logistic regression was applied on success and failure of each evaluated criteria.

The restoration failure rates were calculated for each criterion at each recall period as follows:

$$Failure\,percentage = \frac{F(previous) + F(current)}{F(previous) + N(current)} \times 100$$

whereby *F (previous)* represents the previous failures before the current recall examination, *F (current)* represents the number of failures seen in current recall, and *N (current)* represents the total number of restorations seen in the current recall.[36]

RESULTS

Initially, 80 patients were screened for the study, of which 24 were excluded (14 did not meet the inclusion criteria and 10 refused to participate). Thus, 56 patients (44 men and 12 women) with a mean age of 54 years were enrolled in the study. A total of 294 restorations were placed, 98 in each of the three groups involved in the study (Figure 1). The characteristics and distribution of NCCLs in each group are presented in Table 1. At baseline, all restorations were 100% successful with regard to the criteria evaluated (fractures/retention, marginal adaptation, marginal staining, secondary caries, and postoperative sensitivity).

The overall recall rate at 18 months was 90.81% (267 restorations out of 294). A total of nine restorations in the A-1SEA group, eight restorations in the P-1SEA group, and 10 restorations in the RMGIC group could not be evaluated as the patients moved and did not return for follow-up evaluation.

Functional Criteria

From the cumulative failure rates, the retention rates calculated for each group at 6, 12, and 18

