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Clinical Effectiveness of Composite Resin Bonded with Universal Adhesive for the Restoration of Non-Carious Cervical Lesions Using Air Abrasion: A Randomised Controlled Trial

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ABSTRACT

Restorative treatment is very challenging for non-carious cervical lesions (NCCLs) due to functional and structural complexities. The purpose of this randomised controlled trial (RCT) was to evaluate the clinical performance of nanocomposite restorations bonded using universal adhesive in self-etch mode with and without air abrasive surface treatment for NCCLs. A total of 70 NCCLs, from a group of consenting patients who fulfilled the inclusion criteria, were recruited for the study. The study was carried out following CONSORT guidelines. Block randomisation was done for equal allocation of lesions into; Group 1 (surface treatment with alumina air abrasion) and Group 2 (control group without mechanical surface treatment). The lesions were restored with nanocomposite using a universal bonding agent in self-etch mode. The clinical performance of the restorations was evaluated by two examiners using modified United States Public Health Service (USPHS) criteria at baseline, 3 months, 6 months and 12 months. A Chi-square test was performed for inter-group comparison. Cochran's Q test and Dunn's post hoc analysis were used for intra-group comparison. The inter-group comparison revealed no statistically significant difference between the experimental and control group for all the parameters assessed. With the intra-group analysis, it was found that there was a significant decrease in the performance of the restorations concerning marginal staining, marginal adaptation and surface texture during the evaluation period ($p < 0.05$). However, all of them demonstrated clinically acceptable performance. According to the results of this RCT, it was concluded that airborne particle abrasion of NCCLs did not improve the clinical performance of nanocomposite resin bonded using universal adhesive.

Keywords: *Air abrasion; dentinal sensitivity; non-carious cervical lesions; nanocomposite; universal adhesive system*

INTRODUCTION

Loss of tooth structure, at the cementoenamel junction (CEJ) or cervical area of the tooth, which is not related to dental caries, is referred to as non-carious cervical lesions (NCCLs). These lesions may be due to erosion, abrasion and abfraction (Bartlett & Shah, 2006). They present in a variety of forms, ranging from shallow grooves to broad dished-out lesions to large wedge-shaped defects (Levitch *et al.*, 1994; Bartlett *et al.*, 1999). The enamel layer is thinnest at the CEJ which makes it structurally weak (Aw *et al.*, 2002). The reported prevalence of NCCLs ranges from 5% to 85% regardless of form or etiology, and the wide disparity may be due to heterogeneous situations and the absence of a common diagnostic criterion (Levitch *et al.*, 1994).

Restoration of cervical lesions must be considered if the defect is not shallow, in case of sub-gingival lesions where plaque control is difficult, in conditions where non-invasive treatment for dentinal hypersensitivity has failed, in situations where the tooth is a candidate for prosthetic abutment for removable prosthesis, and also based on esthetic demands by patients (Peumans *et al.*, 2020). Composite resins, glass ionomer cement (GIC), or a combination of materials are commonly used for restoring NCCLs. However, composite resins are mostly preferred due to their favourable aesthetic and mechanical properties (Burgess *et al.*, 2004).

The treatment of cervical lesions can be challenging and studies have shown a range of restoration loss from 0% to 50% (Heintze *et al.*, 2010). The reason for this retention loss could be due to the fact that NCCLs have denatured collagen and hyper-mineralised dentin, which hinders substrate bonding. The elevated quantity of minerals, high degree of sclerosis causes difficulty in substrate adhesion which leads to retention loss. The formation of a hybrid layer is of prime importance for material adhesion (Ichim *et al.*, 2007). Cervical sclerotic dentin has more tubular deposits when compared to normal dentin which results in lesser resin penetration after acid etching. Dentinal tubules obliterated with crystalline deposits will be less effectively etched than normal dentin. To overcome this, chemical (EDTA or acid etchant), as well as mechanical treatment (air abrasion or diamond bur) of dentin surface before the application of the adhesive was proposed to improve the adhesion of resin composites (Flury *et al.*, 2015; Rocha *et al.*, 2018). Air abrasion involves a stream of much focused particles such as aluminum oxide being ejected onto a surface to roughen it. On the dentin surface, this pre-treatment step can increase the surface area as well as improve the adhesion by accentuating resin tag length (Freeman *et al.*, 2012; Lima *et al.*, 2021). Hence a randomised controlled trial (RCT) was designed to test the null hypothesis that air abrasion of NCCLs does not influence the clinical performance of nanocomposite restorations bonded with universal adhesive.

