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Clinical Efficacy Of Universal Adhesives For The Restoration Of Non Carious Cervical Lesions: A Randomized Clinical Trial

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Conflicts of Interest: Nil

Abstract

The efficacy of adhesive agent is an important aspect in restoring non carious cervical lesion 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 formulation in NCCLs in permanent dentition using either a self- etch or selective-etch approach.

Methods

100 NCCLs selected according to inclusion criteria were involved for the restoration and were

randomly divided into 2 groups (self etch and selective etch). All the participants received prophylaxis prior to the restorative treatment. Prior to the treatment a Preoperative data for each patient was recorded in a predesigned case sheet. Patients were assessed for the preoperative sensitivity by applying air for 10 seconds from a airway syringe placed 2cm from the lesion. Proper shade of the composite was determined using shade guide. and retraction cord was placed. The NCCLs were restored using G-Premio Bond adhesive and Genial flow in selective etch mode and self etch mode. After removal of retraction cord the restoration was finished and polished according to standard protocol. Restorations were evaluated at one week, 6 months and 12 months using modified USPHS criteria for marginal staining, fracture and postoperative sensitivity. Descriptive statistics was performed to assess the proportion of each score of 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 the groups at different evaluation intervals. Cohen's Kappa statistics was used to assess the inter examiner reliability.

Results

Recall rates were 100% at the baseline 98% at 6 month and 78% at 12 month evaluations. The result showed that neither the self etch nor the selective etch mode had significant changes in ALPHA /BRAVO /CHARLIE scores ($P>0.05$). Percentage wise comparison showed that less changes reported in the selective etch group compared to self etch group.

Conclusion

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

Keywords

Non Carious Cervical Lesions, Universal Adhesive, Selective Etch, Self Etch.

Introduction

Non carious cervical lesions are a challenge in dental practice as multifactorial etiologies are involved in their development2. Non carious cervical lesions usually form as a result of slow and progressive loss of mineralized dental structure caused by the association of different phenomena such as Erosion, Abrasion, And Abfraction. Although, some patients may not experience adverse effects from the presence of NCCLs, many experience sensitivity, ranging from mild to severe.59 The presence of NCCLs may also compromise the esthetics of the dentition. For decades, resin adhesives have been used to restore non-carious cervical lesions for esthetics and/or patient comfort.59

Laboratory studies have demonstrated that adhesion to non carious cervical lesion is compromised resulting in reduced bond strength.7 This reduction in bond strength in non carious cervical lesion occurs due to molecular/chemical structural alterations, that may result in dentin which is less favorable to bonding.2 The presence of sclerotic layer in non carious cervical lesions could make it difficult for the hybrid layer to form because of the lower degree of primer diffusion and adhesive infiltration.2

The recently developed universal adhesive has an additional chemical bonding potential between the functional monomers and the components of dentin.1

The functional monomer 10-methacryloyloxydecyl dihydrogen phosphate has demonstrated good chemical bonding potential to hydroxyapatite through the formation of a 'nano-layer' capable of enhancing the effectiveness and longevity of bonds.2 Studies have shown that this bond is more stable to hydrolytic degradation than other functional monomers.2 It also has a low solubility of calcium salts with long and hydrophobic spacer carbon chain.2Since 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. (2012) indicates that use of a multimode adhesive with selective etching of enamel with phosphoric acid provides better bonding efficacy than when the adhesive is used as a self- etch alone.60

Two in-vivo studies have also indicated a significantly improved performance of the selective enamel etch technique, though only one of the studies utilized a one-step universal adhesive.(47,11) The other afore mentioned study used a two-step bonding system which comprised of a self-etch primer and separate bonding resin, as opposed to a one-step system. Few other studies failed to demonstrate a significant difference between the two techniques.(34,61)

Hence the purpose of this prospective randomized double blind clinical trial was to evaluate the efficacy of the newly formulated "universal" dental adhesive in restoration of non-carious cervical lesions in permanent dentition using either a self- etch or selective-etch approach.

Materials and Methodology

Study Design and Ethical Clearance

The experimental design followed the Consolidated Standards Of Reporting Trials(CONSORT) statement updated in 2017. This is a prospective randomized, double blind controlled clinical trial which was carried out in the Department of Conservative Dentistry and Endodontics, Mithila Minority Dental College and Hospital, Darbhnaga - 846001, between 2018-2019. The nature of the study was explained and informed consent was obtained from all the participants prior to the commencement of the treatment (ANNEXURE-I). The study protocol was reviewed and approved by the college institutional committee of Mithila Minority Dental College and Hospital (ANNEXURE-II). This study has been registered with the clinical trial registry of India. The study was designed according to the CONSORT (2017) guidelines.

2017 CONSORT checklist of information to include when reporting a randomized trial assessing nonpharmacologic treatments (NPTs)*. Modificationsof the extension appear in italics and blue.

Section/Topic Item	Check list item No.	CONSORT item	Extension for NPT trials
Title and abstract			
	1a	Identification as a randomized ~~trial~~ in the title	*Refer to CONSORT extension for abstracts for NPT trials*
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as ~~parallel~~, factorial) including each ~~allocation~~ ratio	When applicable, how care providers were allocated to trial group
Participants	4a	Eligibility criteria for participants	When applicable, eligibility ~~criteria~~ for centers and for *care providers*
Interventions†	5	~~The~~ interventions for each group ~~with~~ sufficient details to allowreplication, ~~including~~ how andwhen they were actually ~~administered~~	Precise details of both the experimental treatment

Section/Topic Item	Check list item no	CONSORT item	Extension for NPT trials
	5b		Details *of whether and* how ~~the~~ interventions werestandardized.
	5c		Details *of whether and* how adherence of care providers to the protocol was assessed or enhanced
	5d		*Details of whether and how adherence of participants to interventions was assessed or enhanced*
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with Reasons	
Sample size	7a	How sample size was determined	When applicable, details of whether and how the clustering by care providers or centers was addressed
	7b	When applicable, explanation of any interim analyses and stopping Guidelines	
Randomization			
- Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomization; details of any restriction (such as blocking and block size)	
- Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	

