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A Randomised Controlled Trial of a Universal Bonding Agent at Three Years: Self Etch vs Total Etch

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ABSTRACT

General dental practice is increasingly being recognised as the ideal situation for the conduct of clinical trials into the longevity of restorations. The aim of this study was to investigate the survival of 64 nanofilled resin composite (Filtek Supreme XTE) restorations placed principally in loadbearing cavities using a Universal dentine bonding agent (Scotchbond Universal), in five UK dental practices by members of the UK-based practice-based research group, the PREP Panel. A split mouth design was used, comprising patients who required two restorations, with one of the restorations receiving a total etch approach using phosphoric acid and the other being placed using a self-etch approach. The results indicated good performance of the restorations examined, with no difference, in terms of marginal characteristics, between the restorations which received total etching and those which did not.

INTRODUCTION

PRACTICE-BASED RESEARCH

It may be considered that dental practice increasingly should become the prime location for clinical dental research, given that dental practice is the real world, and given that, if a technique or material is to be successful, it must be readily operable in the dental practice situation. Practice-based research has been considered as "the silent partner in dental practice, and the scaffolding on which we build and sustain a practice".[1] In addition, the volume of clinical material seen in general dental practice makes dental practice an area of importance in the assessment of new techniques and materials. Since the majority of restorations, worldwide, are placed in the real world of general dental practice, it may be considered that it is here that the performance/survival of restorations should predominantly be assessed.[2]

The performance of a restorative material by one operator is necessarily subjective, but when practitioners band together to form a group in order to evaluate new materials in dental practice, the results are likely to be more objective and generalizable. One such group in the UK is the group of practice-based researchers known as the PREP (Product Research and Evaluation by Practitioners) Panel. This group was established in 1993 with six general dental practitioners, and has grown to contain 32 dental practitioners located across the UK and one in mainland Europe. It has completed circa 80 projects – "handling" evaluations of materials & techniques, and more recently, clinical evaluations (n=9) of between 1 year and 5 years.[3]

SELECTIVE ENAMEL ETCHING

Buonocore, using 60% phosphoric acid, was the first, in 1955, to describe the etching of enamel in order to obtain adhesion to this substrate,[4] heralding the dawn of adhesive dentistry, and, ultimately, minimally invasive dentistry alongside the development of resin composite materials, with these materials becoming increasingly used worldwide.[5] With the bond to enamel becoming a given, subsequent research and development by manufacturers of dental materials turned to the development of reliable dentine bonding agents. While these were initially classified in generations,[6] this terminology has increasingly been dropped, probably due to failure of to accurately define which material was which generation. Dentine bonding agents therefore increasingly became classified into the "Etch and Rinse" materials, in which both the enamel and dentine were etched with circa 35% phosphoric acid, and the so-called "Self Etch" materials, in which the bonding agent was said to have a sufficiently low pH to etch the enamel, as well as infiltrating the smear layer and penetrating into the dentinal tubules.[7] However, it may be considered that dentists were being deluded into thinking that a material with a pH in the region of 2.0 to 2.5 (for example, the pH of one so-called self-etch materials, Clearfil SE, is 2.3[8]) would etch the enamel as vigorously as phosphoric acid with a pH of 0.4, all the more relevant when one considers that pH is a logarithmic scale. The concept of "Selective enamel etching" was therefore born into Restorative Dentistry, with one of its first uses being described in the study by Peumans and colleagues.[9]

More recently, Universal bonding agents have been introduced, with the authors' definition of a Universal bonding agent being one which:

- is capable of being used in whichever etching mode that the operator considers appropriate (total etch, self etch or selective enamel etch)
- may be used for direct and indirect dentistry, the latter generally in conjunction with a resin-based luting system from the same manufacturer as the bonding agent, which incorporates a material-specific initiator.

Another factor that many (but not all) of this new group of bonding agents have in common is the resin 10-MDP (originally developed by Kuraray in the 1980s), with this providing not only a micromechanical bond via a hybrid layer, but also a chemical bond to hydroxyapatite.[7,10]

STUDY OBJECTIVES

To evaluate the clinical performance of pairs of restorations formed in Filtek Supreme XTE™* resin composite, placed using Scotchbond™ Universal (3M ESPE, Seefeld, Germany) adhesive in total-etch and self-etch applications in a split-mouth design study over three years.

MATERIALS AND METHODS

Five general dental practitioners (GDPs) of the PREP Panel, the UK practice-based research group, participated. After ethical approval was obtained, each GDP was asked to place 10 paired restorations formed in Filtek Supreme XTE (3M, St Paul, MN, USA) resin composite and using Scotchbond Universal™adhesive (3M, St.Paul, MN, USA), one placed using the adhesive in total-etch mode and the other in self-etch mode. The restorations were reviewed at one-year, two years & three years (+/- 3 months) by one independent examiner along with the practitioner who placed the restorations, using modified USPHS criteria, with, should a disagreement occur, a third examiner who would be asked to review the restoration.

