Clinical efficacy of universal adhesives for the restoration of noncarious cervical lesions: A randomized clinical trial

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Abstract

Introduction: The efficacy of an adhesive agent is an important aspect in restoring noncarious cervical lesion (NCCL) as studies have proved that compromise in adhesive agent results in reduced bond strength. The purpose of this prospective randomized double-blind clinical trial was to evaluate the efficacy of the newly formulated “universal” dental adhesive in the restoration of NCCLs in permanent dentition using either a self-etch or a selective-etch approach.

Materials and Methods: The study was done following the consolidated standards of reporting trials. 100 NCCLs randomly divided into 2 groups were restored using G-Premio Bond adhesive and Genial flowable composite in selective etch mode and self-etch mode. Restorations were evaluated at 1 week, 6 months, and 12 months using modified US Public Health Service criteria for marginal staining, fracture, and postoperative sensitivity. Statistical analysis was performed using appropriate tests.

Results: Recall rates were 100%, 98%, and 78% at the evaluation time. The result showed that neither the self-etch nor the selective etch mode had significant difference in ALPHA/BRAVO/CHARLIE scores (P > 0.05). Percentage-wise comparison showed less changes reported in the selective etch group compared to self-etch group.

Conclusion: It was concluded that there was no statistical significance between the groups for the parameters evaluated, but selective etch performed better than self-etch group.

Keywords: Noncarious cervical lesions; randomized controlled clinical trial; selective etch; self-etch; universal adhesive

INTRODUCTION

Restoration of noncarious cervical lesions (NCCLs) are a challenge in dental practice as multifactorial etiologies are involved in their development.[1] Although some patients may not experience adverse effects from the presence of NCCLs, they compromise the esthetics of the dentition. For decades, resin composites have been used to restore NCCLs for esthetics and/or patient comfort.[2,3] However, there has always been a dilemma about total etch and self-etch adhesives.

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The recently developed universal adhesive has an additional chemical bonding potential between the functional monomers and the components of dentin.[4] Studies have shown that this bond is more stable to hydrolytic degradation than other functional monomers.[1] Since dentin and enamel substrates are vastly different with respect to their composition and require different bonding protocols, some practitioners have advocated a “selective etch” procedure, in which the enamel and dentin are etched differently, but may still be bonded using the same bonding agent. An in-vitro study by Hanabusa et al. indicates that use of a universal adhesive with selective etching of enamel with phosphoric acid provides better bonding efficacy than when the adhesive is used as a self-etch alone.[5] Few other studies failed to demonstrate a significant difference between the two techniques.[6,7]
Hence the objective of this prospective randomized double-blind clinical trial was to evaluate the influence of two different application strategies (self-etch and selective-etch) on the clinical behaviour of a new universal multimode adhesive in restoration of NCCLs in permanent dentition over 12 months using the US Public Health Service (USPHS) evaluation criteria. The null hypothesis tested was that bonding to NCCLs using self-etch and selective etch strategy would result in similar retention levels over 12 months of clinical service.

**MATERIALS AND METHODS**

**Study Design and Ethical Clearance**
This prospective randomized, double-blind controlled clinical trial was designed according to the consolidated standards of reporting trials statement updated in 2017. The study protocol was reviewed and approved by the institutional Ethical Committee (KIMS/IEC/D0001/2020) and registered in clinical trial registry of India (REF/2018/06/020400). The nature of the study was explained and informed consent was obtained from all the participants prior to the commencement of the treatment. Those who qualified for the study were recruited in the order in which they reported for the screening session, thus forming a convenience sample.

The study followed parallel-group design in which participants of ages between 35 and 55 years, with a minimum of two NCCLs occurring on at least one side of the jaw were selected. Posterior teeth \( n = 100 \) having healthy periodontium in contact with the opposing teeth and with a normal occlusal relationship were included in the study. Cervical lesions involving only buccal surface with <50% of the cavosurface margin of enamel were involved. The depth of cavity was not >2 mm and width of cavity was not >3 mm as measured by a probe. Individuals with chronic systemic disease, periodontal problems, allergy to any materials used, bruxism and other parafunctional habits were excluded from the study. Both the groups were homogenous in terms of age, gender, tooth type, and number of teeth involved.

