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Randomized Clinical Trial

The effect of ethanol wet bonding technique on postoperative hypersensitivity of Class II composite restorations: A randomized trial

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ABSTRACT

Background: To evaluate the effect of Ethanol Wet Bonding Technique (EWBT) on postoperative hypersensitivity (POH) of composite restorations in premolar teeth.

Materials and Methods: In this randomized trial, 24 patients with at least three proximal carious lesions with similar axial depth and position of gingival floor in their premolars were enrolled. Following cavity preparation, the teeth were randomly assigned to one of three groups: (1) Class II resin-based composite (RBC) restoration using an etch-and-rinse adhesive + wet bonding technique (Control); (2) RBC restoration using EWBT + hydrophobic adhesive; and (3) RBC restoration using EWBT + hydrophilic adhesive. Tooth hypersensitivity was evaluated before and 1, 3, 7, 14 and 30 days after treatment according to the Visual Analog Scale. Data were analyzed statistically with Kruskal–Wallis and Friedman tests ($P = 0.05$).

Results: All teeth showed similar levels of hypersensitivity after treatment (both $P > 0.05$). Furthermore, there was no difference between POH levels of the test and control groups at any control period ($P < 0.05$). Friedman test indicated that the POH significantly reduced within time in all groups ($P < 0.05$).

Conclusion: Application of ethanol-wet bonding technique, either with hydrophobic or hydrophilic adhesives did not affect the POH of Class II composite restorations in premolars.

Key Words: Adhesives, dental caries, dentin, ethanol

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INTRODUCTION

Postoperative hypersensitivity (POH) can be defined as a pain associated with mastication or with sensitivity to thermal and sweet stimuli that occurs in a tooth 1 week or more after restoration.[1] POH is a common problem, especially when composite materials are used.[2] Although POH is multifactorial in nature, gap formation between the restoration and tooth structure is the main reason for its occurrence. This gap is commonly the result of polymerization shrinkage of composite materials, which can cause the movement of fluid and chemical substances down to dentin tubules, resulting in hypersensitivity. Ultimately, these gaps can also lead to microleakage,

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induce recurrent caries, degradation of the resin-dentin bond; reducing the bond strength over time.[1]

Water Wet Bonding Technique (WWBT) was introduced by Kanca *et al*.[2] to overcome the drawbacks of dry bonding technique, which may result in incomplete resin infiltration into demineralized, over-dried dentin when etch-and-rinse adhesive systems were applied.[3] However, recent studies concluded that adhesive resins cannot completely replace the water from interfibrillar spaces,[4-6] and the remnant water may plasticize adhesive resins or hydrolyze the exposed collagen fibrils, which may affect the long-term survival of resin-dentin interface.[7,8]

To address this issue, some researchers described the Ethanol Wet Bonding Technique (EWBT) where water is replaced by ethanol, a polar solvent. Ethanol can chemically dehydrate the demineralized collagen matrix and expand the interfibrillar spaces through shrinkage of collagen fibrils.[9,10] This results in improvement of resin penetration in exposed collagen fibrils and dentinal tubules. Furthermore, replacement of water with ethanol leads to less hydrophilicity of the collagen matrix, and thus, more hydrophobic adhesive can be used in ethanol saturated dentin which may improve the bond durability.[9,11,12] Two methods have been suggested for presenting ethanol to the matrix network. In the first method, increasing concentrations of ethanol are used for replacing water. Considering the fact that using increasing concentrations of ethanol in clinical situations is impractical,[7] another method known as "simplified ethanol dehydration" has been suggested. In this technique, absolute ethanol (100%) was applied for 1–3 steps.[13] It should be considered that the application of EWBT has no adverse effect on human pulp. Scheffel *et al*.[14] demonstrated that the response of human pulp to EWBT is the same as WWBT and only mild inflammation was observed.