Section/Topic Item	Checkli st item no.	CONSORT item	Extension for NPT trials

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	~~Whether or not those administering co-interventions were blinded to group assignment~~ If done, who was blinded after assignment to interventions (e.g., participants, care providers, *those administering co-interventions*, those assessing outcomes) and how
	11b	If relevant, description of the similarity of interventions	~~If blinded, method of blinding and description of the similarity of interventions~~
	11c		*If blinding was not possible, description of any attempts to limit bias*
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	When applicable, details of whether and how the clustering by care providers or centers was addressed
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome	The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider or in each center
	13b	For each group, losses and exclusions after randomization,	

Section/Topic Item	Checklist item no.	CONSORT item	Extension for NPT trials
	13c		~~For~~ *each group, the delay ~~between~~ randomization and the initiation of the intervention*
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	When applicable, a description of care providers (case volume, ~~qualification~~, expertise, etc.) and centers (volume) in each ~~group~~
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary	18	Results of any other analyses	

Section/Topic Item	Checklist item no.	CONSORT item	Extension for NPT trials
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	Generalizability (external validity) of the trial findings according to the intervention, comparators, patients, and care providers and centers involved in the trial
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

*Additions or modifications to the 2010 CONSORT checklist. CONSORT = Consolidated Standards of Reporting Trials

†The items 5, 5a, 5b, 5c, 5d are consistent with the Template for Intervention Description and Replication (TIDieR) checklist

Eligibility Criteria

The outpatients at the Department Of Conservative Dentistry And Endodontics, Mithila Minority Dental College and Hospital, Darbhanga - 846001, were examined to determine if they met the inclusion and exclusion criteria . Those who qualified for the study were recruited in the order in which they reported for the screening session, thus forming a convenience sample.

Participants who were in a good general health and at least 18 years of age, having an acceptable oral hygiene level were selected. All patients were given oral hygiene instructions before the operative treatment was performed.

Inclusion Criteria

- Patient requiring restoratons in the cervical region in a minimum of two sides and one tooth on each side
- Cervical lesions with a depth of 1-3mm and width of 2-4mm
- Patients willing to participate and sign the informed consent form

- Subjects who have natural dentition directly opposing the test restoration.
- Patients with good oral hygiene.

Exclusion Criteria

- Individual with a chronic systemic disease with or without oral manifestations.
- Individual with periodontal problems.
- Subjects with known allergy to any materials used.
- Individual with bruxism and other parafunctional habits

Outcomes

The restorations were assessed for -

- Retention in terms of complete, partial and no retention.
- Marginal staining in terms of no discoloration, slight superficial staining anddeep staining.
- Presence or absence of postoperative sensitivity.

Values were assessed each at baseline six month and one year follow up.

Randomization, Blinding and Allocation Concealment

The randomization process for selection of participants was performed using computer generated tables. Details of the allocated groups were recorded .The operator was not blinded to group assignment, when administering interventions, however participants and evaluators were blinded to the group assignment making it adouble blind randomized controlled trial.

Group 1 - Universal adhesive in Self Etch mode restored with flowable composite(G – Premio Bond and Genial Flow)

Group 2 - Universal adhesive in Selective Etch mode restored with flowable composite (G – Premio Bond and Genial Flow)

Interventations and Restorative Procedure

All the participants received prophylaxis prior to the restorative treatment. The features of the NCCLs were evaluated prior to the placement of the restorations. Pre- operative photograph of NCCL was recorded.

Prior to the treatment a Preoperative data for each patient was recorded in a predesigned case sheet. Patients were assessed for the preoperative sensitivity by applying air for 10 seconds from a airway syringe placed 2cm 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 inselective etch mode and self etch mode.

Table 1.

Materials Used In The Study

Ultradentetchant	Gel	37% phosphoricacid	Selective Etch Approach 37% phosphoric acid was applied for 10-15 sec only onenamel. Then it was rinsed thoroughly for 15secs and gently air dried. Adhesive was applied and evaporated by gentle air thinning for 5 secs and light cured for 10 secs. Self Etch Approach Adhesive was applied without any previous acid etching. Adhesive was evaporated by gentle air thinning for 5 secs and light cured for 10 secs.
G-P BOND (GC Corporation Tokyo, Japan) REMIO	Universal Adhesive	MET, MEPS, methacrylate monomer, acetone, water,initiator, silica (1.5)	
Genial flow	Amorphous universal injectable nanohybrid composite	Matrix: UDMA Bis-MEPP, TEGDMA, pigment photo-initiator Filler: Silicon dioxide Strontium glass	In both the groups after adhesive application, flowable composite was usedand light cured for 30 secs
Shade matching guide (VITA Shade guide)			
Retraction cord (Ultradent)			
Cord Packer			
Cotton rolls			
Check Retractor			
Light Curing Unit (Valo-Ultradent)			
Finishing And Polishing Kit For Composite (SHOFU)			

Protocol For Selective Etch

Non carious cervical lesion selected according to inclusion criteria were involved for the restoration. Shade selection was done using shade guide and retraction cord was placed. The lesions were etched with a 37% orthophosporic acid gel for 15 seconds only on enamel, rinsed with water spray for 15 seconds and dried with oil-free air for 5seconds, until the dentin was dried out but not over dried. 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 20seconds, according to manufacturer's recommendations. Then the adhesive was evaporated by gentle air thinning for 5 seconds and light cured for 10 seconds. After adhesive application flowable composite was used and light cured using LED unit for 20 seconds. After removal of retraction cord, the restoration was finished and polished according to the standard protocol.

