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Five Year Clinical Evaluation of Restorations Placed in a Low Shrinkage Stress Composite in UK General Dental Practices

ABSTRACT

This paper evaluates the five year clinical evaluation of restorations formed in a low shrinkage stress resin composite material (3M ESPE Filtek Silorane, Seefeld, Germany) and placed in the general dental practices of five members of the PREP Panel, a group of UK practice-based researchers. Results indicated satisfactory performance of the material under evaluation, other than for marginal staining, which affected 60% of the restorations evaluated after five years, albeit with less than 10% of the circumference of the restorations being affected. CLINICAL RELEVANCE: The low shrinkage stress material, Filtek SiloraneTM, demonstrated good clinical performance in the majority of parameters which were assessed at five years.

INTRODUCTION

PRACTICE BASED RESEARCH

The value of practice-based research has been previously discussed,[1] with the arena of general dental practice having been considered the ideal environment in which to carry out evaluations of the handling of dental materials and their clinical effectiveness. It is the "real world" in which the majority of dental care is provided, worldwide.

A UK-based group of practice-based researchers is the PREP (Product Research and Evaluation by Practitioners) Panel. This group, established in 1993, have completed over 70 projects – including eight clinical evaluations of restorations placed under general dental practice conditions.[2] It is apparent that the advantages of practice-based research are now being recognised, as demonstrated by the formation of groups in the USA and The Netherlands.[3,4]

LOW SHRINKAGE STRESS DENTAL MATERIALS

Resin-based dental materials are becoming increasingly used[5] worldwide, and it may be considered that this trend will be accelerated following the signing of the Minamata Agreement in which world governments agreed to ban the use of mercury for a wide variety of indications (for example, lighting, fertilisers, and thermometers) and phase down the use of dental amalgam. The final ratification of the Minamata Convention on Mercury has recently stated that individual nations can work to gradually scale down the use of dental amalgam, rather an unworkable complete ban, with this having been announced recently.[6]

In this regard, most used among potentially available non-mercury containing materials is resin composite.[5] However, this material is not without disadvantages when compared with dental amalgam. It has been shown to take longer than amalgam to place[7] and shrinks on polymerisation, with the potential to set up stresses in the restored tooth unless these are managed, although the clinical relevance (at least in respect of restoration longevity), of polymerisation shrinkage stress has recently been challenged.[8]

Research, development and the introduction of new commercial resin composite materials have sought to avoid the potential clinical problems of polymerisation shrinkage and stress. For example, the so-called "bulk-fill" resin composites use low shrinkage stress resin chemistries (such as "stress decreasing resin", SDR, Dentsply) and have been reported to reduce stresses in the restored tooth[9] and, most recently, provide good clinical service.[10] Other technologies include materials with reduced resin conversion (ELS Saremco: Switzerland), higher filler loading (Quix-Fill, Dentsply) or larger molecular weight monomers (Kalore, GC) which have been developed in an attempt to overcome the problems associated with polymerisation shrinkage.

Polymerisation stress is not an intrinsic material property, but a complex interaction of volumetric shrinkage, elastic modulus, rate of polymer conversion, cavity configuration (the ratio of bonded to 'free' surface area) and compliance of tooth tissue.[11] It follows that the development of materials that help reduce the magnitude of stress upon polymerisation may be beneficial for short- and long-term effectiveness. One such material, developed over a decade and commercialised in 2005, is Filtek Silorane (3M ESPE), the properties of which were reviewed in by Burke *et al*.[12] and tested by Lien and Vanderwalle in 2010.[13] In brief, this material was reported to exhibit:

A novel polymerisation characteristic compared with contemporary dental resin composites by cationic ring-opening polymerisation of "silorane" monomers; a hybrid formed of both siloxane and oxirane structural moieties[14]

Low polymerisation shrinkage. In this regard, Naoum *et al*.[15] tested the real time polymerisation shrinkage profile of Filtek Silorane and three conventional composite materials. Their results indicated that Silorane and Kalore (GC) exhibited lower shrinkage rates and lower shrinkage volumes compared with the other materials, and suggested that clinicians selecting a composite must consider the rate of polymerisation as well as the total volumetric shrinkage[15]

Lower compressive strength, but similar diametral and higher flexural strength properties compared with some other more conventional resin composite types; Beautiful (Shofu, San Marcos, CA, USA), Dyract Extra and Esthet-X (Dentsply:York, PA, USA), and Filtek Supreme and Filtek Z250 (3M ESPE, St Paul, MN, USA)[13]

Low solubility due to the inherent hydrophobic properties of the siloxane groups[16]

Lower thickness oxygen inhibition layer, although this was not found to affect strength of bond between increments[17]

While short term evaluations of the survival of restorations using Filtek Silorane,[18] and one long term study, by Schmidt *et al*.[19] have been published, it is the purpose of this study to assess, at five years, the clinical performance of restorations, formed using a low shrinkage stress resin composite restorative material, (Filtek Silorane, 3M ESPE) placed by five members of the PREP Panel in general dental practice and primary dental care.

