Two year clinical evaluation of a low-shrink resin composite material in UK general dental practices

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ABSTRACT

Objective. A novel resin composite system, Filtek Silorane (3M ESPE) with reduced polymerization shrinkage has recently been introduced. The resin contains an oxygen-containing ring molecule ('oxirane') and cures via a cationic ring-opening reaction rather than a linear chain reaction associated with conventional methacrylates and results in a volumetric shrinkage of ~1%. The purpose of this study was to review the literature on a recently introduced resin composite material, Filtek Silorane, and evaluate the clinical outcome of restorations formed in this material.

Methods. Filtek Silorane restorations were placed where indicated in loadbearing situations in the posterior teeth of patients attending five UK dental practices. These were evaluated, after two years, using modified USPHS criteria.

Results. A total of 100 restorations, of mean age 25.7 months, in 64 patients, were examined, comprised of 30 Class I and 70 Class II. All restorations were found to be present and intact, there was no secondary caries. Ninety-seven per cent of the restorations were rated optimal for anatomic form, 84% were rated optimal for marginal integrity, 77% were rated optimal for marginal discoloration, 99% were rated optimal for color match, and 93%% of the restorations were rated optimal for surface quality. No restoration was awarded a "fail" grade. No staining of the restoration surfaces was recorded and no patients complained of post-operative sensitivity.

Significance. It is concluded that, within the limitations of the study, the two year assessment of 100 restorations placed in Filtek Silorane has indicated satisfactory clinical performance.

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1. Introduction and literature review

1.1. 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 the latter 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 and a perception that the training of general practitioners in research methods may be incomplete. However, there are many reasons why dental practice increasingly should become the prime location for clinical dental research. Dental practice is the real world, better representing the day-to-day handling, placement and service life of resin composites. 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" [1]. An advantage for the practitioner is the benefit of being involved in something not normally within the daily routine of practice, and that patients have been found to approve of practitioner involvement in research, with the practice and practitioner's professional image being enhanced [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. All of this is possible when practitioner-based research groups are teamed with the expertise available in academic institutions. Perhaps the most well known group of practice-based researchers is the Clinical Research Associates (CRA) founded by Gordon Christensen in Utah, USA over thirty years ago. A UK-based group of practice-based researchers is the PREP (Product Research and Evaluation by Practitioners) Panel. This group was established in 1993 with 6 general dental practitioners, and has grown to contain 33 dental practitioners located across the UK and one in mainland Europe. It has completed over 50 projects—"handling" evaluations of materials and techniques, and more recently, clinical evaluations ($n = 9$) of restorations at one year and up to five years. This paper describes the early performance of a novel resin composite restorative material, Filtek Silorane (3M ESPE, Seefeld, Germany), when placed in loadbearing situations in posterior teeth of patients attending the practices of five members of the PREP Panel.

1.2. Resin composite restorations and polymerization contraction stresses

The majority of conventional resin composite restorative materials shrink up to 3% on polymerization, resulting in stresses at the (bonded) restoration margin, or within the restorative material itself [3], with the clinical result of these stresses being [3]:

Table 1 – Clinical techniques which have been suggested to reduce or overcome the effect of polymerization contraction stresses.

- Incremental placement, with one increment touching only one wall of the cavity, and, limiting the size of the increments
- Ramped curing, in which the curing light does not reach its maximum intensity for up to 20 s
- Pulse activation, in which the resin composite material is cured for 5 s and then left for up to 5 min [5]
- Use of macro-fillers to reduce resin volume: however, this has not been shown to improve clinical effectiveness [6]
- Placement of a flowable composite base layer which has been shown to reduce microleakage at the gingival margin in Class II cavities in a number of *in vitro* experiments [7,8]
- Use of a chemically cured composite or glass ionomer base

- Internal microcracks within the bulk of the material.
- Separation of the bonding agent from the cavity wall, with resultant marginal leakage and post-operative sensitivity.
- Enamel microcracks, with a resultant white line adjacent to, or at a distance from the restoration.
- Deformation of tooth, also leading to pain post-operatively, generally when the patient bites on a cusp.

Shrinkage stress is not an intrinsic material property and the magnitude of the stresses depends on a number of factors, including properties that are intrinsic to the material, such as:

- volumetric shrinkage,
- the modulus of elasticity,
- the degree of cure (polymer conversion),
- the coefficient of thermal expansion,
- silanization characteristics at the resin-filler interface,

and clinically oriented factors such as:

- the rate of cure and polymerization kinetics,
- the configuration of the cavity into which the restoration is placed,
- compliance of the remaining tooth structure.

In this respect, it has recently been demonstrated that it is in larger, rather than smaller, Class I cavities that the effect of the so-called configuration factor may be most relevant [4].

A number of clinical techniques have been suggested to reduce or overcome the effect of polymerization contraction stresses. Table 1 [5–8] presents some of the techniques which have been advocated for minimizing stress. The benefits of certain techniques such as "soft-start" or "ramped" curing, or the use of flowable resin composites is debated in the literature. The former method may lead to decreased structural integrity and, depending on material formulations, the latter may increase polymerization shrinkage compared with conventional techniques.