**Sample size estimation**
Estimated sample size \( = \frac{(Z_{\alpha} + Z_{\beta})^2 \times 2 \times S^2}{d^2} \)

\[ Z_{\alpha} = 1.96 \text{ (95% confidence, 5% alpha error, two tailed test)} \]

\[ Z_{\beta} = 1.28 \text{ (10% beta error, power 90%)} \]

\[ S = \text{Standard deviation} = 0.4 \text{ (pilot study)} \]

\[ d = \text{Expected difference} = 0.3 \]

Sample size = \[ \frac{(1.96 + 1.28)^2 \times 2 \times 0.4^2}{0.3^2} = 10.5 \times 2 \times 0.16 = 37.33 = 38 \]

To compensate for any drop out (30% expected) a sample size 50 (38 + 12) estimated for each group.

Estimated sample = 100 (50 each group).

**Randomization and allocation concealment**
Randomization was done using computer-generated tables by a staff member not involved in the research protocol. Sequentially numbered, opaque, and sealed envelopes containing allocated groups recorded on cards were opened on the day of the restorative procedure to reveal the allocation assignment. The operator was not blinded to group assignment when administering interventions; however, participants and evaluators were blinded to the group assignment [Figure 1].

GROUP 1 - Universal adhesive in selective etch mode restored with flowable composite (G – Premio Bond and Genial Flow).

GROUP 2 - Universal adhesive in self-etch mode restored with flowable composite (G – Premio Bond and Genial Flow).

**Interventions and restorative procedure**
All the participants received oral prophylaxis prior to the restorative treatment. The features of the NCCLs were evaluated prior to the placement of the restorations. Preoperative photograph of NCCL was recorded.

Prior to the treatment, preoperative data for each patient were recorded in a predesigned case sheet. Patients were assessed for the preoperative sensitivity by applying air for

![Figure 1: Materials used for restoration](image-url)
10 s from an airway syringe placed 2 cm from the lesion. Proper shade of the composite was determined using shade guide. The NCCLs were restored using G Premio Bond adhesive and Genial flow in selective etch mode and self-etch mode.

**Protocol for selective etching**

NCCL selected according to inclusion criteria were involved for the restoration. Shade selection was done using shade guide and retraction cord was placed. The lesions in the selective etch group were etched with a 37% orthophosphoric acid gel for 15 s only on enamel, rinsed with water spray for 15 s and dried with oil-free air for 5 s. The universal adhesive system was applied wetting all the cavity surfaces uniformly and was gently agitated on the entire enamel and dentin surface for approximately 20 seconds, according to manufacturer’s recommendations. Then the adhesive was evaporated by gentle air thinning for 5 s and light cured for 10 s. After adhesive application, flowable composite was used and light cured using LED unit for 20 s. After removal of retraction cord, the restoration was finished and polished [Figure 2].

**Protocol for self-etching**

The same protocol used in selective etching was followed with the elimination of etching of enamel [Figure 2].

**Clinical evaluation**

Restorations were evaluated at 1 week, 6 months, and 12 months using modified USPHS criteria (alpha, beta, Charlie) for marginal staining, fracture, and postoperative sensitivity [Figure 2]. Two experienced dentists not involved in the clinical procedure evaluated the restorations during the follow-up.

