Journal of Dentistry 43 (2015) 1083–1092

Contents lists available at ScienceDirect

Journal of Dentistry

journal homepage: www.intl.elsevierhealth.com/journals/jden

A new universal simplified adhesive: 36-Month randomized double-blind clinical trial

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ARTICLE INFO

Article history:
Received 30 April 2015
Received in revised form 16 June 2015
Accepted 2 July 2015

Keywords:
Dental bonding
Universal adhesives
Clinical trial

ABSTRACT

Statement of the problem: It is still debatable which technique should be used with universal adhesives, either etch-and-rinse (wet or dry) or self-etch strategy (with or without selective enamel etching).
Purpose of the study: To evaluate the 36-month clinical performance of Scotchbond Universal Adhesive (SU, 3M ESPE) in non-carious cervical lesions (NCCLs) using two evaluation criteria.
Methods/materials: Thirty-nine patients participated in this study. Two-hundred restorations were assigned to four groups: ER*m*: etch-and-rinse + moist dentin; ER*d*: etch-and-rinse + dry dentin; *Set*: selective enamel etching; and SE: self-etch. The same composite resin was inserted for all restorations in up to 3 increments. The restorations were evaluated at baseline and at 6-, 18-, and 36-months using both the FDI and the USPHS criteria. Statistical analyses were performed with Friedman repeated measures ANOVA by rank and McNemar test for significance in each pair ($\alpha = 0.05$).
Results: Eight restorations (ER*m*: 1; ER*d*: 1; *Set*: 1 and SE: 5) were lost after 36 months, but only significant for SE when compared with baseline ($p = 0.02$ for either criteria). Marginal staining occurred in 6.8% of the restorations (groups ER*m*, ER*d*, and *Set*) and 17.5% of the restorations (group SE), with significant difference for each group when compared with baseline using the FDI criteria ($p < 0.04$), while statistical significance was reached only for SE when compared with baseline using the USPHS criteria ($p < 0.03$). Twenty-eight and 49 restorations were scored as *bravo* for marginal adaptation using the USPHS and FDI criteria, respectively, with significant difference for each group when compared with baseline ($p < 0.05$).
Conclusions: While there was no statistical difference among bonding strategies when a universal adhesive was used, there were signs of degradation when the universal adhesive was applied in SE mode. The FDI criteria remain more sensitive than the USPHS criteria, especially for the criteria marginal staining and marginal adaptation.

1. Introduction

Several generations of dentin adhesives have been launched within the last 20 years. Dentin adhesives are unique in the sense that they may be the biomaterials used in Health Sciences that change commercial names more often, making it extremely difficult for clinicians to stay updated and to decide which adhesive to use in their patients. In the past dentists have been instructed by manufacturers how to use dentin adhesives – either as self-etch (SE) or as etch-and-rinse (ER) adhesives.

The ER adhesion strategy requires previous dentin demineralization with phosphoric acid in order to expose collagen fibrils for resin infiltration. However, it is necessary to keep etched dentin moist to achieve an adequate resin monomer infiltration into the interfibrillar porosity created by phosphoric acid [1–3]. Furthermore, both the dentin permeability and the hydraulic conductance increase upon removing the smear layer and opening the dentinal tubules [4],which affects the degree of moisture on the etched dentin surface. As a result, a consensus has not been established regarding the ideal degree of moisture, making it a challenge for clinicians and researchers alike. The ideal moisture contents

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http://dx.doi.org/10.1016/j.jdent.2015.07.005
0300-5712/

depends of several factors: (1) operator skills [5]; (2) interpretation of manufacturers' instructions [6,7]; and (3) solvent in the adhesive composition [2].

Nevertheless, the 'wet bonding' technique has been recommended for dentin bonding for almost 20 years [1,8]. In non-carious cervical lesions (NCCLs), the wet bonding technique did not increase the retention rate when compared with dry dentin in clinical studies when two-step ER adhesives were used [9–11], mainly if the adhesive was applied actively [10,11]. However, there are no long-term (over 24 months) clinical studies published in the literature testing this hypothesis.

SE adhesives are not affected by the degree of moisture, mainly because SE adhesives interact with the smear layer and underlying dentin without removing the former [12]. Therefore, SE adhesives do not increase dentin permeability nor hydraulic conductance of dentin [13]. Unfortunately, one of the main drawbacks from applying SE adhesives to dentin and enamel is their inability to etch enamel to the same depth that phosphoric acid does [14–16]. To overcome this shortcomings, the application of selective etching of enamel margins with phosphoric acid has been recommended by different authors prior to the application of SE adhesives [17,18]. The procedure has become popular among clinicians, mainly because some manufacturers instructions have suggested selective enamel etching prior to using their SE adhesives.

In spite of a deeper enamel etching pattern, when compared to SE mode, selective enamel etching does not always result in increased retention rate, even after long-term clinical evaluation in non-carious cervical lesions (NCCLs) [19–21]. This might be explained by the fact that only 2-step SE adhesive were previously evaluated [19–21]. In spite of unreliable *in vitro* and clinical longevity associated with 1-step SE adhesives compared to 2-step SE adhesives [22–24], to extent of our knowledge, no clinical studies have evaluated the use of selective enamel etching prior to the application of a 1-step SE adhesive.