In addition to the loss of bond durability over the time, exposed collagen at the base of hybrid layer called "hybridoid layer" can also result in hypersensitivity.[5] Some studies concluded this "hybridoid layer" may increase postoperative sensitivity in etch-and-rinse adhesive in comparison with self-etch ones. Because in self-etch adhesives, simultaneous demineralization and resin infiltration are observed and hybridoid layer may not form.[15,16] Improvement of resin infiltration through EWBT may reduce the POH of composite restorations. Accordingly, the aim of this study was to evaluate the effect of Ethanol-wet bonding technique on POH of Class II composite restorations. The null hypothesis was that the application of Ethanol-wet bonding technique, either with hydrophobic or hydrophilic adhesives had no effect on the POH of Class II composite restorations.

MATERIALS AND METHODS

Study design and participants

For this randomized, double-blind prospective clinical trial, the patient referred to Restorative Department of Mashhad Dental School. The study protocol was approved in the committee of medical ethics of Mashhad University of Medical Sciences (IR. mums. REC.1394.23) and informed consent forms were signed by all participated patients and registered in Iranian Registry of Clinical Trials (registration code # IRCT 201111288[24]2N1) on September 27, 2016. Twenty-nine patients from both genders, ranging from 18 to 35 years of age (mea$n$ = 27 ± 2.17) participated in the study.

For patients, who accepted to participate in the study, the inclusion criteria were:

1. In preoperative bite-wing radiographies:
   a. The existence of three proximal carious lesions in three premolar teeth that did not extent over ½ thickness of dentin and the gingival floor were above cementoenamel junction (CEJ)
   b. Only one proximal surface should be decayed, and no previous restoration should be on these teeth.
2. Ability of perform suitable isolation the tooth for composite restorations.

The exclusion criteria were as follows:

1. Moderate-to-severe periodontitis, gingival recessions, and poor oral hygiene
2. Bruxism or clenching
3. High dental caries risk
4. Xerostomia
5. Unable to make suitable isolation for composite restoration
6. Extension of gingival floor was at CEJ or under CEJ in one of the prepared cavities
7. The depth of axial wall was more than 1.5 mm in one of the prepared cavities.

The preoperative sensitivity was evaluated by the Visual Analog Scale (VAS). For this purpose, the adjacent teeth were isolated with putty, cold stimulation (Cold Spray Endo-Ice, Coltène/Whaledent

Inc., 235 Ascot Pkwy, Cuyahoga Falls, OH 44223, United States) was performed for 2s at the midbuccal level of the tooth crown, and the patients were asked to grade their sensitivity on a 0–10 scale ranging from "no sensitivity" to "unbearable sensitivity." Prior to treatment, those with moderate-to-severe sensitivity (Score 3≤) were excluded from the study.

A total sample size of 24 patients/teeth for each group will be effective to observe an effect size of 0.57 with a power of 80% and a significance level of 5% using Java applets for power and sample size.

Restorative procedure

Seventy-two restorations were placed in 24 patients. Following local anesthesia, tooth shade was selected by using Vita shade guide before rubber dam isolation. Thereafter, the cavities were prepared using a #245 diamond fissure bur (Sun Shine, Dental Burs, CA, USA) and the residual carious tissue was removed by a round bur (Sun Shine). The teeth were included in the study after cavity preparation if:

a. The gingival wall was located approximately 1.0 mm above the CEJ, axial depth was 1–1.5 mm and buccolingual extension of the cavity was 1/2–2/3 of intercuspal width
b. The restorative procedure did not require indirect or direct pulp treatment
c. The cavity extensions were evaluated with periodontal probe and if they had not one of conditions mentioned above, the patient was excluded from the study.

The restoration procedures for all cavities were the same except for bonding application techniques. Following cavity preparation, a sectional metal matrix (Palodent PLus, Dentsply, Milford, Connecticut, USA) and a wooden wedge were placed. The enamel and dentin surfaces were acid etched with 32% phosphoric acid gel (Scotchbond Etchant, 3M ESPE, ST. Paul, USA), for 30 s and 15 s, respectively, and were rinsed off for 20 s and gently dried for 5s with oil-water free air spray. In each patient, the selected teeth were randomly allocated into the following groups: (1) Class II resin-based composite (RBC) restoration using a hydrophilic etch-and-rinse adhesive (Adper Single Bond 2, 3M ESPE, ST. Paul, USA) + WWBT (Control); (2) RBC restoration using EWBT + hydrophobic adhesive (Margin Bond, Coltène/Whaledent, Altstätten, Switzerland); (3) RBC restoration using EWBT + hydrophilic adhesive (Adper Single Bond 2).