**Statistical analysis**

The data were analyzed using the statistical package SPSS 22.0 (SPSS Inc., Chicago, IL, USA) and level of significance was set at $P < 0.05$. Descriptive statistics was performed to assess the proportion of each score for the respective groups. Normality of the data was assessed using Shapiro–Wilkinson test. Inferential statistics to find out the difference within the groups was done using Friedman’s test at multiple intervals and McNemar’s test was used to assess the scores at two different evaluation intervals. Chi-square test was also used to assess the scores between

### Table 1: Comparison of selective etch and self-etch group - 6 months

|                  | Selective etch | Self-etch | $P$ | Difference (%) |
|------------------|----------------|-----------|-----|----------------|
| Marginal discoloration |                |           |     |                |
| Alpha            | 91.8           | 93.8      | 0.97| 2              |
| Bravo            | 8.1            | 6.1       | 0.97| 2              |
| Charlie          | No change      | No change |     | 0              |
| Retention        |                |           |     |                |
| Alpha            | 93.8           | 89.7      | 0.78| 4.1            |
| Bravo            | 6.1            | 10.3      | 0.78| 4.2            |
| Charlie          | No change      | No change |     | 0              |
| Postoperative sensitivity |            |           |     |                |
| Alpha            | 95.9           | 93.8      | 0.96| 2.1            |
| Bravo            | No change      | No change |     | 0              |
| Charlie          | 4.1            | 6.2       | 0.96| 2.1            |

* $P<0.05$ is statistically significant (Chi-square test). Chi-square analysis between the groups at 6 months interval shows no significant difference in scores between the groups regarding marginal discoloration, retention, and postoperative sensitivity ($P>0.5$)

### Table 2: Comparison of selective etch and self-etch group - 1 year

|                  | Selective etch | Self-etch | $P$ | Difference (%) |
|------------------|----------------|-----------|-----|----------------|
| Marginal discoloration |                |           |     |                |
| Alpha            | 92.3           | 87.1      | 0.83| 5.2            |
| Bravo            | 5.1            | 7.6       | 0.93| 2.5            |
| Charlie          | 2.5            | 2.5       |     | 0              |
| Retention        |                |           |     |                |
| Alpha            | 89.7           | 84.6      | 0.24| 5.1            |
| Bravo            | 7.6            | 10.2      | 0.93| 2.6            |
| Charlie          | No change      | No change |     | 0              |
| Postoperative sensitivity |            |           |     |                |
| Alpha            | 89.7           | 84.6      | 0.84| 5.1            |
| Bravo            | No change      | No change |     | 0              |
| Charlie          | 10.2           | 15.3      | 0.84| 5.1            |

* $P<0.05$ is statistically significant (Chi-square test). Chi-square analysis between the groups at 1 year interval shows no significant difference in scores between the groups regarding marginal discoloration, retention, and postoperative sensitivity ($P>0.5$)
the groups at different evaluation intervals. Cohen’s Kappa statistics was used to assess the inter examiner reliability.

**RESULTS**

In total, 100 restorations of NCCLs were performed. Recall rates were 100% at the baseline and 98% at 6-month and 78% at 12-month evaluation.

The analysis was performed by Friedman test (where multiple intervals involved) and McNemar’ test was used when two intervals are compared. The analysis showed no significant difference in scores (\(P > 0.05\)) between different evaluation intervals regarding marginal discoloration, retention, and postoperative sensitivity. The analysis showed no significant difference in scores (\(P > 0.05\)) between different evaluation intervals regarding marginal discoloration, retention, and postoperative sensitivity.

Chi-square analysis between the groups at 6 months interval shows no significant difference in scores between the groups regarding marginal discoloration, retention, and postoperative sensitivity (\(P > 0.05\)).

Chi square analysis between the groups at 1-year interval shows no significant difference in scores between the groups regarding marginal discoloration, retention, and postoperative sensitivity (\(P > 0.05\)).

**DISCUSSION**

This study compared the clinical performance of a new universal adhesive in self-etch and selective etch mode in restoring NCCLs. The study failed to reject the null hypothesis, as there were no statistically significant differences in the clinical parameters for the two bonding strategies tested in this study. Correlation with age and gender of treatment outcome was not considered as it was not included in the objectives of the study.

The success of composite resin in restoration of NCCLs depends largely on the properties of the bonding agent used. The major part of the bonded tooth surface consists of dentin, while only at the incisal/occlusal side, the adhesive restorative material is bonded to enamel. Thus adhesive bonding agents must be capable of providing equally effective bonds to both enamel and dentin, despite them being vastly different structures in terms of composition and natural variability. Literature so far indicates that the most durable bond to enamel is obtained following an etch-and-rinse approach and to dentin by a mild self-etch approach.