Protocol for Self Etch

Non carious cervical lesion selected according to inclusion criteria were involved for the restoration. Shade selection was done using shade guide and retraction cord was placed. 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 20seconds, according to manufacturer's recommendations. Then the adhesive was evaporated by gentle air thinning for 5 seconds and light cured for 10 seconds. After adhesive application flowable composite was used and light cured using LED unit for 20 seconds. After removal of retraction cord, the restoration was finishedand polished according to the standard protocol

Clinical Evaluation

Restorations were evaluated at one week, 6 months and 12 months using modified USPHS criteria (alfa, beta, Charlie) for marginal staining, fracture and postoperative sensitivity. Two experienced dentists not involved in the clinical procedure evaluated the restorations at the follow up.

Statistical Analysis

Data was analyzed using the statistical package **SPSS 22.0** (SPSS Inc., Chicago, IL) and level of significance was set at **p<0.05**. **Descriptive statistics** was performed to assess the proportion of each score of 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 McNamara's test** was used to assessthe scores at two different evaluation intervals**. Chi square test** was also used to assess the scores between 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 thebaseline, 98% at 6 month and 78% at 12-month evaluations.

Marginal discoloration

All of the restorations in the selective etch and self group were scored as Alpha (retained)at the baseline visit.

7 restorations were scored bravo (moderate marginal discoloration) during the 6- month evaluation period out of the 49 restorations, (4 from selective etch group and 3 from self etch group). According to the evaluation criteria marginal staining was absent in 91.8% in selective etch and 93.8% for self etch , with no statistical difference identified between the groups .($p<0.05$)

5 restorations were scored bravo (slight and superficial staining) during the 12-month evaluation period out of the total 39 restorations (2 from selective etch and 3 from self etch) .3 restoration were scored Charlie (missing) during the 12-month evaluation period out of the total 39 restorations. (1 from selective etch and 2 from self etch) . According to the evaluation criteria marginal staining was absent in, 92.3% in selective etch and 87.1% for self etch, Percentage wise comparison showed that less changes reported in the selective etch group compared to self etch etch group but no statistical difference was identified between the groups .($p<0.05$)

When the data from six month results from each group were compared with their baseline findings and when the data from six month results from each group were compared with their one year data, there was no significant difference between both the groups

Retention rates

All of the restorations in the selective and self etch group were scored as Alpha(retained) for retention at the baseline visit.

8 restorations were scored bravo (partially retained) during the 6-month evaluation period out of

the 49 restorations, (3 from selective etch group and 5 from self etch group) . According to the evaluation criteria retention rate was 93.8% in selective etch and 89.7% for self etch, with no statistical difference identified between the groups, ($p<0.05$)

7 restoration were scored bravo (partially retained) during the 12-month evaluation period out of the total 39 restorations(3 from selective etch and 4 from self etch) .3 restoration were scored Charlie (missing) during the 12-month evaluation period out of the total 39 restorations. (1 from selective etch and 2 from self etch) . According to the evaluation criteria retention rate was 89.7% in selective etch and 84.6% for self etch, Percentage wise comparison showed that less changes reported in the selective etch group compared to self etch group but no statistical difference was identified between the groups .($p<0.05$)

When the data from six month results from each group were compared with their baseline findings and when the data from six month results from each group were compared with their one year data , there was no significant difference between boththe groups

Postoperative Sensitivity

All of the restorations in the selective and self etch group were scored as Alpha (no postoperative sensitivity) for postoperative sensitivity at the baseline visit 5 restorations were scored Charlie (postoperative sensitivity) during the 6-month evaluation period out of the 49 restorations, (2 from selective etch group and 3 from self etch group) . According to the evaluation criteria postoperative sensitivity was notseen in 95.9% in selective etch and 93.8% for self etch, with no statistical difference identified between the groups .($p<0.05$)

10 restorations were scored Charlie (postoperative sensitivity) during the 12-month evaluation period out of the total 39 restorations. (4 from selective etch and 6 from self etch) . According to the evaluation criteria rate postoperative sensitivity was notseen was 89.7% in selective etch and 84.6% for self etch , Percentage wise comparison showed that less changes reported in the selective etch group comparedto self etch group but no statistical difference was identified between the groups

.($p<0.05$)

When the data from six month results from each group were compared with their baseline findings and when the data from six month results from each group were compared with their one year data , there was no significant difference between boththe groups

Table-3

Selective etch-
Scores at different time interval (loss to follow up not included)

Groups 1 Week6 Months -1 Year				
Marginal Discolouration	Alpha	50	45	36
	Bravo	-	4	2
	Charlie	-	-	1
Retention	Alpha	50	46	35
	Bravo	-	3	3
	Charlie	-	-	1
Post Operative Sensitivity	Alpha	50	47	35
	Bravo	-	0	0
	Charlie	-	2	4

Table-4

Percentage change in scores at different time interval

		1 Week	6 Months	1 Year	P Value	%Difference (1 Week-1 Year)
Marginal Discolouration	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%		10.3%
Post Operative 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/Mc Nemar test))

The analysis was performed by Friedman test (where multiple intervals involved) andMcNemar' 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 discolouration, retention and post operative sensitivity(.(p>0.05)

Table - 7

Comparison of selective etch and self etch group - 6 months

		6 Months		P Value	%Difference
		SelectiveEtch	Self Etch		
Marginal Discolouration	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
Post Operative 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, retentionand post operative sensitivity(p>0.5)

Table - 8

Comparison of selective etch and self etch group – 1 year

		1 Year		P Value	% Difference
		SelectiveEtch	SelfEtch		
Marginal Discolouration	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	5.2%	0.84	5.2%
Post Operative Sensitivity	Alpha	89.7%	84.6%	0.83	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, retentionand post operative sensitivity(p>0.5)