METHODS

The methodology for the study has previously been reported.[12] However, in brief:

- Ethical approval was obtained
- Five members of the PREP Panel who had previous experience in the clinical evaluation of dental materials were recruited and each asked to recruit a sufficient number of patients to provide a minimum of 20 class I or II restorations per centre, to a maximum of three restorations per patient
- Clinicians to follow the stated patient inclusion and exclusion criteria
- Clinicians to place the material to a maximum depth of 2.5mm per increment
- Clinicians to follow the manufacturer's instructions with regard to curing time
- Assessment by one independent examiner along with the PREP Panel member who placed the restoration(s), using modified USPHS criteria *(Table 1)*.

The study objectives were as follows:

To evaluate the five-year clinical performance of posterior restorations formed in Filtek SiloraneTM in adult patients, with primary end points being:

- Retention of the restoration
- Lack of fracture of the restoration
- Margin integrity
- Secondary caries status

And, secondary end points being:

- Health of gingival tissues surrounding the restored teeth, as assessed by the criteria presented in Table 2
- Colour match
- Stain resistance
- Surface quality

Table 1: USPHS Criteria used in the evaluation (*=unacceptable);
Anatomical form
0 = Restoration continuous with tooth anatomy
1 = Slightly under- or over- contoured restoration
2*= Restoration is undercontoured, dentine or base exposed
3*= Restoration is missing; restoration causes pain in tooth or adjacent tissue.
Secondary caries
Examine all visible margins
0 = No visible evidence of caries contiguous with the margin of the restoration
1*= Caries is evident contiguous with the margin of the restoration
Marginal adaptation
0 = Restoration is contiguous with existing anatomic form, sharp explorer does not catch
1 = Explorer catches, no crevice is visible into which the explorer will penetrate
2*= Crevice at margin, enamel margin exposed.
3*= Obvious crevice at margin, dentine or lute exposed
Marginal discolouration, enamel margins
0 = No discolouration present
1 = Slight staining present, can be polished away.
2 = Obvious staining, cannot be polished away
3*= Gross staining
Marginal discolouration, dentine margins
0 = No discolouration present
1 = Slight staining present, can be polished away.
2 = Obvious staining, cannot be polished away
3* =Gross staining
Surface roughness
Grade for labial and palatal margins
0 = Smooth surface
1 = Slightly rough or pitted
2 = Rough, cannot be refinished
3*= Surface deeply pitted and irregular
Colour match
Examine margin for colour match to tooth substance, where visible
0 = Very good/good colour match, restoration almost invisible
1 = Slight mismatch in colour, shade or translucency
2*= Obvious/gross mismatch, outside the normal range
3*= Gross mismatch
Gingival health: To be assessed adjacent to the restoration
1 = Optimum gingival health
2 = Mild inflammatory changes, no bleeding, slight colour change/oedema
3 = Moderate inflammation, bleeding on probing, redness, oedema & glazing
4 = Severe inflammation, marked redness & oedema, spontaneous bleeding

Table 2. Criteria used for gingival health

1= Healthy gingivae
2= Mild inflammation – slight colour change, slight oedema, no bleeding on probing
3= Moderate inflammation – redness, oedema and glazing, bleeding on probing.
4= Severe inflammation – marked redness and oedema, tendency to spontaneous bleeding

RESULTS

Of the 127 restorations placed at baseline, eight restorations were lost to the trial for the reasons presented in Table 3, with 70 restorations (recall rate 59%), of mean age 62 months (range 54 – 68 months) in 45 patients (28 Female and 17 Male) of mean age 53 years, being examined at 5 years. The remaining forty-nine patients were not reviewed due to patients' inability to attend review appointments.

Table 3. Reasons for loss of restorations to the trial, other than patient unavailability

	Year 1	Year 2	Year 3	Year 5	Total
Tooth extracted		2			2
Secondary caries			2		2
Restoration #			1		1
Patient died		1			1
Patient moved away		1	1		2

The distribution of 70 restorations (composed of 17 Class I and 53 Class II) is presented in Table 4.