MATERIALS AND METHODS

This study was a RCT that evaluated the effect of air abrasion on the clinical performance of composite resin restorations in NCCLs. Institutional Ethical Committee clearance was obtained with a reference number of 18102. The study was registered in Clinical Trial Registry India with reference number CTRI/2019/01/016969. The clinical performance of the restorations was evaluated by two independent examiners using modified United States Public Health Service (USPHS) criteria at baseline, 3 months, 6 months and 12 months. This research was a double-blind RCT and followed the CONSORT guidelines (Schulz *et al.*, 2010).

Sample Size Calculation

A total of 17 patients with 70 NCCLs were enrolled in the study. The sample size was estimated based on the study by de Medeiros

et al. (2015). The effect size for the 1-year interval was 0.3 at 80% statistical power with a two-sided significance level of 5%. A sample of 32 teeth in each group was calculated. The final sample size for each group was set to 35 to account for 10% attrition.

Inclusion and Exclusion Criteria

All consented patients aged more than 18 years old with a minimum of two NCCLs per patient on the buccal aspect with a lesion depth from 0.5 to 2 mm and occluso-gingival height from 0.5 to 3 mm with good to fair oral hygiene and low caries index were included in the study. Teeth with cervical carious lesions, previously restored teeth, teeth with pulp and periapical disease, depth greater than 2.5 mm, occluso-gingival height greater than 3 mm, teeth with poor access and visibility, sub-gingival lesions, high caries index and patients allergic to composite restoration were excluded.

Pre-Operative Data Collection and Preparation

Each patient was explained about the study, treatment to be done and written informed consent was taken from the patient. Each patient was sent to the Department of Periodontology, for oral prophylaxis one week before the treatment. Before the treatment, the following parameters were recorded for each NCCL which included demographic data of the patient, location of the lesion, depth and occluso-gingival height of the lesion as well as the degree of sclerosis (Table 1). Degree of sclerosis was accessed visually, where the non-sclerotic dentin is non-opaque, slightly sclerotic dentin is opaque, moderately sclerotic dentin is yellow and severally sclerotic dentin is transparent (Van Landuyt *et al.*, 2008). Pre-operative sensitivity with compressed air was measured with Schiff's scale where the scoring is as follows: 0 = no response to air stimulus; 1 = mild response (where the subject does not request discontinuation of stimulus); 2 = moderate response (where subject requests discontinuation or moves away from air stimulus); 3 = severe response (where subject considers stimulus to be painful and requests its discontinuation) (Schiff *et al.*, 2009; Rocha *et al.*, 2020).

Randomisation

After the data were recorded, the operator was given a closed sealed envelope and treatment was done according to the sequence given in the envelope. In this RCT, a block randomisation method with a block size of four was used to equally assign the teeth to include in the study into two treatment groups. Microsoft Excel 2010 was used to generate the blocks. The two groups were Group 1 (with air abrasion) and Group 2 (without air abrasion). A total of 16 envelopes with a block size of four (e.g., AABB, ABAB, ABBA, BAAB, BABA, BBAA) were prepared by an investigator who was not involved in the implementation of the study. To conceal, the allocation was individually placed in opaque and sealed envelopes. This was opened by the operator immediately before intervention. Based on the sequence in an envelope, the teeth were assigned to either the study group (letter A) or the control group (letter B).

Restorative Procedure

At first the lesion of interest was cleaned free of debris or plaque using pumice slurry. Adjacent teeth were isolated with a mylar strip or Teflon tape. In the experimental group, the lesions were air abraded with alumina particles of 27 microns (μm), at 80 psi pressure, with the tip of the air abrasion unit (Prep start air abrasion system, Danville 200198-00REVM San Ramon, CA) placed at a distance of 1–2 mm in a sweeping motion. Adequate isolation was achieved with cheek retractors, cotton rolls, gingival retraction cord and high-volume suction. Universal bonding agent (3M ESPE single bond universal adhesive [ESPE Platz, Seefeld, Germany]) was then applied followed by restoration with nano-hybrid composite (3M ESPE, Filtek™Z350XT,