To obtain the advantage of simple bonding protocol with enhanced micromechanical interlocking and chemical bonding, universal adhesive was introduced in 2011.

Despite similar composition to older self-etch adhesives, universal adhesive contains specific carboxylate and/or phosphate functional monomers that bonds ionically to dentin, forming hydrolytically stable calcium salts on hydroxyapatite in the form of “nanolayering” which enhances the effectivity and longevity of bonds.

Inadequate etching of enamel with self-etch adhesives result in low bond strength, inferior-marginal adaptation, and higher rate of marginal discoloration, selective etching of enamel margins with phosphoric acid is being recommended prior to the application of self-etch adhesives.

Although selective etching of enamel margins prior to the application of self-etch adhesives can minimize the limitation of self-etch, an accidental dentin etching may occur and jeopardize bonding efficacy to dentin.

In the present study the results showed that, when universal adhesive (G Premio bond) was used in selective and self-etch mode, clinical failures began to appear at 6 months and continued to appear at 12 months. Although the self-etch techniques tended to exhibit less clinical efficacy at 6 and 12 months, there were no significant differences in any of the criteria evaluated, which highlighted a better bonding efficacy of the G-Premio bond in both the mode.

The universal adhesive used in this study (G PREMIO BOND) is an “intermediately strong” (\(\text{pH} \approx 1.5\)) adhesive which shows a transition between “strong” and “mild” etching characteristics of the hybrid layer formed. It has typically a hybrid layer with demineralized top layer and partially demineralized base. G Premio bond consists of MDP, 4-MET, MEPS, BHT, acetone, dimethacrylate resins, initiators, and water as the main components.

The 10-MDP forms a strong ionic bond with calcium from hydroxyapatite of enamel and dentin, also resulting in a calcium salt immediately and after long term water storage, while 4-MET acts as a demineralizing and an adhesion-promoting monomer due to the carboxylic groups attached to the aromatic group. In addition, MDP can penetrate into the etched wet-dentin and upon ionization in the presence of water might play a role as a self-etching primer, subsequently creating further demineralized dentin. The monomer also has a strong...
potential to interact chemically with apatite at the bottom of the demineralized dentin. Absence of HEMA in the bonding agent improves the nanolayering.

It is also interesting to observe that even when the SE was applied after selective enamel etching, the retention pattern did not improve significantly. The clinical trials that compared the benefits of selective enamel etching before application of SE adhesives do not report improved retention rates of composite resin restorations in NCCLs, and this finding has also been observed in the present study. On the other hand, selective enamel etching with SE adhesives can reduce marginal discoloration at the restoration interface after medium/long-term clinical service. This is due to micromechanical bond of the adhesive at the enamel margin of NCCL.

The results of the present study showed that after 12 months [Table 2] of clinical service a total of 3 restorations failed as a result of debonding – 1 bonded with the Selective Etch approach and 2 bonded with the self-etch approach which highlighted a good bonding efficacy of the G-Premio Bond when used in both strategies. This good bonding ability may be related to the kind of chemical bond produced by this adhesive with the dental substrates. The clinical problems noted in this study were relatively minor, and perhaps reflect the improved adhesives more than anything else. However, the real test for these materials will be their performance over longer periods of clinical service.

Even though the evaluation of parameters at the intervals was done by two evaluators, the values of only one of the examiners was considered for further statistical analysis as there was strong reliability between the examiners (Cohen's Kappa statistics - 0.89).

Similarly, there was no statistical significance at the intergroup levels for assessment of marginal discoloration and postoperative sensitivity when assessed at all time intervals. This may be because of short follow-up time.