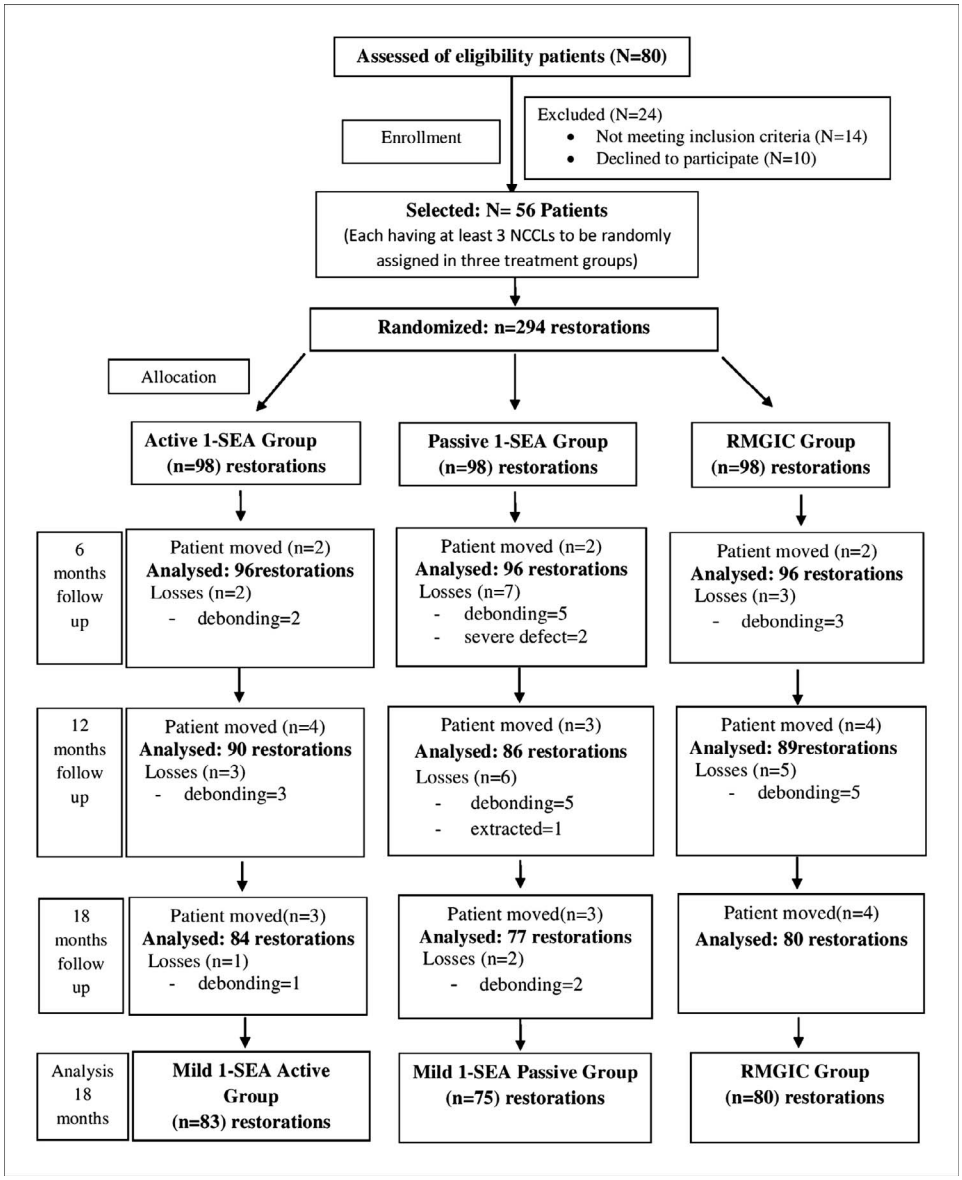

Figure 1. *Consort flow diagram of participants throughout the trial.*

months were 97.92%, 94.57%, and 93.26% for the A-1SEA group; 94.80%, 89.02%, and 86.21% for the P-1SEA group; and 96.87%, 91.31%, and 90.91% for the RMGIC group, respectively.

A total of six restorations from the A-1SEA group, 12 restorations from the P-1SEA group, and eight restorations from the RMGIC group were rated as clinically unacceptable during the 18-month follow-up period (Table 3). There was no statistically significant difference among the three groups with regard to the fractures/retention scores ($p>0.05$). However, when analyzing within the group, the factor recall period was statistically significant in all the groups at 12 and 18 months when compared with the baseline, except for the P-1SEA group, where it was significant at six months also ($p<0.05$).

With regard to the marginal adaptation, only one restoration in the P-1SEA group had clinically unacceptable results at six months, which needed to be replaced; however, the results were not statistically significant between the groups and within the groups ($p>0.05$).

Esthetic Criteria

Marginal staining was noted in one restoration of the A-1SEA group, four restorations of the P-1SEA group, and eight restorations of the RMGIC group during the 18-month follow-up period. Of these, 12 restorations were rated as clinically acceptable;

Table 3: *Number of Restorations Evaluated in Each Group at Each Recall Period According to the FDI Criteria*[37]

FDI Criteria	Score	Baseline			6 mo			12 mo			18 mo		
		A-1SEA	P-1SEA	RMGIC	A-1SEA	P-1SEA	RMGIC	A-1SEA	P-1SEA	RMGIC	A-1SEA	P-1SEA	RMGIC
Marginal Staining	VG	98	98	98	96	92	92	93	87	84	91	82	82
	GO	—	—	—	—	—	—	—	—	—	—	—	—
	SS	—	—	—	—	—	3	—	—	6	1	3	8
	UN	—	—	—	—	1	—	—	1	—	—	1	—
	PO	—	—	—	—	—	—	—	—	—	—	—	—
Fractures and retention	VG	98	98	98	96	92	95	93	87	90	92	85	90
	GO	—	—	—	—	—	—	—	—	—	—	—	—
	SS	—	—	—	—	1	—	—	1	—	—	1	—
	UN	—	—	—	—	—	—	—	—	—	—	—	—
	PO	—	—	—	2	5	3	5	10	8	6	12	8
Marginal adaptation	VG	98	98	98	96	92	95	93	87	90	92	85	90
	GO	—	—	—	—	—	—	—	—	—	—	—	—
	SS	—	—	—	—	—	—	—	—	—	—	—	—
	UN	—	—	—	—	1	—	—	1	—	—	1	—
	PO	—	—	—	—	—	—	—	—	—	—	—	—
Postoperative sensitivity	VG	98	98	98	96	93	95	93	88	90	92	86	90
	GO	—	—	—	—	—	—	—	—	—	—	—	—
	SS	—	—	—	—	—	—	—	—	—	—	—	—
	UN	—	—	—	—	—	—	—	—	—	—	—	—
	PO	—	—	—	—	—	—	—	—	—	—	—	—
Secondary caries	VG	98	98	98	96	93	95	93	88	90	92	86	90
	GO	—	—	—	—	—	—	—	—	—	—	—	—
	SS	—	—	—	—	—	—	—	—	—	—	—	—
	UN	—	—	—	—	—	—	—	—	—	—	—	—
	PO	—	—	—	—	—	—	—	—	—	—	—	—