It could also be considered that some or all of these additional stages lead to increased technique sensitivity during placement of resin composite restorations, and indeed, that these stages, which are designed to reduce polymerization contraction stress, could be a source of operator stress! The use of a resin with reduced polymerization shrinkage, with a

net volumetric shrinkage of nil could therefore be an advantage to the clinician.

1.2.1. *Resin composite modification and reduced shrinkage stress*

The magnitude of polymerization shrinkage stress generated at the tooth-restoration interface and extent of any gap formation is a multifactorial process. It might be considered that commercial resin composites with lower elastic modulus (i.e. "flowables") do not necessarily reduce the magnitude of shrinkage stress since the volume or viscosity of the resin component is reduced and volumetric shrinkage will increase. Likewise, resin composites with lower volumetric shrinkage generally exhibit higher shrinkage stress since materials with high filler loads exhibit increased elastic modulus [9] and an increased change in stiffness on cure. Accordingly, low-shrinking materials do not necessarily provide lower contraction stress. However, materials that exhibit reduced shrinkage using alternative resin chemistries rather than increasing filler loads may reduce stress values of constrained composites.

Bisphenol glycidyl methacrylate (BisGMA) has been used as a resin in dental composite restoratives since its development and introduction by Bowen in 1958 [10], However, this is a viscous resin which would be unworkable as a dental restorative when filler particles are added, and, accordingly, it is necessary to add a diluent resin to the material to allow the manufacture of a resin composite material which is readily handled by dental healthcare workers [11]. This diluent resin is, in many materials, triethylene glycol dimethacrylate (TEGDMA). Its polymerization contraction is *circa* 5%, thus increasing the overall polymerization contraction of the resin composite material to which it is added. Manufacturers have obviated the use of TEGDMA, in materials introduced in the late 1990s, by substituting BisGMA in part with less viscous resins such as urethane dimethacrylate (UDMA) and bisphenol ethoxylated methacrylate (BisEMA), thereby reducing the polymerization contraction from ~3% to 2%. In this respect, improved filler particle morphologies, which improve packing and reduce shrinkage, may also play a part.

The significant decrease in use of TEGDMA in commercial materials has played a role in reducing shrinkage stress and cuspal deflection of wide MOD cavities [12]. A similar reduction in cuspal movement was demonstrated when an Ormocer material (Admira: Voco, Cuxhaven, Germany) with a polymerizaton contraction of 2% was used [13]. However, the resins used in the above materials are based upon methacrylate chemistry and it would appear impossible to reduce the polymerization shrinkage of these materials to much less than the values stated above because of the inherent nature of the resins and polymerization reaction involved, although a dimer acid based material, in which phase separation purportedly reduces shrinkage without decreasing polymer conversion, has recently been reported [14].

The use of alternative chemistries has been at the forefront of research and development for dental resin composites for many years. Researchers have investigated the use spiro-orthocarbonate resins which expand on polymerization [15]. However, poor reactivity and decreased mechanical properties have precluded their viability as a commercial material.

Moreover, it might be argued that a net zero shrinkage or even expansion would be more detrimental than <3% shrinkage of methacrylates which allows for water uptake during service. The use of thio-lene resins may provide a suitable replacement for conventional resins and have been subject of modern resin research. The thio-lene chemistry offers a "step-growth" rather than the "chain-growth" curing characteristic associated with methacrylates. This has been reported to provide more control of the curing process and reduce polymerization shrinkage stress [16].

1.2.2. *Filtek Silorane*™

Filtek Silorane (3M ESPE Dental Products, Seefeld, Germany) (hitherto, in this paper, termed Silorane) has recently been marketed and is based on an innovative resin matrix [17]. The epoxy-based resin, which contains an oxygen-containing ring molecule ('oxirane'), cures via a cationic ring-opening reaction rather than a linear chain reaction associated with conventional methacrylates and results in a volumetric shrinkage of ~1%, which may reduce the deleterious effects of shrinkage stress at the tooth-restoration interface. In this respect, work by Watts in 2007 has demonstrated substantially reduced polymerization shrinkage stress in comparison to other resin composite restorative materials [18]. The incorporation of a siloxane molecule (hence the term **"silo**(xane)(oxi)**rane"**) has resulted in a material with comparable material properties [19], and increased hydrolytic stability [20], compared with conventional materials.

Because of the comparatively recent introduction to dentistry of Silorane, there is not a large volume of research into its properties and performance. However, the results of a number of experiments may be considered to be of interest, particularly those published in the peer reviewed literature.

1.2.2.1. *Mutagenic effects.* Silorane has been found to have no mutagenic effects when analyzed for the formation of chromosomal aberrations and the induction of gene mutations in mammalian cells [21].