Table-9

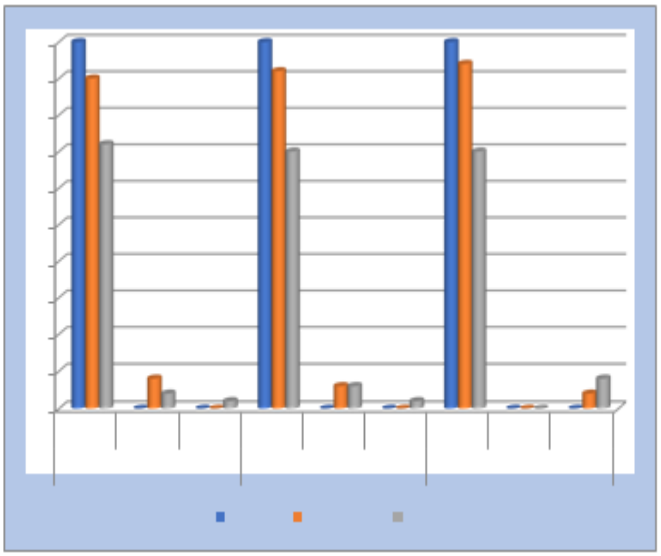
Examiner Reliability

		Kappa value
Marginal discoloration	Alpha	0.93
	Bravo	0.88
	Charlie	0.89
Retention	Alpha	0.94
	Bravo	0.84
	Charlie	0.82
Post operativeSensitivity	Alpha	0.99
	Bravo	0.88
	Charlie	0.86
Mean kappa value 0.89		

Cohen's Kappa statistics.- 0.89(strong reliability between the examiners

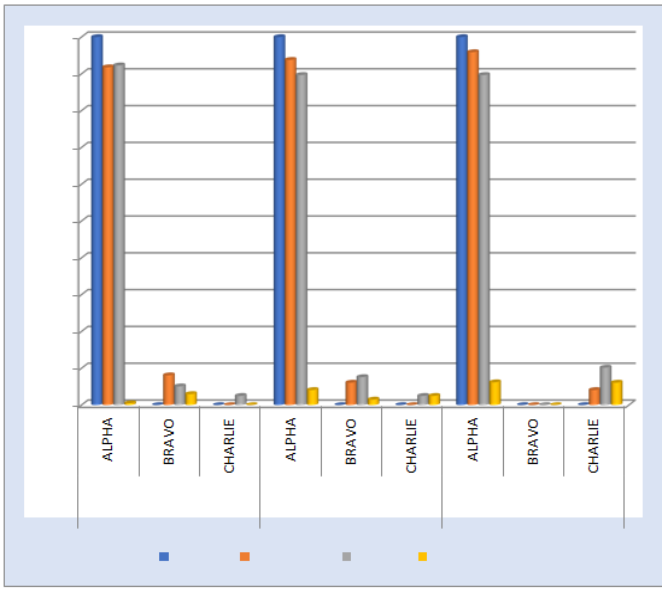
Value of Kappa	Level of Agreement	% of Data that are Reliable
0-.20	None	0-4%
.21-.39	Minimal	4-15%
.40-.59	Weak	15-35%
.60-.79	Moderate	35-63%
.80-.90	Strong	64-81%
Above .90	Almost Perfect	82-100%

Graph 1



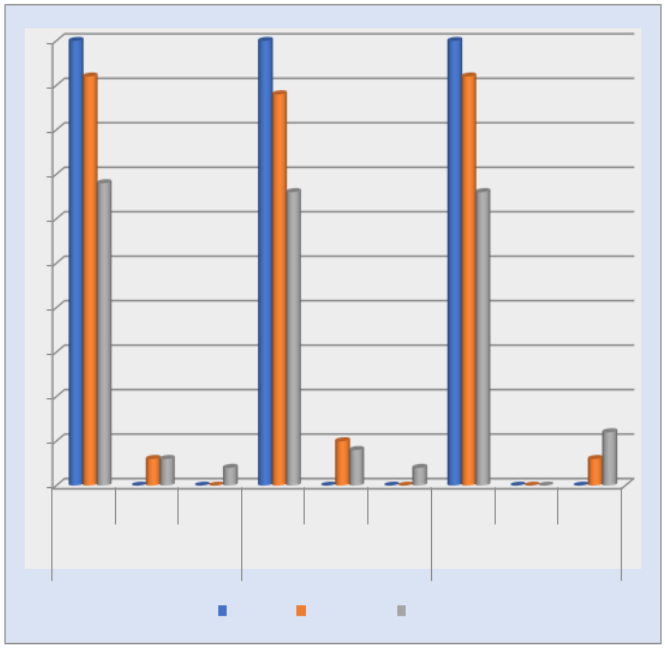
Selective Etch - scores at different time interval (loss to follow up notincluded)

Graph 2



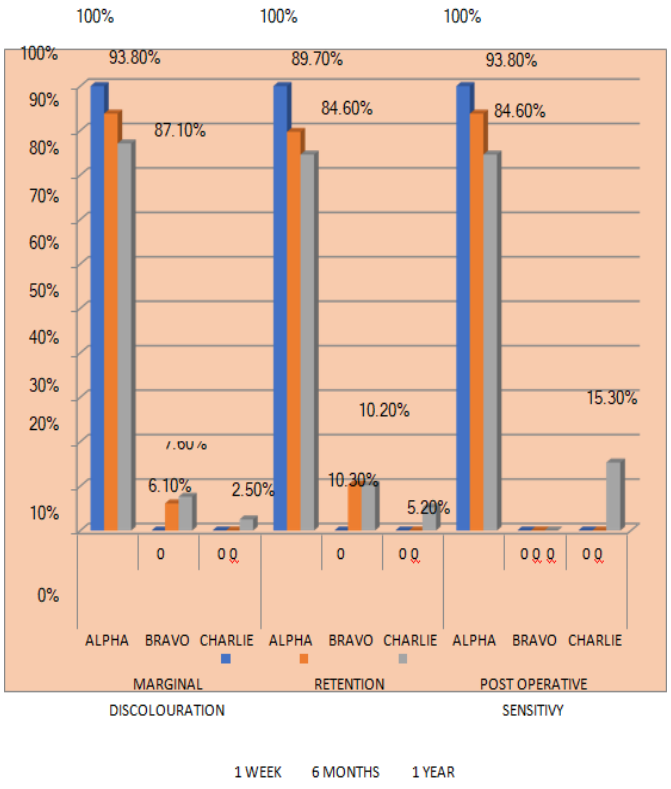
Selective etch - percentage of scores at different time interval