Table 1 Demographic data with characteristics of lesions

Serial no.	Category	Parameter	Group 1	Group 2	Chi-square value	*p*-value
1	Age (years old)	–	53.51 ± 6.40	53.035 ± 6.68	0.310	0.757
2	Sex	Male	21	17	1.711	0.425
		Female	14	18		
3	Oral hygiene status	Good	19	19	0.00	0.59
		Fair	16	16		
		Poor	–	–		
4	Teeth included	Anterior	10	11	0.13	0.99
		Posterior	25	24		
		Right	21	22		
		Left	14	13		
5	Occluso-gingival height	< 1.5 mm	16	11	8.56	0.05
		1.5–2.5 mm	14	24		
		> 2.5 mm	5			
6	Depth of the lesion	0.5–1.0 mm	8	11	3.16	0.21
		1.0–1.5 mm	22	23		
		1.5–2.0 mm	5	1		
7	Degree of sclerosis	No	30	28	0.40	0.38
		Slight	5	7		
		Moderate	–	–		
		Severe	–	–		
8	Occlusal wear facet	Yes	27	23	1.12	0.21
		No	8	12		
9	Antagonist tooth	Present	32	31	0.16	0.50
		Absent	3	4		
10	Parafunctional habits	Present	5	5	0.00	1.00
		Absent	30	30		

Universal Restorative syringe kit [3M Oral care, St. Paul, USA]) of desired shade as per manufacturer instructions. The excess was removed with Shofu composite finishing burs followed by finishing and polishing using Sof-Lex discs (3M Sof-Lex polishing discs system kit, [3M Oral care, St. Paul, USA]). The control group received similar treatment excluding the air abrasion. Patients were provided with post-operative instructions that needed to be followed.

Evaluation

Two evaluators, well experienced restorative dentists, who were not aware of the type of restorative procedure done, were calibrated about the evaluation using modified USPHS criteria (Ryge, 1980; Durão *et al.*, 2021) described in Table 2. Readings were recorded at the baseline, 3 months, 6 months and 12 months using the Williams periodontal probe (Hu-Friedy, Chicago,

IL, USA). When there was disagreement between the evaluators, they came to a consensus and a single score was recorded. Post-operative sensitivity with compressed air was recorded using Schiff's scale at baseline, 3 months, 6 months and 12 months.

Statistical Analysis

Statistical analysis was done using Statistical Package for Social Science (SPSS) software, version 20.0 (IBM software, SPSS Inc, Chicago IL). A Chi-square test was done for inter-group analysis to compare Group 1 (with air abrasion) and Group 2 (without air abrasion) at each time for retention, marginal staining, marginal adaptability, surface texture and gingival response. Level Cochran's Q test with Dunn's post-hoc analysis was done wherever applicable. Cochran's exact test was used when sample requirements were not met, for intra-group analysis at various time intervals i.e., between baseline, 3 months, 6 months and 12 months. The results were considered significant if the *p*-value was below 0.5.

RESULTS

The baseline characteristics of the teeth randomly allocated into experimental and control groups did not show a statistically significant difference (Table 1). Out of 70 samples, 65 samples completed the 12 months follow-up (32 in Group 1 and 33 in Group 2). One sample was lost at 3 months and two samples were lost to follow-up at 6 months in Group 1. In Group 2, a total of two samples were lost to follow-up at 3 and 6 months (Fig. 1).

The retention in this study had given clinically acceptable results; however, there was a loss of one restoration at 12 months period from Group 1. The inter-group comparison for retention was not statistically significant. Although marginal adaptation in the group decreased over one year, there was no statistically significant difference noted when comparing the groups ($p > 0.05$). Increased marginal staining was noted in both the groups at 6 and 12 months when compared to baseline. There was no

Table 2 Modified USPHS criteria

Category	Rating scale		Criteria
	Acceptable	Unacceptable	
Retention	A		Retained
	B		Partially retained
		C	Missing
Marginal staining	A		None
	B		Superficial staining (removable, localised)
		C	Deep staining (not removable, generalised)
Marginal adaptation	A		Closely adapted, no crevice is visible
	B		Crevice is visible, explorer will penetrate
		C	Crevice in which dentine is exposed
Surface texture	A		Smooth as the adjacent tooth structure
	B		Rougher than the adjacent tooth structure
		C	Rougher than the adjacent tooth structure and contains pits
Gingival response	A		Absence of inflammation
	B		Mild inflammation
		C	Moderate or severe inflammation
Recurrent caries	A		None
		C	Present

