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A three-year clinical evaluation of a one-step self-etch and a two-step etch-and-rinse adhesive in non-carious cervical lesions

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ABSTRACT

Objectives: The aim of the study was to assess a one-step self-etch adhesive (Futurabond M, 1-SE) and a two-step etch-and-rinse adhesive (Solobond M, 2-ER) used in combination with the nano-hybrid composite (Amaris) in a prospective clinical study on non-carious cervical lesions.
Methods: 110 restorations were placed in 40 patients and graded over 36 months according to aesthetical, functional and biological criteria (Clinical Oral Investigations 2007;11:5). The four-step etch-and-rinse adhesive Syntac classic (4-ER) combined with the nano-hybrid composite Tetric EvoCeram was used as a control. Cumulative failure rates (CFR), retention rates and Kaplan–Meier survival curves were calculated for each observation period.
Results: After 3 years, the CFR of 33.3% in the 2-ER group was significantly higher compared to those of the 1-SE group (9.1%, $p = 0.019$) and of the 4-ER group (8.3%, $p = 0.035$). Additionally, retention rates in the 1-SE and the 4-ER groups were higher compared to 2-ER ($p = 0.012$ each) after 36 months. Annual failure rates ranged between 2.8% for 4-ER, 3.0% for 1-SE and 11.1% for 2-ER. During the study, restorations in all groups showed progressive marginal deterioration within the limits of clinical acceptance. After 3 years, restorations in the 2-ER and the 4-ER group showed more small defects at dentin than at enamel margins.
Conclusions: The 1-SE group was clinically as successful as the 4-ER, with both performing better than the 2-ER group. Futurabond M/Amaris can be recommended for the restoration of sclerotic non-carious cervical lesions.
Clinical significance: Number protocol 192/2008.

1. Introduction

Clinical studies remains the definitive way of collecting scientific evidence on the clinical effectiveness of a restorative treatment. Adhesives should best be assessed on Class V restorations.[1] The lack of macro-mechanical retention and a small C-factor ensure that material properties of the composite, such as polymerization shrinkage, play a subordinated role and that the emphasis is particularly on retention by the

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adhesive. With cavity margins located in enamel as well as in dentin, marginal adaptation (fracture, gap, staining/microleakage) to both tooth structures becomes a further key parameter in evaluating the clinical effectiveness of adhesives. For these reasons, non-carious cervical lesions (NCCL) have been used predominantly in clinical trials evaluating adhesive systems.

NCCLs are formed as a result of abrasive-erosive-ablative stress exposing mostly hypermineralized sclerotic dentin with partial or total obliteration of dentin tubules, thus offering unfavorable preconditions for dentin bonding.[2,3] It is to be taken into account that this dentin differs substantially from dentin after caries excavation or from sound dentin as mainly used in laboratory studies.[4] Hence it is a special challenge for an adhesive system to micromechanically interlock with hypermineralized dentin[5] and to maintain it over a long period in an environment that is subject to high tensile strains.[6–8] Therefore, because of the more challenging conditions of the dentin substrate, the results from clinical studies on NCCLs cannot be directly compared to results of restorations applied to normally mineralized and freshly cut dentin.

The interaction with the tooth is generally based on two different bonding strategies: the etch-and-rinse (4-step, 3-step, 2-step) or the simplified and less technique-sensitive non-rinse self-etch (2-step, 1-step) approach.[9] While the first strategy always includes a separate etching/conditioning step prior to the application of the adhesive system, the second integrates the etching/conditioning process into the application step.

A large number of studies regarding clinical effectiveness inrestoring NCCLs have been conducted comparing bonding strategies, adhesive systems and variations in application (e.g. ±enamel etching, ±prior dentin roughening, ±enamel bevelling). In the last decade, there have been conflicting reports regarding the widespread belief that etch-and-rinse adhesives bond more effectively to dentin in NCCLs than self-etch adhesives do.[10–13] In a systematic review of 26 clinical studies with at least 18 months of follow-up, a wide variation between adhesives of the same category regarding their bonding strategy has been shown.[14] Clinical behaviour was found to be highly product-dependent.