More recently dentists have been able to use dentin adhesives according to their own judgment or tailored to a specific clinical situation. These new adhesives are known as 'universal' adhesives, as they can be used as SE adhesives, ER adhesives, or using a selective enamel etching approach. It has been also suggested by manufacturers of universal adhesives that dentin can be maintained wet or dry before the application of the respective universal adhesive. Unfortunately, only short-term clinical [25,26] and *in vitro* studies have been published [27–37] without a clear understanding as to which degree of moisture is recommended.

The aims of this randomized double-blind clinical trial were to study the influence of different application strategies on the clinical behavior of a new universal adhesive (Scotchbond Universal Adhesive, 3M ESPE, St. Paul, MN, USA) placed in NCCLs, over the course of 36 months, using two evaluation criteria, World Dental Federation (FDI) or United States Public Health Service (USPHS) criteria. The null hypotheses tested were: (1) that bonding to NCCLs using the self-etch strategy, associated or not with selective enamel etching, or using the etch-and-rinse strategy, applied on dry or moist dentin, would not result in similar retention over 36 months of clinical service and; (2) Different evaluation criteria, FDI or USPHS criteria, would not result in different outcomes for the same data.

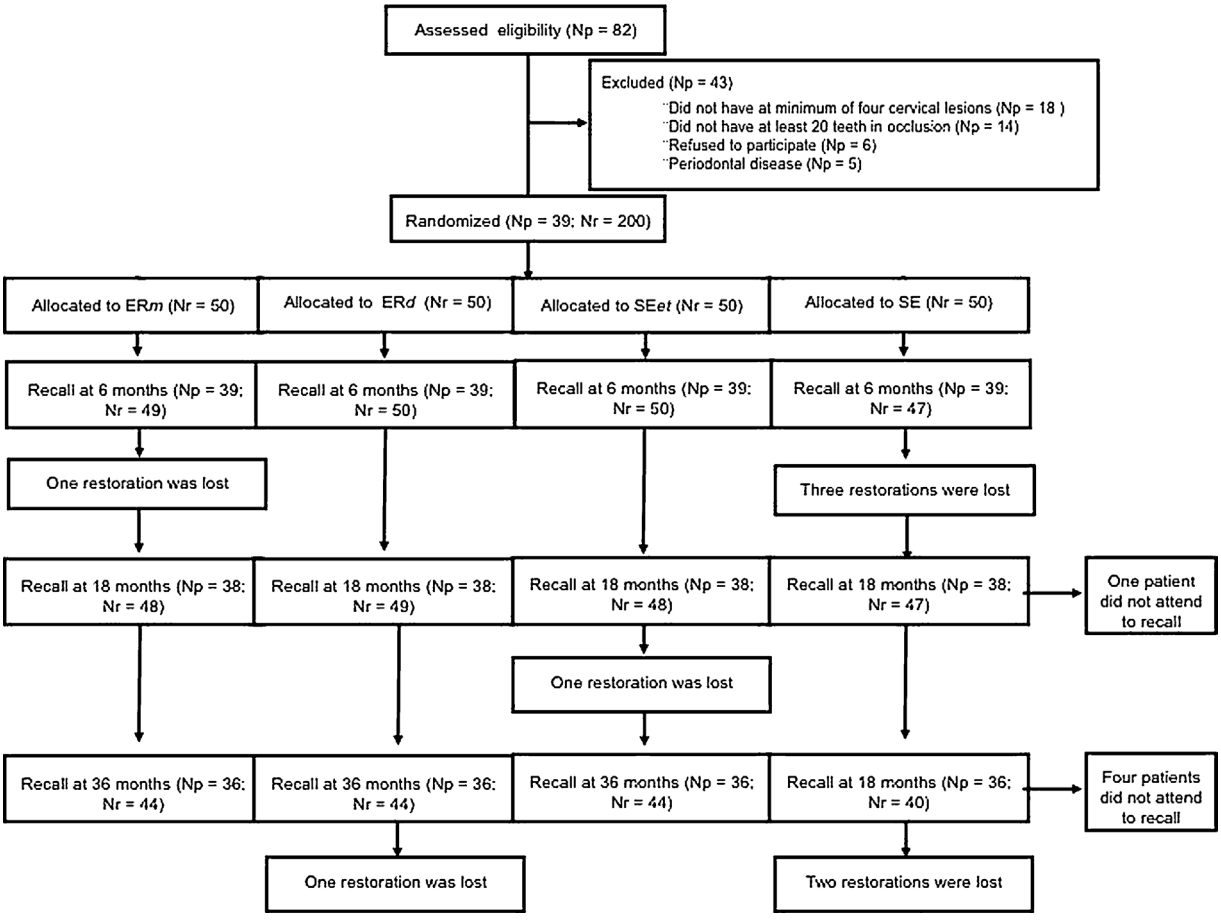

Fig. 1. Flow diagram. Np: number of patients, Nr: number of restorations. SE = self-etch; *Set* = selective enamel etching; ER*d* = etch-and rinse, dry dentin; ER*m* = etch-and rinse, moist dentin.