Table 4. Distribution of the restorations examined at 5 years

	Molar	Pre-Molar	Total
Upper Class I	12	0	12
Class II	17	14	31
Lower Class I	4	0	4
Class II	18	5	23

Thirty-four (n= 24) of the restorations involved the replacement of one or more cusps and 74% (n=53) were placed under rubber dam isolation.

Parameters assessed, using the USPHS criteria, were:

Retention and lack of fracture

All of the restorations examined were present and intact.

Anatomic form

Ninety-three per cent of the restorations examined were rated optimal for anatomic form, with no unacceptable scores. (100% Optimal at one-year, 97% at Year 2, 95% at Year 3)

Margin integrity

Sixty-four per cent of the restorations were rated optimal for marginal integrity (90% Optimal at one-year, 83% optimal at Year 2, 78% at Year 3) with no restorations rated unacceptable.

Margin discolouration

Twenty-nine per cent of the restorations were rated optimal for marginal discolouration (96% Optimal at one-year, 77% optimal at Year 2, 51% at Year 3) and none were scored unacceptable. Where the marginal discolouration score was not optimal an estimate (agreed by both examiners) was made of the percentage of margin discoloured. A mean of 9% of the margin was discoloured in these cases (range 2 – 70%). (12% at Year 3)

Secondary caries

No cases of secondary caries were detected.

Gingival health

Three surfaces (mesial, facial and distal) of the teeth involved were scored for gingival health according to the criteria in Table 2. The results for gingival health adjacent to Class II restorations are presented in Table 5.

Table 5. Gingival health adjacent to the Class II restorations examined in the study

	Baseline	Year 1	Year 2	Year 3	Year 5
Facial	1 97% 2 3%	1 95% 2 5%	1 98% 2 2%	1 100%	1 100%
Mesial	1 97% 2 3%	1 94% 2 6%	1 96% 2 4%	1 98% 2 2%	1 99% 2 1%
Distal	1 97% 2 3%	1 96% 2 4%	1 96% 2 4%	1 99% 2 1%	1 94% 2 6%

Colour Match

All of the restorations were rated optimal for colour match. As these were all posterior restorations a very slight shade difference was regarded as optimal.

Stain Resistance

Surface staining was noted in 2 restorations (3%). On questioning the patients they were either smokers or liked dark tea. (No staining of the restoration surface was recorded at years one & two and 3% at year 3)

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Surface quality

Eighty-three per cent of the restorations were rated optimal for surface quality, with no unacceptable scores. (92% at Years 2 & 3, with 95% Optimal at Year 1)

DISCUSSION

The results of this practice-based evaluation indicate a satisfactory performance of a low shrinkage stress resin composite restorative system, when placed in the "real world" of general dental practice, with patients paying the standard charge for their restorations, albeit being reimbursed for attendance for their review appointments. A total of three of 127 restorations failed during the five years of the evaluation: two restorations having failed because of secondary caries at the time of the three year assessment and one restoration having fractured, also at three years. Two teeth involved in the study were extracted, but this was not associated with the Silorane restorations.

The recall rate may be considered disappointing, but this demonstrates the difficulty in maintaining patient co-operation over a lengthy study period, despite the patients being remunerated for their attendance. In this regard, while review appointment sessions were scheduled to avoid holiday periods and at a time as advised by the practitioner involved to be most advantageous, for some patients the times of the assessment appointments were not convenient due to either work commitments or, pre-arranged holidays. In this regard, the attrition rate in clinical trials has recently been discussed by Jokstad,[20] who argued that, in today's mobile world, the likelihood of a low attrition rate was unrealistic. He further argues that patients who return for follow-up clinical examinations for many years after the initial restoration appointment might not be representative of the population at large. The results are therefore considered to provide an indication of the performance of the material under evaluation under general dental practice conditions.

Few comparative studies are available. Baracco and colleagues[18] published one-year results of 75 restorations, with one third of these being placed using the Silorane system, with the authors concluding that they did not find any advantage of the Silorane-based composite compared with the two other test materials. However, the numbers may be considered low, and one-year evaluations may be considered to not present anything other than the potential for catastrophic failure. One five-year study, by Schmidt and co-workers.[19] These workers evaluated 52 class II restorations in 48 patients in Filtek Silorane and 55 formed in Ceram X (Dentsply), a conventional resin composite, in 48 patients, all placed by the same dentist, with the restorations being assessed by one "experienced dentist/evaluator". The results indicated no difference in any of the parameters assessed, and concluded that there was no clinical advantage of the Silorane-based system over the conventional methacrylate based resin composite.