There are two strategies for evaluating the clinical performance of adhesives. In the 1990s and the early 2000s, the predominant view was to compare product chains, i.e. systems with an adhesive and a composite originating from the same manufacturer. By not combining products from different systems from different manufacturers, incompatibilities between the products should be avoided. However, the current preferred strategy is to compare different adhesives with one and the same composite. Therefore, the primary endpoint for this prospective randomized three-year study was to assess the clinical effectiveness of a new one-step self-etch adhesive in comparison to a two-step etch-and-rinse adhesive in restoring NCCLs. As the secondary endpoint, these two adhesives combined with one and the same composite were compared to an established reference standard system (four-step etch-and rinse adhesive/composite).

2. Materials and methods

The study was approved by the Ethics Committee of the University of Leipzig and performed in accordance with protocol no. 192/2008. All participants were informed about the study and had signed the written informed consent prior to the first treatment. The patients were aged between 18 and 66 years (mean 46.7 ± 14.1) and all required at least 2 restorations of non-carious cervical lesions (NCCL). Criteria for inclusion were a positive pulp status (CO_2-snow) of the trial tooth and a physiological occlusal relationship with natural dentition. Patients were excluded who had less than 20 teeth, heavy bruxism, known allergies to product ingredients, and abutment of test teeth to a fixed or removable prosthesis.

The materials studied were the one-step self-etch adhesive Futurabond M (1-SE) and the two-step etch-and-rinse adhesive Solobond M (2-ER). Both adhesives were combined with the nano-hybrid composite Amaris (Voco GmbH, Cuxhaven, Germany). The four-step etch-and-rinse adhesive Syntac classic (4-ER) combined with the nano-hybrid composite Tetric EvoCeram (IvoclarVivadent, Schaan AG, Schaan, Liechtenstein) was used as a reference restoration system. A total of 110 restorations were placed in 40 patients. Each patient received one restoration with the 1-SE and one with the 2-ER adhesive system and, if a third lesion was detectable, a further restoration with the 4-ER system. The lesions were randomly assigned to the three systems and restored by one of three experienced and skilled clinical operators. The size of the restored lesions varied from shallow (depth ≤1 mm) and medium (depth ≤2 mm) to deep (depth >2 mm),which are equivalent to scores 2, 3 and 4 on Smith and Knight's tooth wear index.[15] The characteristics of teeth and lesions are shown in Table 1.

The restorations were placed according to the following protocol: The tooth was cleaned with a slurry of pumice and water, washed and slightly dried. After shade selection, a retraction cord (Ultrapak, Ultradent Products, Inc., South Jordan, USA) was applied where required to expose the cervical cavity margins. The hypermineralized dentin and the marginal enamel surfaces were prepared using a 15 μm fine-grained diamond bur (Intensiv SA, Grancia, Switzerland). Finally, all lesions were isolated by rubber dam (Dental Dam, Coltène/Whaledent AG, Altstätten, Switzerland). Materials, compositions, and application procedures according to manufacturer's instructions are listed in Table 2. Shallow and medium lesions were filled in bulk, deep lesions in increments. Increments of opaque base shades were cured for 40 s and translucent enamel shades for 10 s. The restorations were contoured with fine-grained diamond burs and polished with flexible silicone rubber polishing points (Shofu Dental GmbH, Ratingen, Germany).

Restorations were assessed 14 days after placement (baseline) and after 6, 12, 24, and 36 months (CONSORT flow diagram, Fig. 1). At all appointments, restorations were examined by the principal investigator (simple-blind rating). Each trial restoration was reassessed using a dental loupe (2.5× magnification) and scored according to aesthetic, functional and biological criteria.[16] All criteria, the corresponding evaluation methods, and the allocation to clinical observation are shown in Table 3. The different criteria were assessed visually, by explorers (Kit-EX: tip diameter 150 μm, 250 μm; Deppeler SA, Rolle, Switzerland), by interviewing, by CO_2-snow, by use of a visual analogue scale and by a periodontal probe (P15/11.5B6; Hu-Friedy Mfg. B.V., Rotterdam/Netherlands). Scoring ranges from