

A randomised controlled trial of a nanofilled composite at three years:

Did selective enamel etching have an effect?

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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 75 nanofilled resin composite restorations placed in an assortment of cavities using a self-etch dentine bonding agent, in five UK dental practices by members of the UK-based practice-based research group, the PREP Panel, with half of the restorations receiving a selective enamel etch and the other half being placed using a self-etching approach. The results indicated good performance of the restorations examined, with no failures being identified and excellent surface characteristics, in terms of colour stability, minimal surface roughness and optimal anatomic form, Selective enamel etching tended to produce less marginal discolouration, although these results were not statistically significant.

INTRODUCTION

Practice-based research

A majority of research into the effectiveness of dental materials is carried out in dental hospitals or other academic institutions, rather than in general dental practice, even though this is where the majority of dental treatment is performed, worldwide. Reasons for this divergence include the potential cost, given that practices are geared to the efficient treatment of patients rather than research. In addition, the training of general practitioners in research methods may also be suboptimal¹.

However, it may be considered that dental practice increasingly should become the prime location for clinical dental research. Dental practice is the real world. Accordingly, if a technique or material is to be successful, it must be readily operated in the dental practice situation.

The importance of practice-based research has been emphasized by Mandel, who considered that “research is not only the silent partner in dental practice, it is the very scaffolding on which we build and sustain a practice”². In this respect, a wide variety of research projects may be considered to be appropriate to general dental practice, including¹, assessment of materials and techniques, clinical trials of restorations, and, assessment of behaviour and attitudes (of dentists as well as patients). An advantage for the practitioner is the benefit of being

involved in something not normally within the daily routine of practice, with patients having been found to approve of practitioner involvement in research, with the practice and practitioner's professional image being enhanced¹.

The volume of clinical material seen in general dental practice makes dental practice an area of fundamental importance in the assessment of new techniques and materials, as success of a material, device or technique could be considered to be its performance in everyday use in a particular dentist's office. This may be considered to differ from the academic environment of restorations assessed following placement in a dental hospital or school. Indeed, restorations assessed following placement in such an environment may be considered to represent *efficacy*, the performance of the material under ideal circumstances, while the performance in dental practice may be considered to represent *effectiveness*, or, how something performs in the real world. Since the majority of restorations, worldwide, are placed in the real world of general dental practice, it is here that the performance/survival of restorations should predominantly be assessed.

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. All of this is possible when practitioner-based research groups are teamed with the expertise available in academic institutions. One such group in the UK is the group of practice-based researchers known as the PREP (**P**roduct **R**esearch and **E**valuation by **P**ractitioners) 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 years³.

Resin composite restorations

Since the ability to bond to enamel was first described by Buonocore in 1955⁴, this has become an integral part of restorative dentistry, facilitating the development of resin composite materials, with these materials becoming increasingly used worldwide⁵. This may be considered to be principally because of patient concerns about the poor appearance of amalgam restorations and anxieties with respect to the use of a mercury-containing filling material, notwithstanding the fact that the employment of adhesive technology may facilitate the use of minimal cavity designs. Patients also appear to be increasingly conscious of the

appearance of restorations in their posterior as well as their anterior teeth, so the aesthetics of restorations formed in resin composite materials has become increasingly relevant.

A rule of thumb for resin composite materials is that decreasing filler particle size leads to improvements in the polishability of the material⁶. Early microfilled composites, such as 3M Silux, with particles of 0.04 microns, provided good polishability. However, the introduction, in 2003, of a nanofilled material (Filtek Supreme™) was considered to provide a new dimension in polish retention⁷. The third generation of this material was introduced in 2009 (Filtek Supreme XTE™), with shading and fluorescence improved over previous versions. Given the highly aesthetic nature of this new material, it would seem appropriate that an assessment is carried out of the performance of restorations formed in this material in both anterior and posterior teeth, and placed by general dental practitioners.

Study Objectives

The purpose of this practice-based clinical trial is therefore to carry out a three-year evaluation of restorations formed in Filtek Supreme XTE nanofilled resin composite, bonded with Adper Easy Bond (Both 3M ESPE), with 50% of restorations being treated with a selective enamel etch, with the teeth receiving this treatment being randomly selected and

the remaining 50% of restorations having no enamel etch, i.e. with the adhesive used in self-etch mode.

Hypothesis

The hypotheses to be tested are that restorations formed in Filtek Supreme XTE™ bonded with Adper Easy Bond (3M ESPE) perform satisfactorily over a three year period and that selective enamel etching of the margins of half the restorations leads to reduced marginal discolouration.

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MATERIALS AND METHODS

Selection of clinicians

Members of the PREP Panel, each of whom have previous experience in clinical evaluations, were asked, by an explanatory letter, if they would be prepared to evaluate the performance of restorations placed in Filtek Supreme XTE™, bonded with Adper Easy Bond. 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

Secondary outcome measures:

- Lack of post-operative hypersensitivity

Ethical standards

Ethics Committee approval was obtained from NRES, West Midlands Research Ethics Committee prior to commencing the study. 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.

