DENTAL MATERIALS 29 (2013) e271–e280

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# A randomized controlled 5-year prospective study of two HEMA-free adhesives, a 1-step self etching and a 3-step etch-and-rinse, in non-carious cervical lesions

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ARTICLE INFO

*Article history:*
Received 6 April 2013
Accepted 9 August 2013

*Keywords:*
Adhesion
Cervical
Clinical
Composite resin
Dental resin
Restoration
Self-etch

ABSTRACT

*Objective.* The aim of this study was to evaluate the 5 year clinical dentin bonding effectiveness of two HEMA-free adhesives in Class V non-carious cervical lesions.

*Material and methods.* A total of 169 Class V restorations were placed in 67 patients with a self-etching adhesive (G-Bond; 67), a 3-step HEMA and TEGDMA free etch-and-rinse (cfm; 51) and a control HEMA-containing etch-and-rinse adhesive (XP Bond; 51) in non-carious cervical lesions without intentional enamel involvement. The restorations were evaluated at baseline and yearly during a 5 year follow-up with modified USPHS criteria. Dentin bonding efficiency was determined by the percentage of lost restorations.

*Results.* During the 5 years, 159 restorations could be evaluated. Good short time dentin retention was observed for the three adhesives, there all adhesives fulfilled at 18 months the full acceptance ADA criteria. At 5 years a cumulative number of 22 lost restorations (13.8%) was observed. The HEMA-free adhesives showed significantly higher dentin retention compared to the HEMA-containing one. Loss of retention was observed for 5 G-Bond (7.9%), 4 cfm (8.3%) and 13 XP Bond (27.1%) restorations ($p < 0.05$). No post-operative sensitivity was reported by the participants. No secondary caries was observed.

*Significance.* The durability in non-carious cervical lesions of the HEMA-free adhesives was successful after 5 years. Despite concerns which have been raised, showed the 1-step SEA one of the best reported clinical dentin bonding effectiveness.



## 1. Introduction

Adhesive systems have revolutionized and are routinely used in operative dentistry to improve retention, sealing and esthetics of resin-based materials. The interaction with the tooth substrates is today based on the etch-and-rinse or the non-rinse self-etch approach. Self-etching adhesives (SEA) contain acidic monomers which simultaneously condition and prime the smear layer

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http://dx.doi.org/10.1016/j.dental.2013.08.203

and underlying tooth tissues. Clinical advantages suggested are its decreased technique sensitivity, decreased application time and decreased risk for re-contamination of the etched tooth surfaces and/or collapse of the collagen network after air drying. Disadvantages reported are that 1-step SEA's are more hydrophilic and can absorb rapidly water which result in higher solubility and water uptake. This may result in polymer swelling, plasticization and weakening of the polymer network [1,2]. One-step SEA's may act as semi permeable membranes, permitting water movement through the layer even after polymerization [3].

Diffusion of monomers into the demineralised tooth tissues to create a hybrid layer is considered to be the essential mechanism of adhesive bonding. HEMA (2-hydroxyethyl methacrylate), an effective hydrophilic methacrylate primer monomer, is frequently present in dental adhesives. It improves dentin bond strength due to its wetting enhancement effect and promotes diffusion of co-monomers by expanding the demineralised collagen [4–6]. In 1-step SEA adhesives HEMA maintain the resin monomers and water in one solution and prevent phase separation [6,7]. However, high HEMA content promotes water uptake and subsequent gradual hydrolytic degradation of the polymers, swelling and staining [8]. Increased water uptake might accelerate the reduction of mechanical properties of the SEA [9]. Omission of HEMA in adhesives leads to phase separation between water and the adhesive monomers, which requires strongly air blowing to remove the water-containing droplets from the interface [6,10,11].

Methacrylate monomers are potent contact allergens and especially the low weight monomer HEMA is considered as one of the most potent ones [12,13]. Fast penetration of non cured monomers through the skin and gloves cause contact dermatitis in dental personal [14–16]. In addition another commonly used low viscous monomer TEGDMA has been associated with cytotoxic reactions [17,18]. Unpolymerized HEMA remain chemically and physically unchanged and can leach up to 30 days [19]. Organic solvents can solve higher amounts compared to water or saliva only [19].