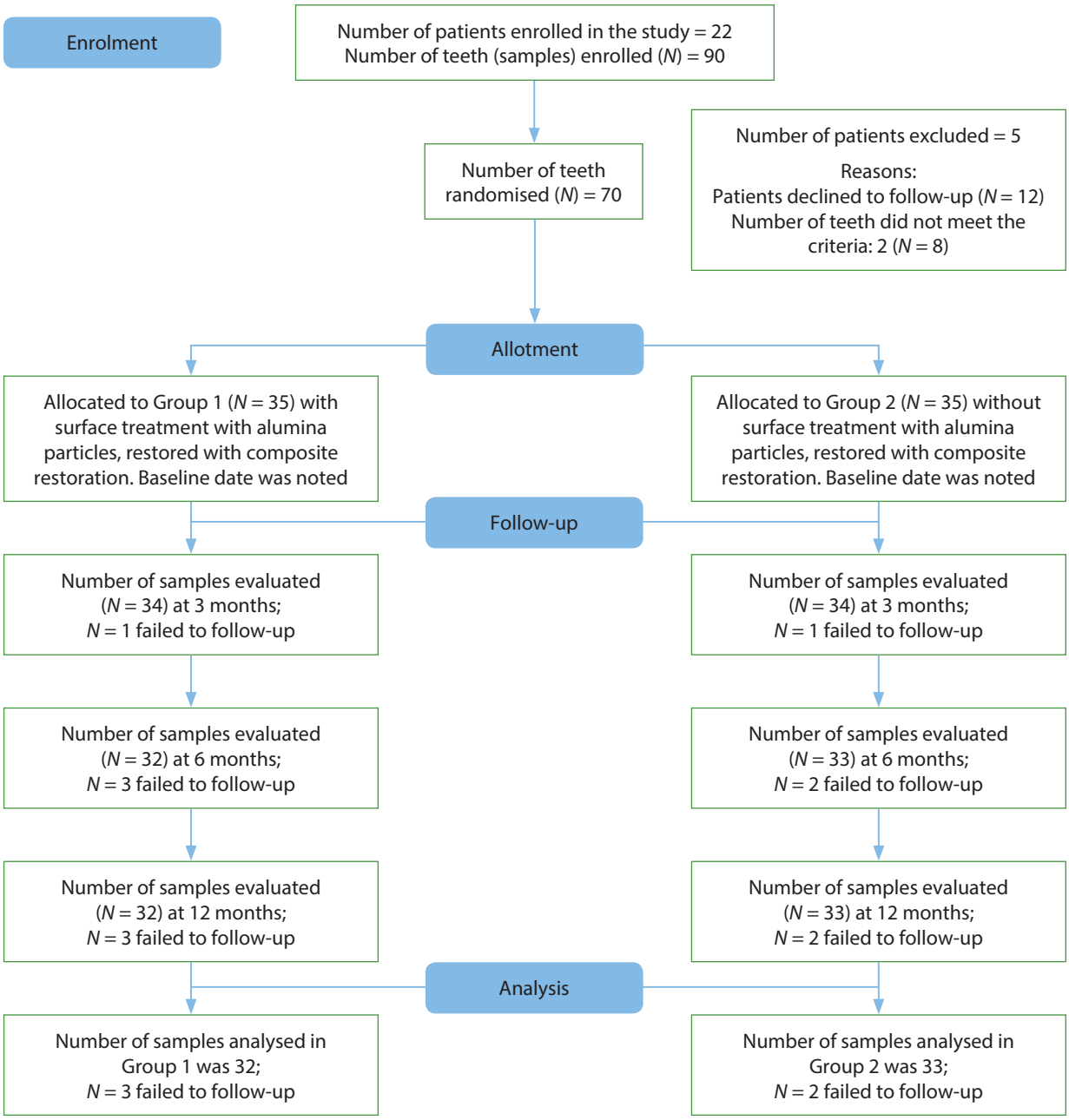

Fig. 1 CONSORT flow chart.

statistically significant difference noted with inter-group comparison (Table 3). None of the samples demonstrated secondary caries during the period of evaluation. The gingival response concerning all the samples was in the acceptable range and there was no significant difference between the groups. There was a marked reduction in dentinal sensitivity post-operatively and it was maintained throughout the follow-up period (Fig. 2).