Graph 3



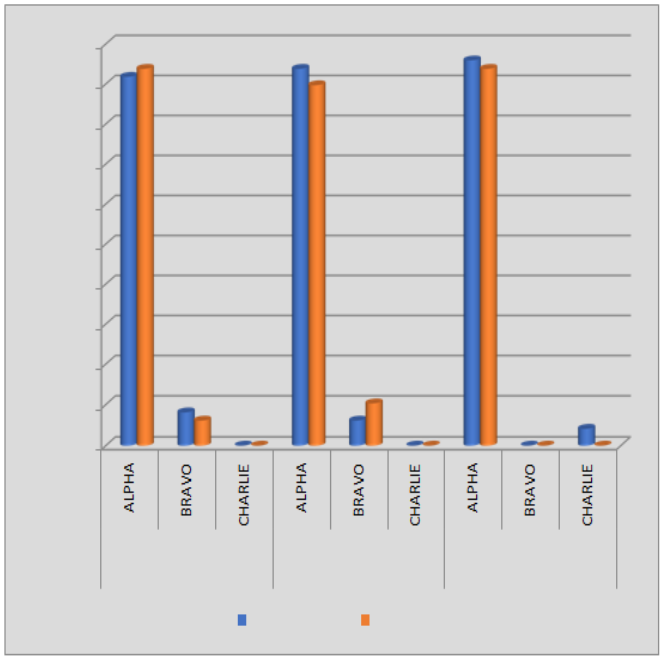
Self etch- scores at different time interval

Graph 4



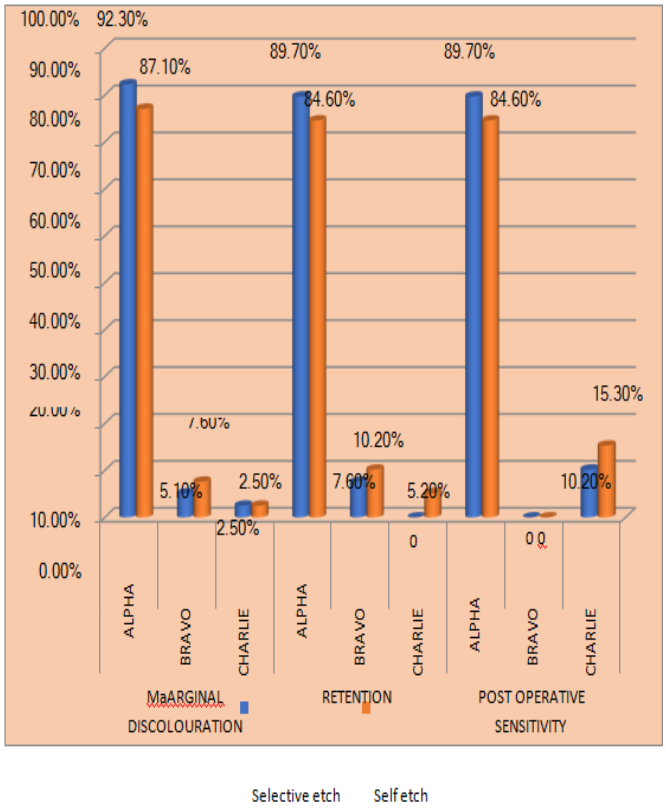
Self etch - percentage of scores at different time interval

Graph 5



Comparison of selective etch and self etch – at 6 months

Graph 5



Comparison of selective etch and self etch – at 1 year

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 nullhypothesis, as there were no statistically significant differences in the clinical parameters for the two bonding strategies tested in this study Most of the studies using universal adhesives found in the literature are laboratory tests and cannot be validated in a clinical scenario.[1] Clinical studies in NCCLs provide the ultimate proof for the evaluation of the performance of adhesive systems, mainly because the most important parameter for evaluation of any restorations for NCCLs isretention.[1]

NCCLs are typically seen on the gingival third of the tooth, where the enamel is thinner and the enamel–dentin bond is weaker than in other regions, facilitating substance loss via erosion, abrasion and abfraction.[10]The surface of NCCLs typically consists of sclerotic dentin, which is resistant to acid etching due to hypermineralized, intertubular and peritubular dentin that may prevent maximum adhesion for restorative procedure.[7]

The success of composite resin in NCCLs restoration depends largely on the properties of the bonding agent used.[7]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.[9] Several contemporary dental adhesives have been documented to provide adequate immediate bond strengths to enamel and dentin.[34] In a systematic review article of Van Meerbeek et al.(2010) a possible relationship was searched between laboratory bond-strength data obtained and the clinical retention rates collected on the clinical effectiveness of contemporary adhesives in non-carious Class-V lesions.[35] They found that in non- carious Class-V clinical trials, published between 1998 and 2009, the conventional 3-step etch & rinse adhesives and (mild) 2-step self-etch adhesives remained the benchmarks for dental adhesion in routine clinical practice, even though the adhesive technology had undergone great progress. This was due to the major drawbacks of all in one adhesive at that point of time.