Abbreviations: VG, clinically very good; GO, clinically good; SS, clinically sufficient/satisfactory; UN, clinically unsatisfactory; PO, clinically poor.

however, severe marginal staining was reported in one restoration of the P-1SEA group that was replaced. There was no statistically significant difference for marginal staining among the three groups tested ($p>0.05$). However, the factor recall period was statistically significant in the RMGIC group at 12 and 18 months compared with the baseline and at six months ($p<0.05$), as shown in Figure 2.

Biological Criteria

No postoperative sensitivity or secondary caries was present in any group over the period of 18 months.

Overall Analysis

Overall clinical success was not significantly different among the groups. It was 93.26% for the A-1SEA group, 84.27% for the P-1SEA group, and 90.91% for the RMGIC group (Table 4). A total of 28 restorations failed over the 18-month period (26 due to retention loss, one due to deficient margins, and one due to severe staining). Lack of retention was the main factor for overall failure of the restorations.

No correlation was found between the clinical performance of the restorations and the tooth type, location, size and shape of the lesion, and dentinal sclerosis.

DISCUSSION

NCCLs are a frequent clinical presentation with multifactorial etiology and increased prevalence with age.[39,40] In these class V cavities, the lack of macromechanical retention and small C-factor minimizes the role of material properties such as polymerization shrinkage, and thus, restoration success mainly relies on the actual bonding potential of the material. GICs are the most preferred material because of their high retention rates and ease of use.[2] However, their major shortcomings are poor surface qualities, marginal staining, and bulk discoloration.[31,41] So there is always a quest for finding a simpler, less technique sensitive material

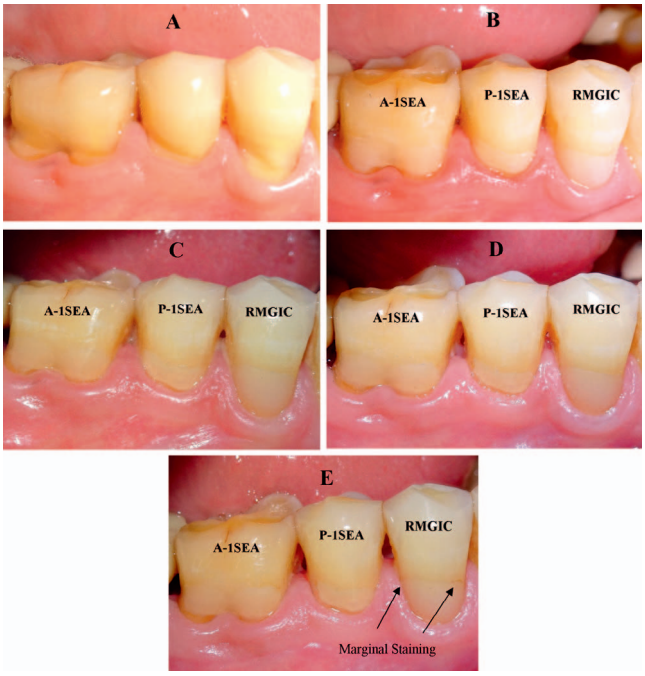

Figure 2. *(A): Preoperative view of NCCLs. (B) Postoperative view at baseline. At 6 months (C), at 12 months (D), and at 18 months (E), marginal staining was observed in the RMGIC group. Arrows points to regions of marginal discoloration.*

with durable bonding and esthetics for restoration of NCCLs.