Patient consent

Patients who required up to three restorations in their anterior or 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.

Patient population

Subjects recruited for this investigation were those who required up to three resin composite restorations of any type and who were willing to attend for recalls for the examination of the restorations. Sufficient numbers of patients were recruited, in five dental practices, to make a total of 75 restorations at baseline.

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 up to three 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 tooth/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 tooth shade was selected using the Filtek Supreme XTE™ shade guide, appropriate isolation obtained, and the restoration placed in accordance with the manufacturer's instructions. For anterior teeth, a minimum of two layers of material was used.

Restorations were placed in conjunction with the self-etch bonding agent, Adper Easy Bond. In the present study, the enamel margins of 50% of the restorations were selectively etched with 35% phosphoric acid prior to application of the bonding agent. The restorations that received the phosphoric acid etching step were selected at random by drawing cards (*etch* or *no-etch*) from an envelope.

Recalls

The reviews of the restorations in the present work were completed at three years \pm 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)⁸. 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. When decisions of assessors differed, a consensus opinion was agreed before the patient was dismissed. In the event of a restoration being unsatisfactory, the mode of failure was recorded and the necessary remedial work carried out.

Statistical analysis

Statistical analysis using a Chi-squared test was run for the variables marginal integrity, marginal discolouration and surface roughness for selective-etch restorations vs the self-etch restorations for years one, two and three.

RESULTS AT THREE YEARS

Forty-four restorations, of the 75 placed, of mean age 36.9 months (range 32 – 40 months) in 35 patients (27 Female, 8 Male, of mean age 53.9 years) were examined, a recall rate of 59%. The 44 restorations comprised of 10 Class I, 28 Class II, 2 Class III, and 4 Class V

restorations, split between the selective etch group and the self etch group, as follows:

Class of restoration	Selective etch	Self etch	Total
I	7	3	10
II	16	12	28
III	2	0	2
V	2	2	4
Total	27	17	44

The distribution of the restorations was as follows:

	Selective etch	Self etch	Total
Upper Molar	1	2	3
Upper Premolar	4	4	8
Upper Incisor	3	0	3
Upper Canine	2	1	3
Lower Canine	0	0	0
Lower Premolar	7	5	12
Lower Molar	10	5	15
	27	17	44

Thirty-two per cent (n= 14) of the restorations in posterior teeth involved the replacement of one or more cusps and 82% (n=36) were placed under rubber dam isolation. Of the 28 Class II restorations examined, 3 (11%) were not in contact with the adjacent tooth.

Retention and lack of fracture

All the restorations examined were present and intact.

Anatomic form

100% of the restorations examined were rated optimal for anatomic form, with no unacceptable scores.

Marginal Integrity

At baseline, 100% of the restorations were rated optimal for marginal integrity. The results are presented below:

	Selective etch	Self etch	Overall
Year One	90% A 10% B	91% A 9% B	91% A 9% B
Year Two	87% A 13% B	89% A 11% B	88% A 12% B
Year Three	63% A 37% B	59% A 41% B	61% A 39% B

Marginal discolouration

The results are tabulated below:

	Selective etch	Self etch
Year One	88% A 12% B	74% A 26% B
Year Two	80% A 20% B	58% A 42% B
Year Three	63% A 37% B	53% A 47% B

Where the marginal discolouration score was not optimal, an estimate (agreed by both examiners) was made of the percentage of the length of the margin which was found to be discoloured. The results at three-years are presented below:

Selective etch	Self etch	Overall
4.4%	4.6%	4.5%
(range (2 – 20%))	(range 2 – 20%)	(range 2 – 20%)

Surface Roughness

The results are tabulated below:

	Selective etch	Self etch
Year One	93% A 7% B	88% A 12% B
Year Two	93% A 7% B	82% A 18% B
Year Three	96% A 4% B	88% A 12% B

Secondary caries

No secondary caries was detected.

Colour Match

All of the restorations were rated optimal for colour match.

Statistical analysis

No statistical difference was found between the selective etch and the self-etch groups ($p>0.05$).

Figures I to IV illustrate typical restorations in the study at 3 years, while Figure V presents one of the large cusp replacement restorations which were included in the study.

DISCUSSION

One year evaluations provide useful data on the performance of restorations, particularly in terms of catastrophic failure. However, it could be argued that dentists and patients, alike, would prefer to receive more long-term data. As three-year data will begin to provide an assessment of the medium term durability of a restorative material or technique in clinical service, it would therefore seem appropriate to evaluate materials and techniques at three years and beyond, representing a more robust test of the performance of restorations placed under general dental practice conditions. This work therefore presents a randomized trial of the materials 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 selective enamel etch. Furthermore, one third of the restorations in posterior teeth involved the replacement of

one or more cusps (FIG V). The study methodology was designed to comply with the CONSORT 2010 Statement for the conduct of randomized controlled trials⁹ and it may be considered to have complied with the majority of these.

