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Two-year clinical trial of a universal adhesive in total-etch and self-etch mode in non-carious cervical lesions☆

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ABSTRACT

Objectives: To compare the clinical performance of Scotchbond™ Universal Adhesive used in self- and total-etch modes and two-bottle Scotchbond™ Multi-purpose Adhesive in total-etch mode for Class 5 non-carious cervical lesions (NCCLs).
Methods: 37 adults were recruited with 3 or 6 NCCLs (>1.5 mm deep). Teeth were isolated, and a short cervical bevel was prepared. Teeth were restored randomly with Scotchbond Universal total-etch, Scotchbond Universal self-etch or Scotchbond Multi-purpose followed with a composite resin. Restorations were evaluated at baseline, 6, 12 and 24 months for marginal adaptation, marginal discoloration, secondary caries, and sensitivity to cold using modified USPHS Criteria. Patients and evaluators were blinded. Logistic and linear regression models using a generalized estimating equation were applied to evaluate the effects of time and adhesive material on clinical assessment outcomes over the 24 month follow-up period. Kaplan–Meier method was used to compare the retention between adhesive materials.
Results: Clinical performance of all adhesive materials deteriorated over time for marginal adaptation, and discoloration ($p < 0.0001$). Both Scotchbond Universal self-etch and Scotchbond Multi-purpose materials were more than three times as likely to contribute to less satisfying performance in marginal discoloration over time than Scotchbond Universal total-etch. The retention rates up to 24 months were 87.6%, 94.9% and 100% for Scotchbond Multi-purpose and Scotchbond Universal self-etch and total-etch, respectively.
Conclusions: Scotchbond Universal in self- and total- etch modes performed similar to or better than Scotchbond Multipurpose, respectively.
Clinical significance: 24 month evaluation of a universal adhesive indicates acceptable clinical performance, particularly in a total-etch mode.

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1. Introduction

The evolution of dental adhesives progressed from 2 bottle systems to single bottle total-etch (5th generation) and self-etch (7th generation) materials. Previous clinical investigations of self-etch adhesives reported that selectively etching enamel produced improved performance [1–4]. The use of traditional self-etch adhesives in a total-etch technique, however, is not indicated to prevent pre-etching dentin deeper than a self-etch adhesive is capable of penetrating [5–7]. The recent introduction of universal adhesives has allowed clinicians the choice of total-etch or self-etch application for a single-bottle adhesive. A clinical evaluation of cervical restorations found no difference in the retention when a universal adhesive was used in total-etch, self-etch, or selective modes after 6 months or 18 months [8,9]. The study found that a

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significantly greater number of restorations placed in a self-etch mode had marginal imperfections at 18 months [9].

Previous laboratory studies of several universal adhesives have evaluated their bond strength in total-etch and self-etch modes. For enamel, several authors [10,11] reported the bond strength of a universal adhesive was significantly improved in the total-etch mode, however, for dentin, other studies [12–14] reported no difference in the immediate bond strength of pre-etched and self-etched dentin with several universal adhesives. For one universal adhesive with a pH of 2.7, a greater bond strength was reported in the self-etch mode with 1 year aqueous storage and immediately. On the other hand, a universal adhesive with a pH of 3.2 improved its bond strength by pre-etching the dentin. In summary, there is a consensus that pre-etching enamel improves the bond strength of universal adhesives but there is not a consensus for pre-etching dentin.

Most universal adhesives contain acidic functional monomers, such as 10-methacryloyloxydecyl dihydrogen phosphate (MDP). MDP contains a polymerizable methacrylate group and a phosphate group capable of forming a stable salt with the calcium in hydroxyapatite. The stability of this calcium salt has been correlated with the high bond strength of MDP to enamel and dentin [17,18]. Additionally, MDP is a hydrophobic molecule which may impart hydrophobicity to an adhesive, decreasing its water permeability [19]. The addition of MDP to a universal adhesive may show favorable clinical comparisons to an adhesive without MDP due to improvements in the chemical bond and a reduction in hydrolytic bond degradation.

The objective of this study was to compare the clinical performance of Scotchbond™ Universal Adhesive 3 M ESPE, St Paul, MN, USA) in self-etch and total-etch modes to a two bottle total-etch adhesive (Scotchbond Multi-purpose, 3 M ESPE) for restoring Class 5 non-carious cervical lesions (NCCLs).