The number of clinical trials in the literature for the new universal adhesive is limited. [34] There is certainly a need for clinical trials as they remain the ultimate way to collect scientific evidence on the clinical effectiveness of a restorative treatment. [34]

This study aims to evaluate the clinical effectiveness of universal bonding agent (GPremio bond) in selective etch and self etch mode, in restorating NCCLs over aperiod of 12 months.

Current adhesion strategies depend on how dental adhesives interact with the smear layer and are grouped into two basic categories: Etch-and-rinse (ER) strategy and self-etch (SE) strategy. [39] ER strategy involves complete removal of the smear layer and superficial hydroxyapatite through etching with a separate acid gel (commonly phosphoric acid) followed by infiltration of adhesive monomers that permeate the micro-porosities forming hybrid tissue known as the resin–dentin inter-diffusion zone or the “Hybrid Layer”. [39] In contrast, the SE strategy makes the smear layer permeable without removing it completely.[39] Self etch does not require a separate phosphoric acid-etch step, as acidic adhesive monomers are utilized to partially dissolve the smear layer, demineralize the underlying

dentin/enamel and the infiltration of monomers is achieved simultaneously.[39]

Although, clinical studies suggest that adhesives utilizing the ER strategy have superior clinical performance for load bearing restorations, many clinicians demand materials or strategies that are simpler and less technique-sensitive.[39] This demand has urged manufacturers to develop more user- friendly adhesive systems. [39] The newest of these are "Universal" or "Multi-mode" adhesives which provide dentists with the choice of selecting the adhesion strategy – ER, SE, or an alternative "selective enamel etching" (SEE) strategy, which is a combination of ER strategy on enamel and SE strategy on dentin. [39]

Despite similar composition to older SE adhesives, Universal Adhesives contain specific carboxylate and/or phosphate functional monomers. [39] The most notable of these monomers is 10-methacryloyloxydecyl dihydrogen phosphate (10-MDP or MDP), a phosphate monomer that bonds ionically to dentin, forming hydrolytically stable calcium salts on hydroxyapatite in the form of "nanolayering" which enhancesthe effectiveness and longevity of bonds. [39]

Studies have shown this bond to be more stable to hydrolytic degradation compared to bonding with other functional monomers because of lower solubility of calcium salts and long,hydrophobic spacer carbon chain.[35]

On the other hand, intermediately strong or strong SE adhesives bind to Ca ions from the hydroxyapatite and also demineralize the substrate producing more soluble Ca salts leading to weaker bond strength.[1]

In non-carious cervical lesions, the major part of the bonded tooth surface consists of dentin, while only at the incisal side, the adhesive restorative material is bonded to enamel. [34] Literature so far indicates that the most durable bond to enamel is obtained following an etch-and-rinse approach, signifying that the distinct enamel etch pattern created by phosphoric acid-etching is utmost important to achieve a durable bond to enamel.[34] When bonding to dentin, a mild self-etch approach is superior, as it involves additional ionic bonding with residual hydroxyapatite (Hap).[35] Hence **in this study** Universal Adhesive was chosen to check their adhesive capacity in selective etch and self etch mode technique.

While bonding to enamel, performing a bevel on the enamel margin may be a good option.[51]While some researchers consider the bevel a solution to improve the bonding of some etch-and-rinse and self-etch adhesive systems, other authors have stated thatthe bevel improves retention only during the first 6-months with no advantage over the non-beveled group after longer periods.[51]

A study done by LN Baratieri et al (2003) evaluated the performance of a 2-step etch-and-rinse adhesive placed in beveled and non-beveled NCCLs.[54] They concluded that beveled enamel margins resulted in significantly better clinical retention only in the first six months. Enamel beveling and composite viscosity appeared to not significantly affect the clinical performance of Class V non-retentive composite restorations after three years. [54] A study done by Thays Regina Ferreira Da Costa et al(2013) evaluated the effect of enamel bevel on the retention rates of composite restorations placed in non-carious cervical lesions (NCCLs) and concluded that enamel beveling may not be clinically relevant for the retention of composite restorations in NCCLs after 12 months.[51]

Peumans M et al (2005) conducted a clinical trial to evaluate the three-year effectiveness of a two-step self-etch adhesive in cervical lesions. They concluded that additional etching of the enamel cavity margins was not critical for its clinical performance.[53]

Therefore in **this study,** no bevel was placed on the occlusal enamel margin ofNCCLs while evaluating the clinical adhesive capacity of the bonding agent.

Problems with restoring NCCLs include difficulty in obtaining moisture control and gaining access to subgingival margins. Rubber dam clamps, gingival retraction cord and periodontal surgery are methods that can be used to retract and control the gingival tissues in order to facilitate access and control moisture. The exudation of gingival fluid is possibly one of the challenges to adhesion in cervical region, which is already impaired by other factors such as the absence of enamel in the gingival wall of the cavity and the characteristics of the dentin in NCCLs.

Gilbert et al (2010) in a practice-based study, collected data on 9890 consecutive restorations done on previously unrestored tooth surfaces from 5810 patients. Most dentists (63%) in this study did not use a rubber dam for any restoration. Rubber dam was used for only 12% of the restorations. They concluded that patient discomfort, insufficient time, technical difficulty, insufficient training, the cost and low fees for treatment were the reasons for not using a rubber dam in routine practice .[58s]Ryan O'Connell and Mala and others reported that almost 50% of the clinicians evaluated in a survey considered rubber dams difficult to apply for restorations of NCCLand almost 50% felt that adult patients do not like it.[55] Heintze and Rousson evaluated 105studies and rubber dam was used only in 47 studies . Although the clinical success rate of restorations applied with a rubber dam compared with cotton rolls/retraction cords showed a trend toward increased retention, the difference did not reach statistical significance.[7]