Table 3: Percentage change in scores at different time intervals for selective etch group (loss to follow-up not included)

|                          | 1 week (%) | 6 months (%) | 1 year (%) | P  | Difference (%) (1 week-1 year) |
|--------------------------|------------|--------------|------------|----|-------------------------------|
| Marginal discoloration   |            |              |            |    |                               |
| Alpha                    | 100        | 91.8         | 92.3       | 0.84 | 8.2                           |
| Bravo                    | -          | 8.1          | 5.1        | 0.89 | 3                             |
| Charlie                  | -          | No change    | 2.5        | -   | -                             |
| Retention                |            |              |            |    |                               |
| Alpha                    | 100        | 93.8         | 89.7       | 0.72 | 10.3                          |
| Bravo                    | -          | 6.1          | 7.6        | 0.91 | 1.5                           |
| Charlie                  | -          | No change    | 2.5        | -   | -                             |
| Postoperative sensitivity|            |              |            |    |                               |
| Alpha                    | 100        | 95.9         | 89.7       | 0.77 | 6.2                           |
| Bravo                    | -          | No change    | No change  | -   | -                             |
| Charlie                  | -          | 4.1          | 10.2       | 0.69 | 6.1                           |

*P<0.05 is statistically significant (Friedman test/McNemar test). The analysis was performed by Friedman test (where multiple intervals involved) and McNemar test was used when two intervals are compared. The analysis showed no significant difference in scores (alpha/bravo/charlie) between different evaluation intervals regarding marginal discoloration, retention, and postoperative sensitivity (P>0.05)

Table 4: Percentage change in scores at different time intervals for self-etch group (loss to follow-up not included)

|                          | 1 week (%) | 6 months (%) | 1 year (%) | P  | Difference (%) (1 week-1 year) |
|--------------------------|------------|--------------|------------|----|-------------------------------|
| Marginal discoloration   |            |              |            |    |                               |
| Alpha                    | 100        | 93.8         | 87.1       | 0.20 | 12.9                          |
| Bravo                    | -          | 6.1          | 7.6        | 0.91 | 1.5                           |
| Charlie                  | -          | No change    | 2.5        | -   | -                             |
| Retention                |            |              |            |    |                               |
| Alpha                    | 100        | 89.7         | 84.6       | 0.19 | 15.4                          |
| Bravo                    | -          | 10.3         | 10.2       | 0.99 | 0.1                           |
| Charlie                  | -          | No change    | 5.2        | -   | -                             |
| Postoperative sensitivity|            |              |            |    |                               |
| Alpha                    | 100        | 93.8         | 84.6       | 0.65 | 6.2                           |
| Bravo                    | -          | No change    | No change  | -   | -                             |
| Charlie                  | -          | 6.2          | 15.3       | 0.46 | 9.2                           |

*P<0.05 is statistically significant (Friedman test/McNemar test). The analysis was performed by Friedman test (where multiple intervals involved) and McNemar test was used when two intervals are compared. The analysis showed no significant difference in scores (alpha/bravo/charlie) between different evaluation intervals regarding marginal discoloration, retention, and postoperative sensitivity (P>0.05)
additional 30% samples were taken into account to maintain 80% power at the end of the trial.

Clinical trials have greater value when published after long term follow-up. However, any clinical trial for restoration of NCCLs provide information and points toward an evidence. This will help the clinicians in decision making in their day to day practice.

**Limitations**

The study could have been evaluated for a period of 18 months instead of 12 months as the The American Dental Association previously stated that for an adhesive system to be adequate and acceptable for clinical use (“full acceptance”) it should have a retention rate above 90% after an observation period of 18 months for restorations placed in NCCLs which remains as the main limitation of this study.

Even though the study included cavity of 2 mm depth and 3 mm width, the correlation of depth, width, tooth type with treatment outcome was not evaluated.

**CONCLUSION**

Within the limitations of this randomized double-blind controlled clinical trial, there was no statistically significant difference in marginal discoloration, retention, and postoperative sensitivity at the end of 12 months in both the groups. However there was difference between the selective etch and self-etch with selective etch technique giving better results. Further long term studies are needed to evaluate the clinical performance of the newly introduced universal adhesive in different adhesive strategies.

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**Conflicts of interest**

There are no conflicts of interest.