SELECTION OF CLINICIANS

Members of the PREP Panel, each of whom had previous experience in clinical evaluations, were asked, by means of an explanatory letter, if they would be prepared to evaluate the performance of restorations placed in Filtek Supreme XTE™, bonded with Scotchbond Universal, using a split mouth design, i.e. would they have sufficient numbers of patients who each required a minimum of two resin composite restorations. Of those who responded positively, five members were selected at random.

PRIMARY OUTCOME MEASURES:

- Retention of the restoration
- Lack of fracture of the restoration
- Margin integrity of the restoration in etch vs non-etch groups
- Secondary caries status
- Appearance of the restoration (colour match and stability)
- Lack of marginal staining
- Stain resistance of the restorative material
- Surface quality

PATIENT CONSENT

Patients who required two restorations in their posterior teeth were asked if they would be prepared to be involved in a clinical trial of their restorations and if they would be prepared to attend the dental practice of the clinician who placed the restoration(s) for one year, two-year and three year evaluations of restorations which they have received. They were given a Patient Information Leaflet explaining what would be involved. Informed written consent was obtained from all patients prior to registration for participation in the evaluation. Implicit in giving informed written consent, each patient was given the right to withdraw from the study at any time.

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PATIENT POPULATION

Subjects recruited for this investigation were therefore those who required two resin composite restorations in loadbearing situations in posterior teeth and who were willing to attend for recalls for the examination of the restorations.

Inclusion and Exclusion criteria for the study

- To be considered appropriate for inclusion in the study a patient must:
- Have been over 18 years of age
- Require two or four tooth-coloured restorations
- Have a molar supported permanent dentition free of any clinically significant occlusal interferences
- Have well maintained dentitions free of any active, untreated periodontal disease
- Be a regular dental attender who agreed to return for assessments.

Patients were excluded from participating in the study if:

- There was a history of any adverse reaction to clinical materials of the type to be used in the study
- There was evidence of occlusal parafunction and/ or pathological tooth wear
- They were pregnant or had medical and/or dental histories which could complicate their attendance for the assessment of the restorations and/or influence the behaviour and performance of the restorations in clinical service
- They were irregular dental attenders.

Additionally, it was specified that the teeth to be included would be in occlusal function and free of signs and symptoms of periapical pathology, both clinically and radiographically.

OPERATIVE PROCEDURES

Where clinically indicated, and with the approval of the patient, appropriate local anaesthesia was obtained. The teeth to be restored were prepared using conventional instruments and techniques. The preparations had the following features:

- Rounded line and point angles
- Resistance and retention form achieved in the usual way from remaining tooth tissues.

The restoration shade was selected using the Filtek Supreme XTE™ shade guide, appropriate isolation obtained, and the restoration placed in accordance with the manufacturer's instructions. Restorations were placed in conjunction with the Universal bonding agent, Scotchbond Universal, used in accordance to the manufacturer's instructions except for the etching process. The etching approach was selected at random by drawing cards (total etch or no-etch) from an envelope, with the first restoration being placed according to which card was drawn, the second being placed using the alternative methodology. In that regard, cavities selected for total etch were subjected to total etching of the enamel and dentine using 35% phosphoric acid prior to application of the bonding agent. For restorations placed using a self-etch approach, the cavity was not etched with phosphoric acid. Isolation was made in such a way to be successful, according to the clinician's discretion.

RECALLS

The reviews of the restorations in the present work were completed at three years ± 3 months from the date of placement of the restoration, the reviews being undertaken by one trained and calibrated examiner (RJC) along with the clinician who placed the restorations. The examiners were blinded to the restorative procedure. All restorations were inspected and assessed according to the codes and criteria based on a modification of the criteria laid down by Ryge and Cvar *(Table 1)*.[11] The assessment included evaluation of anatomic form, margin adaptation, marginal staining, surface roughness, colour match, post-operative sensitivity/discomfort, and presence or absence of secondary caries. In the event of a restoration being unsatisfactory, the mode of failure was recorded and the necessary remedial work carried out.

STATISTICAL ANALYSIS

Given the methodology, we were particularly interested in marginal integrity and marginal discolouration. Accordingly, a Chi-squared test was used to examine the differences between the observations at baseline and year 3 for marginal integrity and marginal discolouration.

RESULTS

At baseline, 64 restorations were placed, while 61 restorations were reviewed at Year 1 (recall rate 95%), 45 at Year 2 (recall rate 70%), and 45 restorations at Year 3 (70% recall rate). These 45 restorations comprised of 22 of each placement mode, together with one extra total-etch mode unpaired restoration. The restorations comprised one Class I & 44 Class II, of mean age 36 months, in 18 patients (12 Female and 6 Male). Twenty per cent (n=9) of the restorations involved the restoration of one or more cusps: 53% were placed under rubber dam isolation. The overall results are presented in Table 2.