AD Loguercio et al (2015) evaluated the influence of isolation method of the operative field on gingival damage, patient's preference and restoration retention in noncarious cervical lesions They concluded that use of cotton rolls/retraction cordwas similar to the use of rubber dam isolation in terms of patient's preference, gingival damage, chairside time and retention rates of adhesive restorations in NCCLs.[55]

Cesar dos Reis Perez et al (2012) conducted a review on "Restoration of NoncariousCervical Lesions: When, Why, and How". They concluded that rubber dam isolationshould be used only whenever possible, as intrinsic anatomical and morphological characteristics of the cervical region create limitations in the placement of the rubberdam and clamp. They were of the view that when adequate rubber dam isolation is difficult or impossible- due to lesions extending proximally or under the gingiva, when part of the tooth structure cannot be isolated, when the dam promoted restorative material accumulation or when access was limited causing problems related to insertion of the restorative material, another isolation method could be employed. They suggested the insertion of non- impregnated retraction cords to helpin moisture control.

Since a number of studies have concluded that the use of rubber dam for isolation didn't have significant effect on the success of restoration in NCCLs compared tothe placement of retraction cord, in this study retraction cord was used. [58,55,7]

A study conducted by Van Meerbeek et al., on the comparison of SEM and TEM evaluation of resin-dentin bonding region, showed that dentin tubules orientation could have a significant effect on the hybrid layer morphology of etch & rinse adhesives. [43]In other words they concluded that the hybrid layer is thicker and the resin tags longer in case of the perpendicular (occlusal, floor) dentinal tubules. Parallel orientation of dentinal tubules (axial, wall) leads to the formation of thinner hybrid layer and absence of resin tags. [43] On the other hand, the tubular fluid flow (TFF) exposed on the dentin surface seems to interfere with the quality of the dentinal adhesive interface and may reduce the resin-dentin bond strength.[43]

The adhesive system should also be selected based on the substrate and the area inwhich the bonding occurs.[43]

A study by Zahra Khamverdi (2018) showed that orientation of dentin tubules led to no significant differences between the G-Premio and Single Bond Universal adhesives in terms of the micro tensile bond strength(μtbs). Adper Single Bond 2 had significantly higher micro tensile bond strength(μtbs) in (axial,wall) orientation, but showed micro tensilebond strength(μtbs) value similar to that of universal adhesives in (occlusal,floor) orientation, which was not statistically significant. [43]

This study compared and evaluated the clinical performance of a new universal adhesive in selective etch and self etch mode in restoring NCCLs. Self-etch (SE) adhesive systems have a simple bonding protocol.[1] The demineralization of the dental substrates is produced by a non- rinsing acidic primer and except in the case of some SE systems, the whole extent of the demineralized dentin depth is impregnated by resin monomers. They usually dissolve the smear layer and do not remove the dissolved calcium (Ca) phosphates.

When universal adhesives are used in self-etch mode, they prevent the collagen collapse by keeping the demineralized dentin moist. The hybrid layer consists of hydroxyapatite debris and the remaining smear layer. The residual dentin moisture depends on the solvent used in the bonding and clinician's performance.[43] Since thetotal demineralized dentin depth is impregnated with resin monomers, the self-etch adhesives are not technique sensitive and can be easily used in areas where it is difficult to completely control the little moisture present especially in posterior teeth.43

The presence of 10-MDP in the adhesive and chemical bonding to dentin is modulated by 2-hydroxyethylmethacrylate (HEMA) which is a part of the adhesive composition.[2] A study by Yoshida and others demonstrated that HEMA significantly reduced nanolayering, because it reduced the hydroxyapatite (HAp) demineralization rate, a prerequisite to the formation of MDP-Ca salts. HEMA interferes, but does not completely inhibit, MDP from interacting chemically with hydroxyapatite (Hap). **Butin case of G premio bond which was used in this clinical trial, HEMA is absent.**

In a study conducted by G Inoue et al (2006) to check the ultrastructure of both intactand caries affected dentin-adhesive interface after artificial secondary caries formation, using scanning electron microscopy and nanoindentation testing, an acid- base resistant zone (ABRZ) was observed beneath the hybrid layer in self-etch adhesive systems. They concluded that ABRZ was highly adhesive-material dependent and that ABRZ is formed only in self-etch adhesive systems but not in etch-and-rinse adhesive systems.

Although the formative mechanism is still unclear, it was assumed that the penetration of the monomers into the tooth tissue beyond the hybrid layer and the chemical interaction between the functional monomer and hydroxyapatite may contribute to the formation of ABRZ. [48] With regard to the ABRZ concept, it is recommended to avoid complete demineralization of dentin by using phosphoric acid, as the procedure compromises complete infiltration of monomers and reduces the chance of an effective chemical bonding and protection of apatite against acid-attack. [48]

Due to the components of self-etch adhesive systems, water sorption and solubility of the bonding resin are significant factors for the mechanical properties of the bonding layer.[48]

The bonding mechanism of self-etch adhesive systems has been intensely investigated and two-fold bonding mechanisms; micro-mechanical interlocking and chemical bonding were described, which seems to be advantageous in terms of restoration durability. [48] The micro-mechanical bonding contributes to provide strength against mechanical stress, while the chemical interaction reduces hydrolytic degradation, keeping the marginal sealing of restorations for a longer period. [48]It has been shown that some functional monomers in self-etch adhesive can chemically interact with the hydroxyapatite in the demineralized tooth layer within a clinically manageable time. [49]

Unfortunately, SE adhesives produce relatively low bond strength values and inferior 1 marginal adaptation to enamel when compared to ER systems.SE adhesives do not produce a retentive etching pattern on enamel, such as that produced by phosphoric acid, which may produce restorations with higher rates of marginal discoloration, a clinical problem in restorations. Although selective etching of enamel margins prior to the application of SE adhesives can minimize this limitation, an accidental dentin etching may occur and jeopardize bonding efficacy to dentin. Also few invitro studies have concluded that etch & rinse mode showed a higher micro tensile bond strength (μTBS) than the self-etch mode, which maybe attributed to the thickness of the hybridlayer. [43]

This inferior etching of self-etch systems may favor debunking at the margins,allowing the infiltration of food stains or bacterial biofilm leading to marginal pigmentation.