2. Materials and methods

This was a single-center, randomized, comparator-controlled, and parallel-designed study with blinding of patients and clinical evaluators. Prior to patient enrollment, an Institutional Review Board approved the clinical trial protocol. Inclusion criteria for patients in the study included: (a) 19 years or older, (b) good general health, (c) available for follow-up visits, and (d) have at least 28 teeth. The following exclusion criteria were used: (a) rampant uncontrolled caries, (b) advanced untreated periodontal disease, (c) >2 cigarette packs/day or equivalent chewing tobacco, (d) systemic or local disorders that contra-indicate dental procedures included in this study, (e) evidence of xerostomia, (f) evidence of severe bruxing, clenching or TMD, (g) pregnancy at the time of screening or tooth restoration, and (h) known sensitivity to acrylates or related materials. Inclusion criteria for restorations in the study included: (a) at least three NCCLs at minimum of 1.5 mm in depth and (b) lesion extending to dentin. Exclusion criteria of the teeth were: (a) periapical pathology or symptoms of pulpal pathology, (b) non-vital or previous root canal therapy, (c) previous pulp cap, (d) tooth hypersensitivity, (e) near exposures on pre-operative radiographs, and (f) caries or previous restoration. Thirty seven patients were enrolled in this study by a clinic coordinator. The nature and purpose of the study, the clinical procedures, and the expected duration of participation was explained to each potential subject and an informed consent was obtained. Patient enrollment occurred from May to December 2011, after which time 37 patients were enrolled. All treatment occurred from January to May 2012, at the School of Dentistry at the University of Alabama at Birmingham.

Each enrolled patient possessed either three ($n = 32$) or six ($n = 5$) teeth that met the inclusion criteria. Of these 126 teeth, 42 were allocated to the control group (Scotchbond Multi-purpose total-etch), 42 allocated to the Scotchbond Universal total-etch group, and 42 allocated to the Scotchbond Universal self-etch group. All enrolled patients participated in the study. Manufacturer's information for all materials used in this study is presented in Table 1. The 5 participating clinicians were calibrated for placement and evaluation of the restorations prior to starting the study. During calibration, restorations were placed in typodont teeth exactly as described in the protocol to standardize all clinical procedures and familiarize dentists with the materials. Patients were given local anesthesia as needed and the teeth were isolated using non-latex rubber dams and metal clamps. Shade selection was performed with the Vita shade guide. Teeth were prepared with a 0.5 mm bevel on the occlusal margin made with an OS-2 bur (Brasseler USA, Savannah, GA, USA) in a highspeed handpiece. The preparations were cleaned with pumice and a prophy cup. For the two total-etch groups, the preparations were etched with the 37% phosphoric acid (Scotchbond™ Phosphoric Etchant, 3 M ESPE) applied with agitation for 15 s, rinsed for 10 s and dried using gentle application of air for 10 s to keep the dentin moist. One coat of the adhesive was applied to the enamel and dentin for 20 s with agitation, air dried for 5 s, and light cured for 10 s using the Elipar Freelight 2 LED curing light (3 M ESPE, output >700 mW/cm^2). The output of the curing light was assessed daily using a LASER power meter (FieldMate, Coherent Inc., Santa Clara, CA, USA) to ensure proper output. Underpowered lights were recharged or replaced. Composite shade selection was determined by comparison with a Vita Shade guide observed under color-adjusted (5600 K) clinical lighting. Filtek Supreme Ultra (3 M ESPE) resin composite was placed in 2 mm increments and cured for 20 s per increment. If dentin or A6B, and B5B shades were used a 40 s cure was applied for each increment. Carbide finishing burs (7404, OS-1, OS-2, Brasseler) were used to remove gross excess and adjust occlusion, followed by finishing and polishing with Sof-Lex (3 M ESPE) and Enhance/PoGo (Dentsply Caulk) points, cups and discs.

The adhesive material/mode used was determined by the clinic coordinator by assigning the lowest numbered tooth to the material randomly assigned based on a computer generated list with a block size of 3. The same procedure was used for patients with six teeth included in the study and two rows of the list were used. The adhesive material/mode used for either tooth was blinded to the patient, however, the difference in packaging of the materials prevented blinding of the restoring dentist. Each patient

Table 1
Composition of test materials.

Material	Manufacturer	Composition
Scotchbond Multi-purpose	3M ESPE	Primer: HEMA, copolymer of acrylic and itaconic acids, water, Adhesive: dimethacylate resins, HEMA, CQ, EDMAB
Scotchbond universal	3M ESPE	Dimethacylate resins, HEMA, MDP, copolymer of acrylic and itaconic acids, ethanol, water, silane, silica fillers, CQ, EDMAB
Filtek supreme ultra universal restorative	3M ESPE	Resin: dimethacylate resins, CQ, EDMAB Fillers: silica and zirconia nanoparticles and silica/zirconia nanoclusters (78.5wt%; 66.3vol%)

Abbreviations: CQ: camphorquinone; EDMAB: ethyl 4-(dimethylamino)benzoate; HEMA: 2-hydoxyethyl methacrylate; MDP: 10-methacyloyloxydecyl dihydrogen phosphate

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