For randomized allocation of teeth for different groups, the teeth number are put in pocket and patients were asked to select one by one. The first selection is assigned to control group, second one to EWBT + hydrophilic adhesive, and the last one to EWBT + hydrophobic adhesive. In this study, the patient and postoperative sensitivity examiners were blinded to experimental groups.

Indeed, the adhesive application in the control group was according to manufacturer's instruction. For the ethanol-wet procedure, the cavity was gently dried with cotton pellets, and the dentin surface was treated with ascending concentrations of ethanol (70%, 80%, 90%, and 100%). Each concentration was applied for 20 s. The cavity was filled with each concentration of ethanol and then gently air dried.

The adhesive was applied in strict accordance with manufacturer's instructions and light cured for 20 s with a Blue Phase C8 (Ivoclar Vivadent, Schaan, Liechtenstein) light-curing unit with an intensity of 500 mW/mm^2.

The cavities in all experimental groups were restored with Filtek Z350 composite (3M ESPE, ST. Paul, USA) in an initial increment of 1.0 mm at the gingival wall. Other increments were placed with thickness of up to 2 mm. Each resin composite layer was light cured for 40 s. After matrix removal, the teeth were postcured buccally and lingually each for 20 s. Finally, finishing and polishing procedures were performed using fine grit diamonds (Sun Shine) and polishing rubber points (Ultradent, Inc., South Jordan, Utah, USA). All restoration margins were etched again for 10s, margin bond was applied and light-cured for 20 s. All clinical procedures were carried out by one experienced, calibrated operator.

The patients were provided oral hygiene instructions and were asked not to use fluoride mouthwashes. Also, the patients were instructed not to use analgesics and anti-inflammatory drug during the study. Those patients with severe postoperative pain or complaints were excluded from the study.

Postoperative evaluations

The patients were recalled 1, 3, 7, 14 and 30 days after treatment. As previous studies, the cold stimulation was used for evaluation of POH.[17,18] A calibrated independent examiner, blinded to treatments applied a cold stimulus as same as before treatment, after which the patients were asked to complete VAS forms. Furthermore, all patients were asked to have any sensitivity to cold or hot; spontaneous pain and pain during the mastication.

Statistical analysis

The normal distribution of data was not confirmed by Kolmogorov–Smirnov test [Table 1]. The data were processed using the SPSS version 11.5 software (SPSS Inc. Chicago, IL, USA). Data of three groups were analyzed using Kruskal–Wallis and Friedman tests with the level of significance set at 0.05.

RESULTS

Initially, 29 patients were recruited to the trial. By the 30-day recall period, 24 patients were available. Five patients were unable to attend recalls [Figure 1].

The VAS scores are presented in Table 2. as mean and standard deviation, Kruskal–Wallis test indicated no significant differences in sensitivity among the three groups at baseline evaluation (P = 0.169). Similarly, there were no significant differences among the experimental groups at different POH evaluation times [P = 0.454 for 24 h, P = 0.324 for 3 days, P = 0.169 for 1 week, P = 0.124 for 2 weeks, and P = 0.122 for 30 days, Figure 2].

In all experimental groups, postoperative sensitivity increased in 24 h, and then gradually decreased in different evaluation times [Figure 3]. Friedman test indicated significant differences in postoperative sensitivity evaluated in different times for each group (P < 0.001).

CONCLUSION

The presence of water is essential for MMP activity. Thus, elimination of water can inhibit MMP enzymes, which may be activated during acid-etching of dentin. This procedure also prevents phase separation of hydrophilic resin monomers. Sadek *et al.*[19] showed stable bond strength and dentinal bond integrity for hydrophobic resins through EWBT after a year. They concluded that less water sorption and more resin penetration are the main reasons for a durable bond. Polymerized hydrophobic resins showed 5 times less water sorption than those of hydrophilic resins.