**REFERENCES**

1. Oliveira B, Ulbaldini A, Sato F, Baesso ML, Bento AC, Andrade L, et al. Chemical interaction analysis of an adhesive containing 10-methacryloyloxycarbonyl dihydrogen phosphate (10-MDP) with the dentin in noncarious cervical lesions. Oper Dent 2017;42:357-66.
2. Jeffrey A, Platt. Clinical Evaluation Of A Universal Adhesive In Noncarious Cervical Lesions [dissertation on the internet-NCT02172664]. Indian University; [2019 may 28]. https://clinicaltrials. Gov/ct2/show/ NCT02172664
3. Lopes LS, Calazans FS, Hidalgo R, Bultrao LL, Gutierrez F, Reis A, et al. Six-month follow-up of cervical composite restorations placed with a new universal adhesive system: A randomized clinical trial. Oper Dent 2016;41:465-80.
4. Swift EJ Jr., Perdigão J, Heymann HO, Wilder AD Jr., Bayne SC, May KN Jr., et al. Eighteen-month clinical evaluation of a filled and unfilled dentin adhesive. J Dent 2001:29:1-6.
5. Hanabusa M, Mine A, Kuboki T, Momoi Y, Van Ende A, Van Meerbeek B, et al. Bonding effectiveness of a new ‘multi-mode’ adhesive to enamel and dentine. J Dentistry 2012;40:475-84.
6. Peumans M, De Munck J, Van Landuyt KL, Poitevin A, Lambrechts P, Van Meerbeek B. Eight-year clinical evaluation of a 2-step self-etch adhesive with and without selective enamel etching. Dent Mater 2010;26:1176-84.
7. Hashimoto M. A review – Micromorphological evidence of degradation in resin-dentin bonds and potential preventive solutions. Journal of Biomedical Materials Research Part B: Applied Biomaterials: An Official Journal of The Society for Biomaterials, The Japanese Society for Biomaterials, and The Australian Society for Biomaterials and the Korean Society for Biomaterials. 2010 Jan; 92 (1):268-80.
8. Vanajasen PP, Dhakshinamoorthy M, Rao CS. Factors affecting the bond strength of self-etch adhesives: A meta-analysis of literature. J Conserv Dent 2011;14:62-7.
9. Heinitze SD, Ruffieux C, Rousson V. Clinical performance of cervical restorations – A meta-analysis. Dent Mater 2010;26:993-1000.
10. McLean DE, Meyers EJ, Guillory VL, Vandewalle KS. Enamel bond strength of new universal adhesive bonding agents. Oper Dent 2015;40:410-7.
11. Inoue G, Tsuchiya S, Nikaido T, Foxton RM, Tagami J. Morphological and mechanical characterization of the acid-base resistant zone at the adhesive-dentin interface of intact and caries-affected dentin. Oper Dent 2006;31:456-72.
12. Nagarkar S, Theis-Mahon N, Perdigão J. Universal dental adhesives: Current status, laboratory testing, and clinical performance. J Biomed Mater Res B Appl Biomater 2019;107:2121-31.
13. Say EC, Özel E, Yurdagüven H, Soyman M. Three-year clinical evaluation of a two-step self-etch adhesive with or without selective enamel etching in non-carious cervical sclerotic lesions. Clinical oral investigations. 2014;18:1427-33.
14. Kubo S, Kasawagi K, Yokota H, Hayashi Y. Five-year clinical evaluation of two adhesive systems in non-carious cervical lesions. J Dent 2006;34:97-105.
15. Khamverdi Z, Kasraei S, Fazelian N, Akbarzadeh M. Effect of tubular orientation on the microtensile bond strength of composite-dentin using universal bonding agents. J Res Med Dent Sci 2018;6:337-44.
16. Nurrohman H, Nikaido T, Takagaki T, Sadr A, Ichinose S, Tagami J. Apatite crystal protection against acid-attack beneath resin-dentin interface with four adhesives: TEM and crystallography evidence. Dent Mater 2012;28:e89-98.
17. Krithikadatta J. Clinical effectiveness of contemporary dentin bonding agents. J Conserv Dent 2010;13:173-83.