Table 3 Comparison of restorations in the treatment groups using modified USPHS at various time intervals

Evaluation criteria	Score	Group 1 (with air abrasion)					Group 2 (without air abrasion)					Inter-group comparison (*p*-value)
		Baseline	3 months	6 months	12 months	Intra-group comparison (*p*-value)	Baseline	3 months	6 months	12 months	Intra-group comparison (*p*-value)	
Retention	A	32	32	30	29		33	33	32	32		Baseline (NA) 3 months (NA) 6 months (0.61) 12 months (0.36)
	B	–	–	2	3	0.06	–	–	1	1	1.00	
	C	–	–	–	–		–	–	–	–		
Marginal staining	A	31	16	11	7		33	19	14	9		Baseline (0.49) 3 months (0.62) 6 months (0.61) 12 months (0.76)
	B	1	16	21	25	<0.001	–	14	19	24	<0.001	
	C	–	–	–	–		–	–	–	–		
Marginal adaptation	A	27	18	12	8		29	19	14	9		Baseline (0.73) 3 months (1.00) 6 months (0.80) 12 months (1.00)
	B	5	14	20	24	<0.001	4	14	19	24	<0.001	
	C	–	–	–	–		–	–	–	–		
Surface texture	A	29	23	18	17		30	24	20	17		Baseline (1.00) 3months (1.00) 6 months (0.80) 12 months-1.00
	B	3	9	14	15	<0.001	3	9	13	16	<0.001	
	C	–	–	–	–		–	–	–	–		
Gingival response	A	29	29	28	27		30	31	31	29		Baseline (1.00) 3 months (0.67) 6 months (0.43) 12 months (0.73)
	B	3	3	4	5	0.50	3	2	2	4	0.53	
	C	–	–	–	–		–	–	–	–		

Note: NA – Not applicable

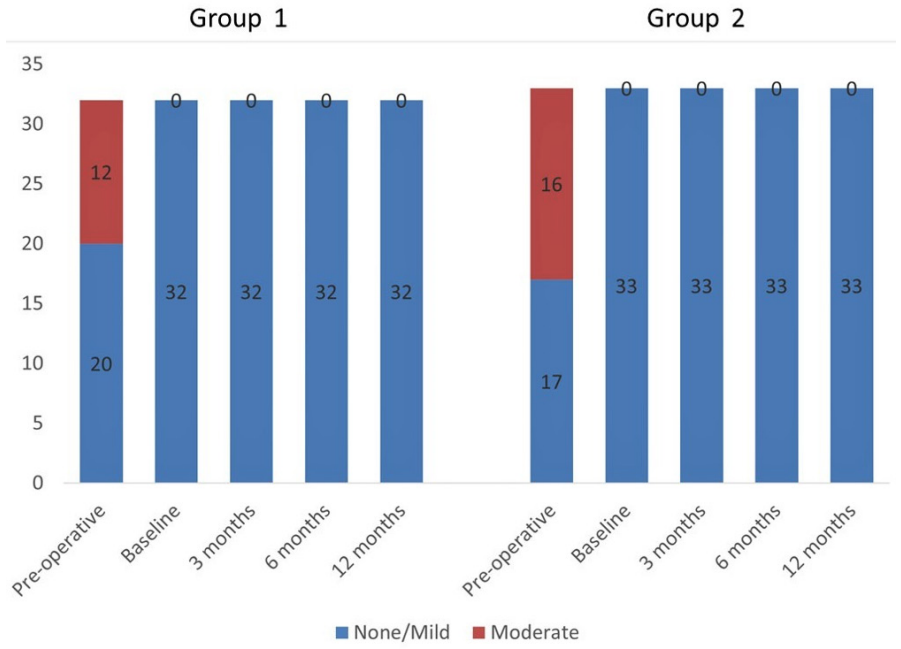

Fig. 2 Graph representing dentinal sensitivity pre-operatively and during subsequent follow-ups (*Teeth with severe response [score 3] were excluded pre-operatively and none of the teeth at baseline and during follow-up showed moderate [score 2] to severe [score 3] response).