A mild one-step self-etch adhesive was selected in the present study because in addition to its single-step procedure, better laboratory and clinical performance was observed compared with the more acidic versions.[5,42-48] G- Bond contains 4-META (4-methacryloxyethyl trimellitic acid) and a phosphate ester as functional monomers,[49,50] which are able to form a chemical bond with the hydroxyapatite of the tooth.[32] Long-term durability of adhesive-dentin bonds also depends on the chemical bonding potential of the functional monomer.[51] An RMGIC was used as a control because of its high long-term retention rates in NCCLs, as observed in a recent literature review by Peumans and others.[17]

In our study, the retention rates at 18 months for the A-1SEA, P-1SEA, and RMGIC groups were 93.26%, 86.21%, and 90.91%, respectively. The fractures/retention scores showed no statistically significant difference between the three groups tested ($p>0.05$) during the 18-month period. This may be because of the similar bonding mechanisms of both the materials to the tooth structure.[3,27,32] In addition to their micromechanical retention, both have the chemical bonding potential to the tooth.[3] Both interact superficially with dentin and do not completely dissolve hydroxyapatite crystals around the collagen, leaving them for chemical bonding. Previous clinical trials found inferior performance of one-step self-etch adhesives in terms of retention compared with the RMGICs.[52-57] These studies, however, used strong self-etch adhesives, which were observed to have low bond strength values, especially to dentin.[5,42-45] With strong self-etch adhesives, all the hydroxyapatite nearly dissolves around the collagen, and bonding primarily is diffusion based.[3]

The retention rates for G-Bond in our study were reported to be lower than in the previous studies.[12,13,58-61] Those studies placed restorations either

Table 4: *Clinical Quality of the Restorations in Percentage From Baseline to 18 Months According to FDI Criteria*[37]

Recall Period	At Baseline			At 6 mo			At 12 mo			At 18 mo		
Group	A-1SEA	P-1SEA	GIC	A-1SEA	P-1SEA	GIC	A-1SEA	P-1SEA	GIC	A-1SEA	P-1SEA	GIC
Number of restorations, n	98	98	98	96	96	96	90	86	89	84	77	80
Recall rate, %	100	100	100	97.96	97.96	97.96	93.88	94.89	93.88	90.82	91.84	89.80
Esthetic score (cumulative)												
Acceptable, %	100	100	100	100	98.96	100	100	98.85	100	100	98.72	100
Nonacceptable, %	0.0	0.0	0.0	0.0	1.04	0.0	0.0	1.15	0.0	0.0	1.28	0.0
Functional score (cumulative)												
Acceptable, %	100	100	100	97.92	93.75	96.87	94.57	88.05	91.31	93.26	85.23	90.91
Nonacceptable, %	0.0	0.0	0.0	2.08	6.25	3.13	5.43	11.95	8.69	6.74	14.77	9.09
Biological score (cumulative)												
Acceptable, %	100	100	100	100	100	100	100	100	100	100	100	100
Nonacceptable, %	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Overall score (cumulative)												
Acceptable, %	100	100	100	97.92	92.71	96.87	94.57	87.1	91.31	93.26	84.27	90.91
Nonacceptable, %	0.0	0.0	0.0	2.08	7.29	3.13	5.43	12.90	8.69	6.74	15.73	9.09

after roughening the cavity surface and placing an enamel bevel or after enamel etching with phosphoric acid, which could be a factor influencing the increased retention of the mild one-step self-etch adhesive.[62] However, as per recent ADA guidelines,[36] any surface treatment in the form of roughening or enamel beveling was not done in our study.