The authors of the present study present an alternative view with their results, namely, that the low shrinkage stress composite provided good survival of restorations placed in a general dental practice situation, with a substantial proportion of the restorations in the present study being cusp replacements. Of particular note is the reported lack of post-operative sensitivity reported in the two-year evaluation by the present authors,[12] which contrasts with reports in the literature which present an incidence of post-operative sensitivity of between 2% and 5% for conventional resin composite materials.[21-23] Furthermore, a study, by Briso and co-workers, of 292 posterior composite restorations reported post-operative sensitivity in 26% of MOD restorations at 24 hours, decreasing to 7% at 90 days and with this sensitivity being higher in larger cavities.[24] The lack of post-operative sensitivity when using a low shrinkage stress material, in conjunction with its self-etch adhesive, is considered to be a significant benefit by the present authors, with their advice to clinicians to determine the shrinkage stress of materials that they are considering using in posterior teeth.

The material under evaluation in the present study has been withdrawn from the market due to reduced availability of one or more of the resin monomers within the Silorane chemistry, but may also have been because the material required its own dedicated bonding system which was time-consuming to use, and possibly also (as indicated by the results of the present work) because this did not provide a sufficiently good etch of the enamel to prevent marginal staining. The results of the present study would appear to indicate that selective enamel etching was required when using the Silorane bonding system, something that has become apparent in the literature, with regard to the so-called self-etch adhesives, in recent years.[25]

Recently introduced so-called bulk fill resin composite restorative materials (as opposed to bulk-fill base materials) which have attempted to increase curing depth whilst minimising shrinkage stress, (such as Filtek Bulk Fill Restorative, Tetric Evoceram Bulk (Ivoclar), Venus bulk-fill (Heraeus)), may step into the gap left by the demise of Silorane. However, there is currently a lack of clinical data, so effects of stress on longevity are unknown, and indicate a need for more clinical studies.

Finally, as posterior composite restorations become increasingly important as the phase down of amalgam suggested by the Minamata Agreement gathers momentum, the current literature provides details that posterior composite restorations in adults may perform well, with a recent systematic review by Astvaldsdotir and colleagues[26] reporting a high survival proportion, with a minimum follow up time of four years, and other positive reports from general dental practice.[27-29] It may therefore be considered that the development of the low shrinkage stress resin composite restorative system Silorane, and notwithstanding their limitations, the use of self-etch adhesive systems and accordant lack of post-operative sensitivity, has been an important step towards understanding the most suitable resin composite material properties that may ultimately replace amalgam, something which is increasingly required in the post-Minamata era.

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Figures 1 to 4 present a selection of restorations reviewed at Year 5

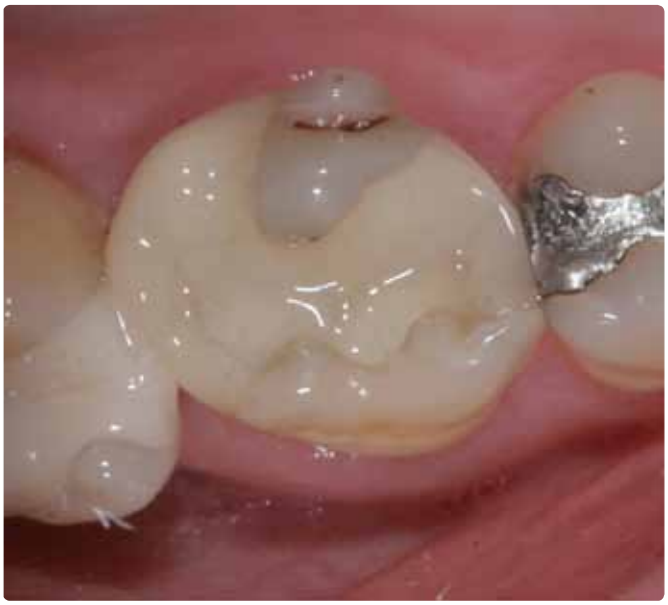

Figure 1: 16 MOD at 5 years (note probe marks from review examination) (PS)