No unacceptable scores were recorded, no secondary caries was detected and no post-treatment sensitivity was reported.

There was no statistical difference between the observations at baseline and year 3 in terms of marginal integrity (P value=0.65) and marginal discolouration (P Value=0.56).

Figures 1 to 5 present representative illustrations of the restorations included in the study.

Table 1. Criteria for restoration evaluation[11] (*=unacceptable)

Anatomic form
A: Restoration is continuous with existing anatomic form, not under contoured.
B: Restoration is under contoured but no dentine or base exposed.
C*: Sufficient restorative material is missing so that dentine or base is exposed.
Margin integrity
A: No visible evidence of a crevice along the margin into which a probe will catch.
B: Probe catches in a crevice along the margin, no exposure of dentine or base.
C*: Visible evidence of a crevice with exposure of dentine or base along the margin
Margin discolouration
A: No discolouration evident at margin.
B: Slight staining at margin
C*: Obvious staining, cannot be polished away.
Colour match
A: Restoration matches adjacent tooth structure in colour and translucency
B: Mismatch in colour and translucency but within an acceptable range.
C*: Mismatch in colour and translucency outside acceptable range.
Surface roughness
A: Smooth surface with no irritation of adjacent tissues.
B: Dull, matte surface, can be refinished.
C*: Shallow surface pitting is present. Rough, cannot be polished

Figure 1: Total etch Class II, 46, 47 at 3 years

Figure 2: Self etch Class II, 36, 37 at 3 years

Table 2. One-, two- and three-year results of the clinical criteria examined in the study

	Year One		Year Two		Year Three	
Criteria	Total-etch	Self-etch	Total-etch	Self-etch	Total-etch	Self-etch
Anatomic form	94% A, 6% B	90% A, 10% B	100%	86% A, 14% B	91% A 9% B	86% A 14% B
Marginal Integrity	81 % A, 19% B	90% A, 10% B	65% A, 35% B	77% A, 23% B	61% A 39% B	61% A 39% B
Marginal staining	77% A, 23% B	83% A, 17% B	74% A, 26% B	77% A, 23% B	61% A 39% B	68% A 32% B
Percentage of margin stained	3 % (range 2 to 10%)	4.0% (range 5 to 10%)	2% (range 2-2%)	7% (range 2 – 15%)	7% (range 2 – 20%)	7% (range 1- 15 %)
Colour match	100% A	100% A	100%	95% A, 5% B	100% A	100% A

Figure 3: Total etch Class II, 16 at 3 years

Figure 4: Self etch Class II, 26 at 3 years

Figure 5: Total etch Class II, 14 and Self etch Class II, 15 at 3 years

DISCUSSION

This work presents a randomized trial of the restorations under evaluation, placed under the conditions of general dental practice, with the patients paying the normal practice fee for their treatment. Half of the restorations were randomly selected to receive a total etch approach using 35% phosphoric acid, while the remainder were placed in self-etch (i.e. no enamel etching with phosphoric acid) mode. The study methodology was designed to comply with the CONSORT 2010 Statement for the conduct of randomized controlled trials[12] and it may be considered to have complied with the majority of these.

The data presented may be considered to indicate the performance of restorations placed under the real life conditions pertaining to UK general dental practice. The results indicate good performance of the restorations examined, with no failures being identified and no scores less than B being recorded in any category. Of particular note is the fact that there is no difference indicated, at three years, between the restorations which received the total etch approach and those which did not. Indeed, the results for the restorations which received the "self etch" treatment (i.e. margins not etched with phosphoric acid) indicated slightly improved performance over the other group, although this was not statistically significant. Although the number of restorations was relatively small, this is not what the perceived wisdom would have expected, given that one would have expected margins etched with phosphoric acid to have demonstrated better marginal integrity and reduced amounts of staining. That this was not the case would appear to indicate that the bonding agent under test performed satisfactorily at three years with respect to the margins of the restorations.