DISCUSSION

The mean age of the participants in this study was approximately 53.51 ± 6.40 in Group 1 and 53.03 ± 6.68 in Group 2. This was in agreement with the systematic review and meta-analysis done by Teixeira *et al.* (2020). The etiology of these lesions is multi-factorial like age, parafunctional habits, faulty occlusion, etc. According to Pegoraro *et al.* (2005), these lesions had a positive correlation with occlusal wear facets compared to age, para-functional habits and orthodontic treatment which supports the present study with 50 out of 70 lesions were reported with occlusal wear facets.

Restoration of NCCLs remains a huge challenge for dental professionals. The innate nature of the lesion coupled with the interaction of the filling material and tooth structure along with the external factors make cervical lesions restoration an uphill task. NCCLs have a non-retentive cavity shape and margins are located on dentin or cementum, which are unfavourable for bonding (Kubo *et al.*, 2013). The degree of sclerotic lesions which were included in this study was mild i.e., only 12 out of 70 lesions were under less than 50% category. These lesions have denatured collagen and hyper-mineralised dentin. The inter-tubular dentin is sclerotic and has high mineral content. In addition to this, bacteria occasionally infiltrate the partially mineralised matrix of the dentin. Tubular occlusion with sclerosed dentin and minerals is difficult to etch compared to normal dentin. These inherent properties make the formation of a hybrid layer difficult, which is of prime importance for material adhesion. Conflicting with this observation, Correia *et al.* (2020) in their systematic review concluded that there is no effect of dentinal sclerosis on the adhesive system and retention of the restoration. NCCLs have a relatively small C-factor, meaning the mechanical properties of the composite are less important to the outcome than the actual performance of the adhesive. Indeed, several clinical studies showed that the type of composite used (hybrid, micro-filled, or flowable) did not influence the bonding performance of adhesives in NCCLs (Peumans *et al.*, 2020).

In the present study, the self-etch mode was used in both groups. These adhesive systems modify the "smear layer" leading to an increase in the bond strength between dentin and restoration (Ruschel *et al.*, 2018). Due to the incomplete removal of the smear layer, SE adhesives exhibit a marked reduction in postoperative sensitivity (Freeman *et al.*, 2012). The universal adhesive system with acidic monomer and 10-methacryloyloxydecyl dihydrogen phosphate (10-MDP) is believed to have a strong affinity to hydroxyapatite crystals which helps in the chemical bonding.

Air abrasion's role as a surface modifier or for mechanical etching is contentious. Few studies have suggested that there is no additional effect after using air abrasion and contrarily, there are studies in favour of air abrasion (Huang *et al.*, 2019; Lima *et al.*, 2021). Roeder *et al.* (1995) concluded that when air abrasion was used for enamel or dentin preparation, it did not alleviate the need for acid etching before bonding. A study conducted by Hannig & Femerling (1998) to assess the effect of air abrasion when used before adhesive systems concluded that treating tooth surface with air abrasion before application of bonding agent and restoring the tooth resulted in increased resistance against stress developed due to polymerisation shrinkage at the dentinal surface. The present literature available does not provide a conclusive opinion on the usage of air abrasion. Further studies with better methodology and larger sample sizes are needed (Banerjee & Watson, 2002). On the contrary, Lima *et al.* (2021), in their systematic review and meta-analysis on how airborne-particle abrasion (APA) using aluminum oxide affects the bond strength of resin-based materials to dentin concluded that APA has no negative effects on the bond strength of resin-based materials to dentin and that a positive influence on dentin bond strength was only achieved in specific APA conditions.

The clinical evaluation of the present study was done using modified USPHS criteria. The sample of the test group had shown a 98% retention rate with a loss of one restoration, which could be because of the depth and increased occlusal stress, flexural forces and strain. In the control group, the retention rates were 100% at 3 months, 6 months and 12 months. These results were similar to a previous study by Burgess *et al.* (2013) that showed a 93.3% retention rate at one year. According to Du *et al.* (2020), the strain at the cervical margins decreased with an increase in defect depth, the effect was significant when the depth of the lesion was 1.5 mm. As the majority of lesions included in this study were up to 2 mm in depth, this factor may also have contributed to the higher retention rates. In a systematic review done by Peumans *et al.* (2014), retention rates at one year were similar to the present study.