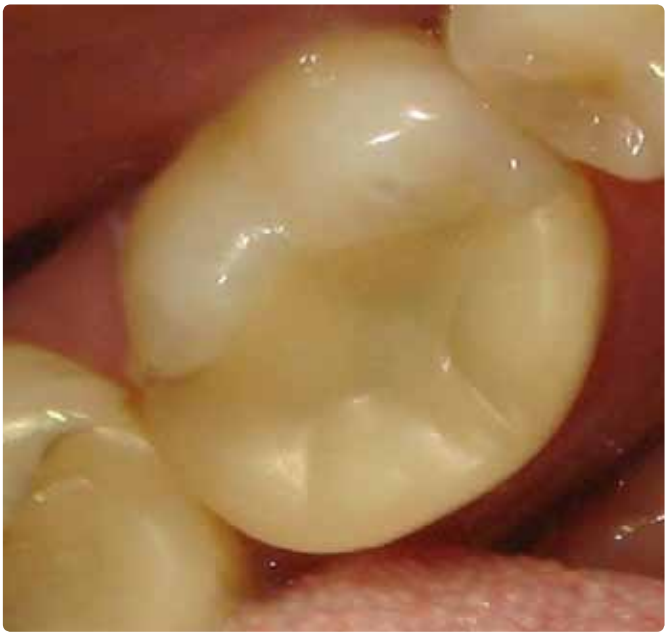

Figure 2: 46 MOD at 5 years (AJ)

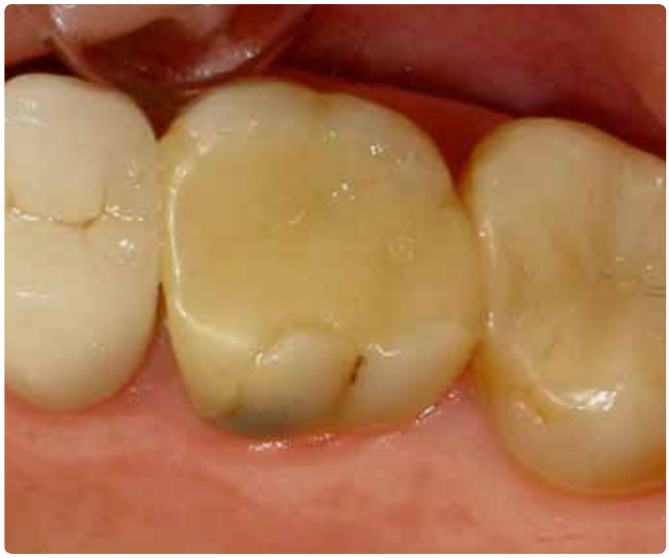

Figure 3: 16 MOD at Year 5 (OT)

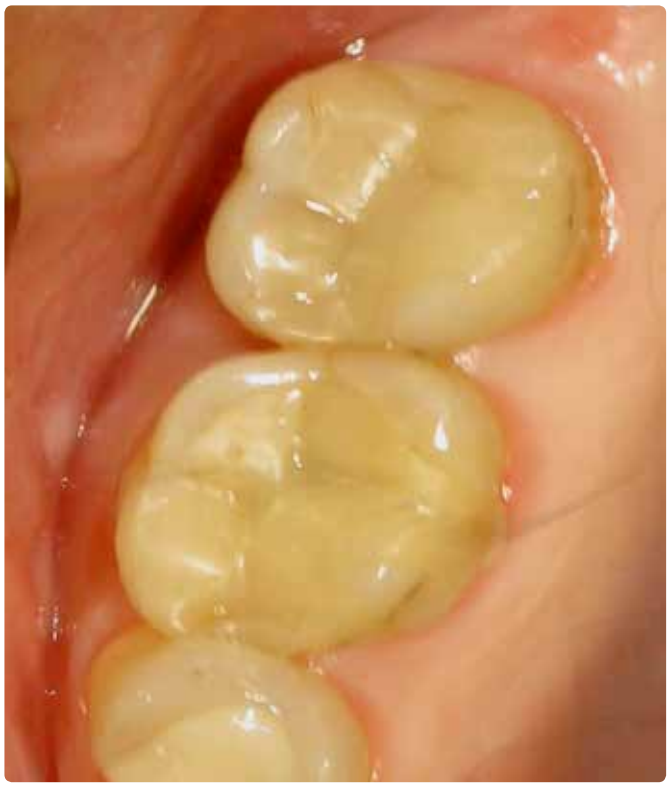

Figure 4: 16 and 17 MOD restorations at Year 5 (OT)

CONCLUSION

Restorations formed in a low shrinkage stress resin composite restorative system and placed under general dental practice conditions in the UK, were found to provide good clinical service at five years, albeit with a high incidence of marginal staining at some sites around the restorations.

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CONFLICT OF INTEREST

The authors do not have any financial interest in the company whose material was used in this study.

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