Laboratory studies on enamel[18-20] and dentin[20-24,26] using simplified self-etch adhesives found increased bond strength values with active application of adhesive. The authors concluded that active application may improve the bonding performance by smear layer dissolution, increased solvent evaporation, and carrying fresh monomer to the basal parts of etched dentin. This was also confirmed by two recent clinical trials employing a two-step etch-and-rinse system[29] and strong one-step self-etch systems.[30] However, a laboratory study by Zhang and Wang[25] did not find a significant effect of agitation on the degree of demineralization or degree of conversion of monomer for a mild self-etch adhesive. Instead, they attributed it to the adhesive's favorable pH value and composition, as monomer acidity has a negative influence on initiating efficacy of co-initiator in self-etch adhesive systems. When applied actively, we found increased retention rates for the mild one-step self-etch adhesive compared with the passive application, although not to a statistically significant level.

With regard to the marginal adaptation, all groups showed excellent results over the 18-month period. Only one restoration of the P-1SEA group displayed a severe marginal gap of >250 μm at six months, which may be because of technical error during placement of the restoration. These clinical results suggest that both materials are strong enough to withstand intraoral chewing stresses as well as expansion and contraction stresses by thermal changes to preserve the marginal integrity.[12]

Staining at restoration margins may result either due to deficiency or excess of the restorative material. Incomplete degree of conversion of monomer is another reason observed in self-etch adhesives because of their high water and hydrophilic monomer content.[63,64] Furthermore, marginal staining is also related to patient factors such as oral microflora and dietary habits.[49,65] Marginal staining was observed in one restoration of the A-1SEA group, four restorations of the P-1SEA group, and eight restorations of the RMGIC group. Most restorations displayed esthetically acceptable results during the 18-month period, with no significant difference between the groups tested. The active application group displayed less marginal staining compared with the passive application. The active application of adhesive with a microbrush might have resulted in better smear layer removal and enhanced demineralization of the surface layer. It might have allowed better penetration of the monomer with resultant improved marginal characteristics.

The RMGIC group showed significantly progressive yet acceptable marginal staining at 18 months when compared with baseline. Our results were similar to the studies that observed an increase in marginal staining in RMGICs over the same period of time.[55,65-69] Despite the excellent retention in NCCLs, RMGICs were commonly observed to show more water sorption and lower esthetic results compared with resin-based restorative materials.[62,66] In contrast, G-Bond showed no significant increase in marginal staining over the period of 18 months. Being HEMA free, it is reported to have the advantage of decreased water sorption and hydrolytic degradation with time.[70,71]

We found no postoperative sensitivity or secondary caries in any of the groups tested. This is believed to be a result of the ability of the adhesives to seal the dentinal tubules and reduce microleakage. Other studies also reported similar results.[12,13,31] Our study found no correlation between the performance of NCCL restorations and tooth type, location, or size and shape of the lesion. Also, the degree of dentin sclerosis was not found to affect the restorations in NCCLs.

The strength of the present study was that the comparison was done between the groups within the same patient, which ruled out inter-individual variance affecting the clinical performance of the adhesives. We used the FDI criteria introduced by Hickel and others,[37] which was found to be more sensitive than the USPHS criteria for short-term clinical evaluation of restorations, as proved by recent clinical trials by Mena-Serrano and others[72] and Lopes and others.[73] However, the limitation of our study was the short evaluation period of 18 months, so further long-term studies are required to evaluate the effectiveness of different application techniques on clinical performance of mild self-etch adhesives.

CONCLUSION

Within the limitations of the study, we can conclude that a mild one-step self-etch adhesive followed by a resin composite restoration can be an alternative to

RMGIC with similar retention and improved esthetics in restoration of NCCLs. Agitation could possibly benefit the clinical performance of mild one-step self-etch adhesives, but this study did not confirm that the observed benefit was statistically significant.

Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of the Post Graduate Institute of Dental Sciences institutional ethical committee. The approval code for this study is PGIDS/IEC/2015/62.

Conflict of Interest

The authors of this manuscript certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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