Assessing the bonding effectiveness of adhesives in vitro showed that 3-step etch-and-rinse adhesives performed best, irrespective of bond strength test [20]. Two-step SEA conducted better than the all-in-one systems [21,22]. However, laboratory tests cannot predict the clinical situation and Class-V clinical trials remain therefore the ultimate studies to test adhesives [20,23]. In an earlier review of clinical Class V studies it was concluded that etch-and-rinse adhesives were more efficient than SEA's [6]. Lower microtensile bond strength have been reported for SEA especially to enamel [20,24]. However, recent Class V clinical trials showed that 1-step SEA's substantially improved with annual failure rates in line with the etch-and-rinse adhesives [20,25].

The disadvantages of HEMA have led to the introduction of HEMA-free less hydrophilic adhesives which may show reduced water sorption, higher stability of mechanical properties, stability of the interfacial bond, improvement in bonding durability and reduced allergenic potential [19,26]. Short time evaluation of HEMA-free adhesives showed a satisfactory performance [27–30].

**Table 1 – Baseline data, distribution and lesion characteristics, of the lesions included.**

| | G-Bond | cfm | XP Bond |
|---|---|---|---|
| Teeth | | | |
| Incisor/cuspidate | 25 | 16 | 23 |
| Premolar | 30 | 19 | 20 |
| Molar | 12 | 16 | 8 |
| Jaw | | | |
| Maxilla | 34 | 40 | 37 |
| Mandible | 33 | 11 | 14 |
| Lesion size | | | |
| Small | 11 | 7 | 18 |
| Medium | 23 | 33 | 19 |
| Large | 33 | 11 | 13 |
| Lesion depth | | | |
| Superfiscial | 24 | 28 | 33 |
| Medium | 27 | 17 | 13 |
| Deep | 16 | 6 | 5 |
| Degree of sclerosis | | | |
| 0% | 19 | 25 | 26 |
| <50% | 6 | 8 | 10 |
| >50% | 42 | 18 | 15 |

The purpose of this study was to determine the long term clinical bonding durability of a 1-step HEMA-free SEA, a 3-step HEMA/TEGDMA-free etch-and-rinse and a 3-step HEMA containing etch-and-rinse adhesive in Class V non-carious cervical lesions without using retention of external lesion surface area. The null hypothesis tested was that there is no difference in durability of the clinical dentin bond formed with the HEMA-free and HEMA-containing adhesives.

## 2. Material and methods

During the period May 2006–October 2007, all patients attending the author's PDHS clinic at the dental school Umeå, for who treatment of non-carious cervical lesions was indicated were requested to participate in the study. No patient was excluded because of caries activity, periodontal condition or parafunctional habits. All participants received informed consent and the study was approved by the commission for medical ethics of the University of Umeå. A total of 169 Class V restorations were placed in 67 patients, 34 men and 33 women with a mean age of 64.7 year (min–max 39–84), who needed treatment of non carious cervical lesions. All restorations were placed by one experienced operator, familiar with adhesive dentistry, in dentin lesions without any intentional enamel involvement. Pre-operatively, the lesions were categorized by the operator compared to lesion models in terms of depth (shallow, moderate, large) and size (small, moderate, large) of the lesion, the area of the dentin surface estimated as sclerotic tissue (0, <50%, >50%) (Table 1) [31].

A single-step, self-etching HEMA-free primer (G-Bond, GC Corp, Tokyo, Japan), a 3-step HEMA/TEGDMA free etch-and-rinse (cfm, Saremco AG, Rebstein, Switzerland) and a 2-step HEMA-containing etch-and-rinse adhesive (XP Bond, Dentsply/DeTrey, Konstanz, Germany) were evaluated in combination with two restorative resinous materials (Table 2). The resin composite Gradia Direct (GC Corp) was used in combination with G-Bond, and els (extra low shrinkage; Saremco) in combination with the two other adhesives. After the