Due to the inadequate etching of self-etch adhesives, selective etching of enamel margins with phosphoric acid has been recommended prior to the application of self- etch adhesives.[63] While some positive effects were observed in some studies,[53,65,66] no significant difference was observed in others.[30,67] Differences in the long-term follow-up may be one of the reasons for such controversy, requiring further analysis of thesestudies to provide a clinical guideline for clinicians in the daily practice. The increase in the retention rates might be due to the higher anchorage that composite resins can get by the improved bonding of the self-etch adhesive systems to the etched enamel. Anna Szesz et al conducted a systematic review and meta-analysis on selective enamel etching in cervical lesions for self-etch adhesives. [64] They concluded that selective enamel etching prior to application of self-etch adhesive systems in NCCLs can produce composite restorations with higher longevity.[64]

In an eight year clinical trial, M. Peumans et al(2018) evaluated a 2-step self-etch adhesive with and without selective enamel etching and found that

following the self-etch approach marginal deterioration at the enamel side was significantly more compared to enamel which was selectively etched with phosphoric acid prior to application of universal adhesive[34]

As these materials are relatively new in the literature, few clinical trials have been conducted to evaluate their clinical performance.

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 ($p<0.05$). 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" (pH≈1.5) adhesive which shows a transition between "strong" and "mild" etching characteristics of the hybrid layer formed.[48] It has typically a hybrid layer withdemineralized top layer and partially demineralized base.[48]

G Premio bond consists of MDP, 4-MET, MEPS, BHT, acetone, dimethacrylate resins, initiators and water as the main components. The dihydrogenphosphate group from 10-MDP monomer is responsible for etching and chemical bonding, while its long carbonyl chain provides the hydrophobic properties and hydrolytic stability to this acidic monomer. 10-MDP forms a strong ionic bond with calcium from hydroxyapatite of enamel and dentin, also resulting in Ca- salt immediately and after long-term water storage.

MET - The 4-MET acts as demineralizing and an adhesion- promoting monomer due to the carboxylic groups attached to the aromatic group.[48] The two carboxylic groups are related to demineralizing properties and monomer infiltration, while the aromatic group provides the hydrophobic characteristics, which tends to reduce the acidity and the hydrophilicity from carboxyl groups. 4-MET monomer is able to form a ionic bond with calcium in hydroxyapatite, resulting in Ca-4MET salt. [48]

In addition, MDP could 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.[49]

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.[1] On the other hand, Selective enamel etching with SE adhesives can reduce marginal discoloration at the restoration interface after medium/long-term clinical service. In this case, micromechanical bond is responsible for the good retention of the adhesive so long as the material produces a well-impregnated hybrid layer and a strong polymer inside thehybrid layer.[1]

The results of the present study showed that after 12 months 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 stratergy. 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 increased expectations for adhesives more than anything else. However, the real test for these materials will be their performanceover longer periods of clinical service.

Even though the evaluation of parameters at the intervals was done by two evaluators, the values of one of the evaluator 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 asssesd at all time intervals. This may be because of short follow up time.

In this study selective etch group performed comparable to self etch group. But Percentage wise comparison showed that less changes were reported in the selective etch group compared to self etch group which can be attributed to the lower bonding ability of self-etch adhesives to unetched enamel than to etched enamel .So it can be concluded that selective etch has better properties than self etch group.

Regardless of the bonding strategy used, the present study observed deterioration of the marginal adaptation even at the short-term evaluation. Although different clinical trials have shown that marginal discrepancies of a composite restoration usually develop early, most of the marginal defects were small and clinically acceptable.[1]

While there is a general consensus that marginal defects can affect the final performance of resin composite restorations, no study has so far observed an association between marginal defects and loss of retention. Marginal defects can cause early marginal discoloration, which may jeopardize the restoration esthetics. Fortunately, restoration re-polishing can amend these discrepancies without causingany damage to the integrity of the restoration.[1]

The other factor to be considered in this study is the dropout rate of 22%. However, during the sample size estimation additional 30% samples were taken into account tomaintain 80% power at the end of the trial.

Clinical trials have greater value when published after long term follow-up. But any clinical trial for restoration of NCCLs provide information and points towards 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 (ADA) 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 non-carious cervical lesions which remains as the main limitation of this study.

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. But 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.

Summary

The purpose of the present study was to evaluate the clinical performance of a universal adhesive in selective etch and self etch mode in restoring non carious cervical lesions(NCCLs) based on modified USPHS criteria.

Patients were selected based on specific inclusion criteria and randomly allocated to anyone of the following groups in this prospective double blind randomized controlled clinical trial.

GROUP I – Universal adhesive in Selective enamel etch mode **GROUP II-** Universal adhesive in Self etch mode

After adhesive application, Genial flow(GC) nanofilled flowable composite was used to restore the NCCLs. The restorations were finished immedietly and polished one week after placement of the restorations.

The outcome was evaluated based on modified USPHS criteria for marginal discoloration, retention and postoperative sensitivity at intervals of 7days, 6 and 12months.

Descriptive statistics was performed to assess the proportion of each score of 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 the groups at different evaluation intervals. **Cohen's Kappa statistics** was used to assess the inter examiner reliability.

Results showed that there was no statistical significant difference between both the groups in marginal discoloration, retention and postoperative sensitivity. But there was difference between the selective etch and self etch with selective etch techniquegiving better results.

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