The null hypothesis could not be rejected by the results of this clinical trial. Ethanol wet bonding, in conjunction with either hydrophilic or hydrophobic adhesives, had no significant effect on POH. Although WWBT is the standardized method for etch-and-rinse

Table 1: The results of Kolmogorov-Smirnov test

Time groups	*P*
Baseline	
Hydrophilic	0.003
Control	<0.001
Hydrophobic	0.001
24 h	
Hydrophilic	0.209
Control	0.619
Hydrophobic	0.092
3 days	
Hydrophilic	0.461
Control	0.187
Hydrophobic	0.101
1 week	
Hydrophilic	0.068
Control	0.220
Hydrophobic	0.047
2 weeks	
Hydrophilic	0.028
Control	0.113
Hydrophobic	0.011
30 days	
Hydrophilic	<0.001
Control	<0.001
Hydrophobic	<0.001

Table 2: The mean values of postoperative sensitivity scores with respect to time (Visual Analog Scale scores)

Time groups	*n*	Minimum	Maximum	Median	Mean±SD
Baseline					
Hydrophilic	24	0.00	6.00	00.00	1.43±0.43
Control	24	0.00	8.00	00.00	0.64±0.39
Hydrophobic	24	0.00	6.00	00.00	0.83±0.33
24 h					
Hydrophilic	24	0.00	7.00	2	2.95±0.43
Control	24	0.00	10.00	3	3.12±0.58
Hydrophobic	24	0.00	6.00	1	2.29±0.47
3 days					
Hydrophilic	24	0.00	7.50	2	2.29±0.48
Control	24	0.00	10.00	2.25	3.11±0.67
Hydrophobic	24	0.00	5.00	1	1.54±0.34
1 week					
Hydrophilic	24	0.00	9.00	1	2.20±0.52
Control	24	0.00	9.00	1	2.04±0.48
Hydrophobic	24	0.00	9.00	0.25	1.12±0.39
2 weeks					
Hydrophilic	24	0.00	10.00	0.625	1.75±0.56
Control	24	0.00	9.00	0.375	1.46±0.43
Hydrophobic	24	0.00	6.00	00.00	0.55±0.25
30 days					
Hydrophilic	24	0.00	3.00	0.0	0.26±0.13
Control	24	0.00	2.00	0.0	0.47±0.43
Hydrophobic	24	0.00	0.50	0.0	0.03±0.02

SD: Standard deviation

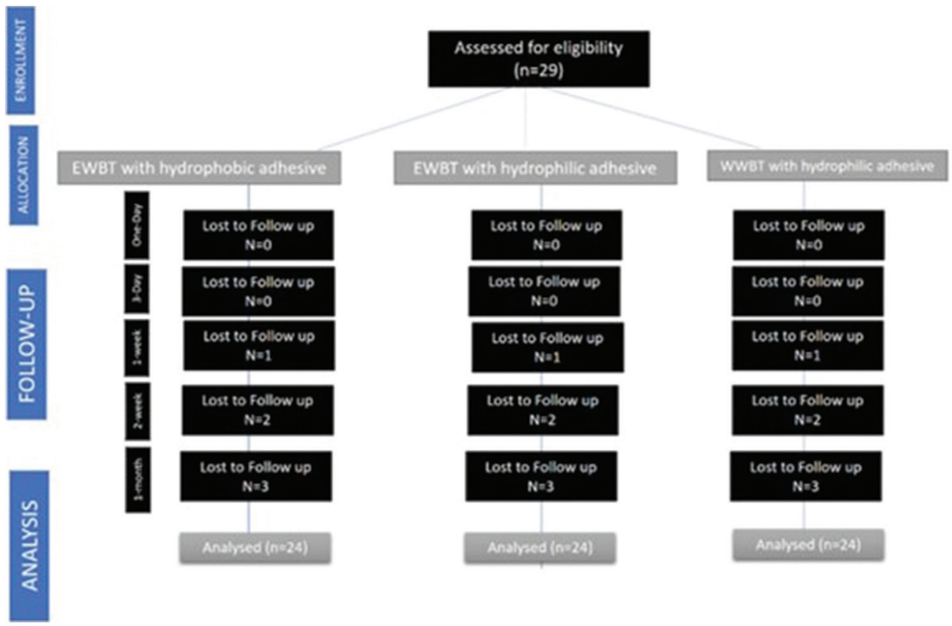

Figure 1: Flow of participants and follow-up to 1 month.