The recall rate was lower than anticipated: this may have been as a result of several factors. First, a higher than usual number of patients appeared to have to move location because of their work (including a number from the Armed Forces – perhaps not the optimum group for participation in a three year clinical evaluation, in hindsight). Second, the independent examiner was scheduled to visit each of the participating practices on only *one* occasion, at a time which was previously considered suitable for the majority of patients. This was obviously not the case in this study, illustrating one of the difficulties in clinical trial work, and practice-based research in particular, namely, patient co-operation with recall visits. On the other hand, it has been considered that patients who do not change their address might, today, be unusual in this age of increasing mobility of the population¹⁰.

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 are the excellent surface characteristics, in terms of colour stability, minimal surface roughness and optimal anatomic form, all of these being potentially due to the

nanofiller utilized in the material under test. This has been previously demonstrated to provide good wear resistance and polish retention^{11,12}, although Kaizer and co-workers¹³, in a systematic review of in vitro studies, contest the previously held view that nanofil or submicron composites possess better surface smoothness than traditional microhybrids. While this is of relevance in the restoration of posterior teeth, it may be considered to be of special importance when teeth in the aesthetic zone are involved.

Given the study methodology which involved the selective enamel etching of 50% of the margins, the condition of these at three years is of interest. "Selective enamel etching" is a relatively new concept in restorative dentistry, with one of its first uses being in the study by Peumans and colleagues¹⁴. When their study was extended to eight years¹⁵, 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, the results of the present study, which included a variety of cavity types at three years, are broadly similar, given that, in the selective enamel etch group, 63% of restoration margins scored A, in comparison with 53% of the restorations in the self-etch group, but with

little difference in marginal integrity, as in the Peumans study¹⁵. The lack of statistical significance in the present study may be as a result of the smaller numbers of restorations at the three year recall. In this regard, the so-called *self-etch* bonding agents were introduced because of dentists' requests for ease of use and speed, with this involving not using phosphoric acid. However, in hindsight, it could be considered that clinicians were naïve to expect materials with a pH of up to 2.5 to provide similar marginal integrity or absence of marginal discolouration on enamel margins as could be obtained using phosphoric acid with a pH of 0.5, remembering that pH operates on a logarithmic scale.. Although the results of the selective enamel etch vs self etch groups in the study did not demonstrate a statistically significant difference, the clinical message from this study is that the so-called self-etch bonding agent used in this work is likely to need an enamel etch with phosphoric acid if marginal integrity is to be optimum.

The hypothesis tested in the present work, that restorations formed in Filtek Supreme XTE™ bonded with Adper Easy Bond (3M ESPE) perform satisfactorily over a three year period, is accepted, while the hypothesis that selective enamel etching of the margins of half the restorations leads to reduced marginal discolouration is rejected.

CONCLUSION

Restorations of varying types, formed in the material Filtek Supreme XTE (3M ESPE) bonded with Adper Easy Bond (3M ESPE) placed under the conditions pertaining to general dental practice in the UK, were found to be performing well at three years. Selective enamel etching tended to produce less marginal discolouration, but did not have an effect on marginal integrity.

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LEGENDS FOR ILLUSTRATIONS

Figure I: Class II restoration, No Selective Etch, LR6 at 3 years

Figure II: Class I restoration, Selective Etch, LR6 at 3 years

Figure III: Class V restoration, Selective Etch, UL3 at 3 Years

Figure IV: Class II restoration, No Selective Etch, LR5 at 3 years

Figure V: Multi-cusp replacement restoration, LL7 Selective Etch at 3 year

Fig I



Fig. II



Fig. III



Fig. IV

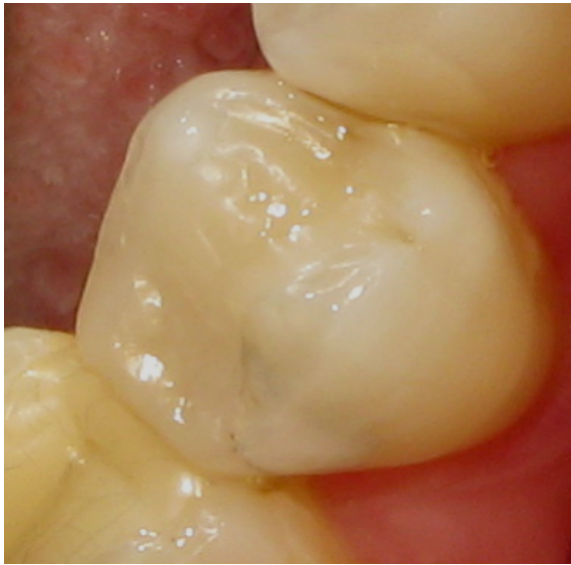


Fig. V



Table 1: Criteria for restoration evaluation⁸ (*=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