While the total etch approach employs the clinical technique in which the enamel and the dentine is etched, "Selective enamel etching" is a relatively new concept in restorative dentistry, with one of its first uses being in the study by Peumans and colleagues.[9] When their study was extended to eight years,[13] the results continued to indicate fewer small marginal defects on enamel in the selective enamel etch group (65% cf 44% in the non-etch group), while there was more superficial marginal discolouration in the non-etch group. These differences were only statistically significant for marginal discolouration. While all the restorations in the study by Peumans were class V[13], the results of the present study, which included principally class II restorations (of which 20% involved the replacement of one or more cusps), demonstrated no difference in margin characteristics, indicating the effectiveness of the bonding agent under evaluation, Scotchbond Universal, at three years. The reasons for this may only be surmised. Scotchbond Universal contains the resin molecule 10-MDP,[14] which has a long history of good bonding capability when used in other materials and other studies.[15,16] However, Scotchbond Universal also contains Vitrebond Copolymer, which has been present in previous 3M-produced dentine bonding agents which has provided systems that are resistant to the detrimental effects of varying humidity.[17] The plurality of carboxylic acid groups in Vitrebond Copolymer interacts strongly with the collagen (hydrogen bonding). In that regard, the combination of 10-MDP and Vitrebond Copolymer would appear, from the results of the present three-year study, to provide effective enamel marginal sealing, whether the enamel margins of the cavity are etched with phosphoric acid or not. In this regard, both a phosphoric acid group (MDP) and a carboxylic acid group (Vitrebond Copolymer) can bond to hydroxyapatite; however, the bond strength of the phosphoric acid group may be considered to be much stronger. Based on these general principles, it may be surmised that chemical bonding to enamel relies mainly on MDP.

Given the relatively recent introduction of Scotchbond Universal, it may not be a surprise that there is little in the previously-published literature for comparison to the present study. However, a number of laboratory and clinical studies have been identified:

- In an extensive laboratory study on universal adhesives, Loguerico and co-workers,[18] using microshear bond strength testing, concluded that selective enamel etching with phosphoric acid might not be crucial for their adhesion to enamel and that "the application of such adhesives in self-etch mode may be a practical alternative to enamel etching in specific clinical situations". This could be considered to be in agreement with the present clinically-based work.
- In addition, Cardenas and colleagues,[19] also using microshear bond strength testing, evaluated three Universal adhesives (Scotchbond Universal; (3M), All-Bond Universal (Bisco Inc.), Futurabond U (VOCO)) in self etch and etch & rinse modes at application times of 20 seconds and 40 seconds,

also agitating the resin on the dentine surface by using manual pressure of 35g on the microbrush. The results indicated improved degree of conversion of the resins at 40 seconds when applied in self etch mode, with the authors adding that the Universal adhesives tested did not have sufficient acidity to produce retentive etching patterns on enamel equivalent to those produced by 35% phosphoric acid, with the authors concluding that "active and prolonged application of universal adhesives in the self-etch mode may be a viable alternative to increase the enamel etching pattern and resin-enamel bond strength". This is of relevance to the present study insofar that it has demonstrated that, at three years, etching the enamel might not be essential.

On the other hand, da Rosa and co-workers,[20] in a systematic review and meta-analysis, considered that the enamel bond strength of universal adhesives was improved with prior phosphoric acid etching.

There are two clinical evaluations which bear comparison with the present work:

- Loguerico and colleagues[21] evaluated, using FDI criteria at three years, 134 restorations bonded using Scotchbond Universal in four etching modalities, concluding that there was no statistical difference among bonding strategies, but adding that there were signs of degradation when the adhesive was applied in self-etch mode. While those results are similar to those in the present work, our results did not indicate such degradation.
- In a further clinical evaluation of Scotchbond Universal in self-etch or total-etch modes in 42 Class V cavities by Lawson *et al*,[22] using Scotchbond Multipurpose as control, 38 restorations were recalled at two years. The results indicated 100% retention for the total etch group and the loss of five restorations in the self-etch group. Marginal discolouration increased over time in all groups, but restorations placed using Scotchbond Universal in self-etch mode exhibited greater marginal staining and the Scotchbond Universal total-etch restorations received the most "perfect" ratings. However, the downside was that the "sensitivity to cold" score in the total etch group was marginally higher than the others.

In the present study, no case of post-operative sensitivity was recorded (or reported). Nevertheless, in light of the findings of Lawson *et al*.[22] and their increased sensitivity in the total etch group, the present authors consider that selective enamel etching, rather than total etching, is well worthy of consideration. It is also relevant to add that, in the studies by Loguerico and colleagues[21] and Lawson *et al*.,[22] class V non-carious cervical lesions were restored, and, while this may be considered to be a severe test of the retentive properties of a bonding agent, in the present study, the restoration margins may have been subjected to the forces of occlusal loading, in itself, a severe test, in which the bonding agent may be considered to have performed well.

Finally, further studies, of longer duration, are indicated in order to determine whether this effectiveness of the marginal characteristics continues in the longer term. However, the clinical message from this study is that the Universal bonding agent used in this work performed satisfactorily at three years whether the enamel margins were etched or not.

CONCLUSION

The results of this study indicate that the restorations placed, using Scotchbond Universal in both total etch and self-etch modes, were performing satisfactorily after three years and that there was no difference in the margin characteristics of the restorations in whichever mode of etching was employed.

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