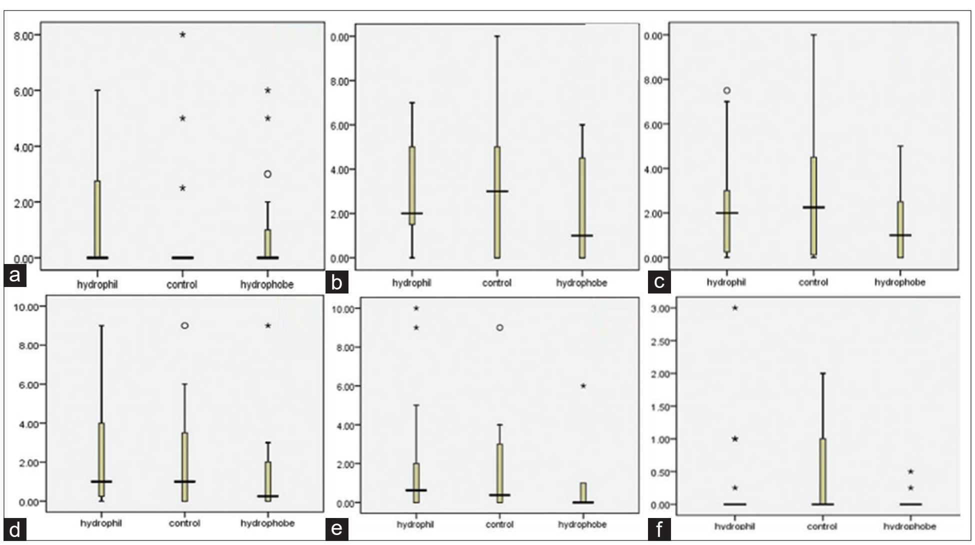

Figure 2: Box plots of postoperative sensitivity scores of experimental groups; (a) at baseline, (b) at 24 h, (c) at 3 days, (d) at one week, (e) at two weeks, (f) at 30 days.

adhesives, many studies show incomplete resin penetration into the demineralized dentin, which in turn, may degrade bond durability. Also, incomplete resin infiltration can decrease the bond strength and dentinal seal by creating a weak zone at base of the hybrid layer. So, the bacteria and their product may enter the dentinal tubules and produce the pulp irritation or tooth sensitivity. Furthermore, presence of voids in the hybrid layer can lead to outward movement of dentinal fluid under functional stress or thermal stimulus. This rapid movement can be interpreted as pain.[20,21]

Marginal gap usually occurs in Class II composite restorations with cervical margins located under the CEJ. This can be due to polymerization shrinkage stress or a mismatch of thermal expansion or elastic modulus between the tooth and restoration materials, which raise concerns about marginal microleakage and POH.[22] Hence, in the current study, the teeth with gingival margins placed 1.0 mm above the CEJ were selected.

The penetration of hydrophobic monomers into the dehydrated-yet fully extended-collagen matrix may be improved by EWBT.[23] Shin *et al*.[24] demonstrated