One of the foremost disadvantages of self-etch adhesives is poor adhesion to unprepared enamel surface leading to marginal discolouration, due to the mild acidity of these adhesives when compared to phosphoric acid (Perdigão & Geraldeli, 2003). Following the previous studies, marginal staining showed a statistically significant reduction over the 12 months follow-up period. Low pH adhesives showed higher marginal staining compared to high pH adhesives due to their dissolving ability (Peumans *et al.*, 2014). Moreover, patient factors such as oral hygiene, and diet also play a role in discolouration of the restoration. Marginal discolouration of restorations maybe because of marginal micro gaps at the tooth-restoration interface. The marginal discolouration is the first sign that the restoration is prone to failure. It is the most common reason for replacement of restoration rather than retention loss. Periodic monitoring of staining is advised to increase the durability of the restoration (Kubo *et al.*, 2013). Intra-group comparison of marginal adaptation showed a statistically significant reduction in both the groups which is in harmony with earlier studies. The relationship between marginal staining and marginal adaptation was indicated in

previous studies (Van Landuyt *et al.*, 2008; Ruschel *et al.*, 2018). Another possibility associated with a crevice along the marginal interface could be a direct result of a fracture of a slightly overlapping marginal excess. Shrinkage stress, the effect of cavity geometry on C-factor, butt joint occlusal margin and self-etch adhesive may also be involved (de Andrade *et al.*, 2011).

Smooth surface texture similar to adjacent tooth structure was achieved at baseline both in the control and test groups. Inter-group comparisons at baseline, 3 months, 6 months and 12 months post-operatively were statistically not significant. The intra-group comparison showed a significant reduction in smoothness at 3 months, 6 months and 12 months. Qin *et al.* (2013), in a 2-year clinical evaluation of the performance of composite with Clearfil AP-X and Filtek Z350 in NCCLs, obtained results like the present study in terms of surface texture, retention and marginal discolouration. Results obtained in this randomised trial were similar to the previous studies in terms of clinical parameters.

The clinical efficacy of composite resin restorations of NCCLs was not improved by air abrasion. Hence the null hypothesis of the present study had to be accepted. Aluminum oxide of 27 μm particle size was used at a distance of 0.5–2.0 mm as recommended by Banerjee *et al.* (2000) and Hegde & Khatavkar (2010), in their review on air abrasion. Lima *et al.* (2021) in their systematic review had suggested the use of particle size greater than 30 μm to improve dentin bonding. The distance from the tip to the tooth surface can also be one of the factors that did not show the effect on surface treatment. Chinelatti *et al.* (2007) had concluded from their study that a 6–8 mm distance from tip to tooth surface had given better results on dentin adhesive interface compared to 2 mm and 4 mm. Therefore further clinical studies evaluating the effect of varying the air abrasion distance, pressure and particle size on the performance of composite restorations is warranted.

The shortcoming of this study was that the follow-up period and the lesions included were inadequate. Additionally, the shape of the lesions was not categorised. Preventive and maintenance therapy could have been considered in this study. For future trials, it would therefore be more appropriate to have a larger sample size and a longer follow-up period to evaluate the effect of air abrasion for the treatment of cervical lesions.

CONCLUSION

There was no difference in the clinical performance of nanocomposite resin bonded with universal adhesive in lesions treated with or without air abrasion using 27 μm alumina particles. Therefore, APA of NCCLs with 27 μm alumina does not provide an additional advantage, and such a step can be eliminated. Nanocomposite resin restoration bonded with a universal bonding agent in self-etch mode when used for restoring NCCLs showed clinically acceptable performance over a one-year follow-up period. Though there was a significant reduction in marginal integrity and an increase in marginal staining and surface roughness of the restorations over the one year of evaluation, all of them were clinically acceptable. The use of a universal bonding agent in the self-etch mode provided good retention for the restorations. There was also a significant reduction in dentinal sensitivity post-restoration, until the period of evaluation.

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