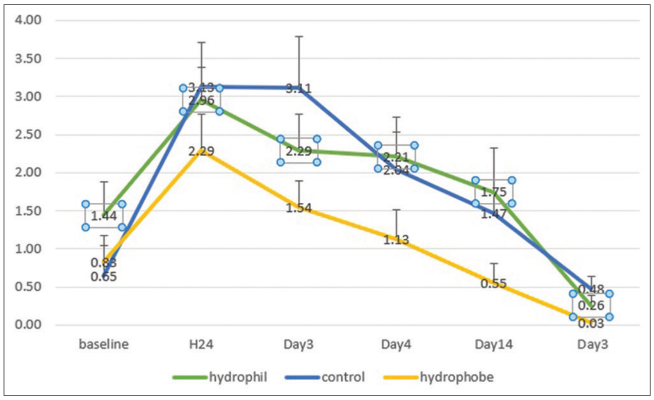

Figure 3: Mean values of postoperative sensitivity scores at different evaluation times.

the gradual decrease in Bis-GMA infiltration in WWBT, whereas relatively homogenous distribution of hydrophobic Bis-GMA occurred in dentinal interface in EWBT. They concluded that utilization of EWBT in corporation with hydrophobic adhesives may improve bond durability due to reduction in collagenolytic activities in dentin.

The more an adhesive penetrates through demineralized collagen fibrils, better the quality of hybrid layer to overcome dissolution and microleakage. This can produce better sealing properties and reduce POH in teeth restored with composite. The results of the current study demonstrated that application of ethanol wet bonding with ascending concentrations may decrease POH but this reduction was not statistically significant.

Although several *in vitro* studies demonstrated better hydrophilic or hydrophobic resin infiltration with EWBT in comparison with WWBT, in clinical conditions positive pulp pressure may affect resin infiltration by the presence of water at the base of hybrid layer.[25] The results of a study by Kuhn *et al*.[26] were consistent with the current study in which they concluded that clinical performance of EWBT is not the same as *in vitro* conditions. They found that positive pulp pressure can prevent infiltration of hydrophobic resin when EWBT was used in clinical condition. Water and proteins present in dentinal fluid can contaminate boning procedure. In the laboratory, this pressure is absent or not high enough when the pulp pressure is simulated. In some studies, the application of hydrophobic adhesives along with tubular occluding agents such as oxalate or poly-glutamic acid during EWBT improved the bond strength and significantly reduced nanoleakge.[27] Chen *et al*.[23] evaluated bond strength and micropermeability of EWBT under simulated pulp pressure and concluded that EWBT should be applied for at least 2 min to improve the bond strength or decrease microleakage. As the application time of EWBT increased, the bond strength increased and dentin micropermeability decreased.

The presence of pulp pressure and application time of EWBT under 2 min may be two explanations for dissimilarities of the findings of the current study. Mortazavi *et al*.[28] and Araujo *et al*.[29] found that the application of EWBT for restoration of noncarious cervical lesions presents equal performance to WWBT groups at 12 months' follow-up.

In the current study, the highest POH was observed at 24 h after treatment and then POH was gradually decreased in the 30-day follow-up period. This result corroborates with those of Briso *et al*.[30] who investigated POH in Class I/II composite restorations after 1, 7, 30, and 90 days after treatment. They observed the highest sensitivity occurred 24 h after restorations and there was a gradual decrease in the occurrence of sensitivity in all groups after 7, 30, and 90 days. Despite the advances in materials and techniques, postoperative sensitivity remains a major concern for both patients and practitioners. Different reasons are suggested in the literature for POH such as polymerization shrinkage of composite materials, improper acid etching or bonding application, tooth preparation margin, and inadequate polymerization of composite.[31] Hence, design a study for the evaluation of POH is so difficult because several factors should be standardized.

In terms of limitations of the study, POH was the sole factor which we were able to evaluate in this study, knowing the fact that there are other elements which contribute to the success of a restoration such as durability or marginal staining that could not be considered within this study. In addition, short follow-up period and small sample size are among other limitations.

Within the limitations of this study, it can be concluded that the application of EWBT in Class II composite restorations in premolar teeth have not significant effect on POH in comparison with WWBT. Further clinical evaluations, with a greater sample size and different types of adhesive are required to fully elucidate the clinical effectiveness of EWBT. What is more, we suggest longer period of follow-ups in the future studies.

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Conflicts of interest

The authors of this manuscript declare that they have no conflicts of interest, real or perceived, financial or non-financial in this article.

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