1.2.2.1.1. *Marginal adaptation.* In a laboratory experiment examining the setting characteristics of commercial composites using a bonded disk method, degree of conversion and cavity adaptation, Silorane exhibited superior properties compared with two dimethacrylate-based materials (Ceram × Mono [Dentsply De Trey, Konstanz, Germany] and Clearfil Majesty [Kuraray, Japan]), in terms of shrinkage strain and marginal adaptation [22]. The authors added that "the setting shrinkage characteristics of resin composites affects their marginal adaptation with dentin and that shrinkage strain rate and time at maximum strain rate were found to be more important than total volumetric shrinkage in predicting the adaptation in dentin cavities".

1.2.2.1.2. *Cusp deflection.* The results of *in vitro* cusp deflection and microleakage of maxillary premolars restored with novel low-shrink dental composites indicated reduced cusp deflection when compared with two conventional materials [23]. Those results concur with those obtained by Bouillaguet and colleagues who showed that cusp movement during polymerization of Silorane induced the lowest tooth deformation when tested against four conventional resin composite materials [24]. Microleakage was also found to be

reduced when a low shrink resin, Hermes (a low shrinkage Silorane prototype) was used [25].

1.2.2.1.3. Physical properties. The physical properties of Silorane, in comparison with four conventional resin composite materials and a giomer, have recently been investigated by Lien and Vandewalle [26]. Their results indicated a lower compressive strength and microhardness for Silorane, but a relatively higher flexural strength/modulus and higher fracture toughness. Silorane was shown to have the lowest polymerization shrinkage, confirming the original testing by Weinmann and co-workers. Their results indicated a 0.94% and 0.99% volumetric shrinkage, respectively, when using the bonded disc and Archimedes method [27]. The physical properties of Silorane have also been tested by Ilie and Hickel, whose results indicated that these were comparable to other clinically successful methacrylate-based composite materials [28]. These workers also noted that there was no difference in degree of cure at depths of 2 mm and 6 mm.

1.2.2.1.4. Shrinkage stress. Shrinkage stress has been found to be reduced for Silorane by Ernst and co-workers [29] when tested against ten conventional resin composite materials.

1.2.2.1.5. Elution. No substances were found to elute from Silorane in water at 72 h, although Silorane monomers and an initiator component were found to elute into a solution of 75 vol% ethanol, although the authors, Kopperud and colleagues, stated that this may not have represented a clinically relevant situation [30]. These data confirm the earlier work of Eick et al. [31] whose results indicated the stability of Silorane in all the aqueous fluids in which it was tested.

1.2.2.1.6. Water sorption and solubility. When tested against two conventional methacrylate-based resins (Z100 and Z250), in water sorption and solubility testing, Silorane showed a lower solubility compared with the methacrylate resins [30]. It has also been shown that the hydrophobicity of the siloxane groups improves the stability of Silorane in biological fluids [31].

1.2.2.1.7. Oxygen inhibited layer. A study by Tezvergil-Mutluay and co-workers [32] suggested that no oxygen inhibited layer (OIL) existed at the surface of a freshly cured sample of Silorane, and incremental bond strengths between successive layers of Silorane were slightly lower than conventional dimethacrylate composites. In addition, these workers demonstrated that the shear bond strength between successive layers of Silorane composite showed a decrease in shear bond strength and an increase in the percentage of adhesive failures when the time of placement between successive layers increased, timing being "fresh", 20 s and 5 min. The finding with regard to OIL differs from the results of a study by Shawkat and co-workers [33] in which the incremental bond strengths of a range of experimental and commercial resin composite materials were tested, with the results indicating a range of oxygen inhibited layer (OIL) thicknesses from 19.2 to 13.8 μm for dimethacrylate-based composites and 9.0 μm for Silorane. No material exhibited a measureable OIL when cured in nitrogen. The authors concluded that the bond strength between successive layers of Silorane should be no different to conventional methacrylate materials [33].

1.2.2.1.8. Bonding to dentin. Bonding to dentin using the Silorane adhesive system (SAS), when investigated by Santini and Miletic [34], was found to produce a hybrid layer of similar thickness as a methacrylate-based adhesive (Excite [Ivoclar Vivadent]) and thicker than the one-step adhesives (G Bond, [GC] and AdheSE [Ivoclar Vivadent]) that it was tested against. This presence of an interaction zone has also been confirmed by the work of Mine and colleagues [35] who also found that the two bottles in the Silorane adhesive system, SSA-Primer and SSA-Bond, were distinguishable as two distinct layers. In this respect, it has been postulated that the high viscosity second layer of adhesive might act as an elastic buffer [36]. In addition, Van Ende and colleagues [36] examined the stress at the adhesive interface with differing configuration factors, with their results indicating that cavity configuration did affect the micro-tensile bond strength of the Silorane adhesive system and considered that an incremental layering technique was still required for placement of Silorane restorations. The authors considered that factors other than polymerization shrinkage influenced the micro-tensile bond strength.

Further work is obviously indicated to test other features of Silorane, such as polymerization exotherm, the properties of the quartz glass filler, wear resistance and hydrophobicity. However, given the generally favorable *in vitro* testing of Silorane, it would appear appropriate to test its clinical effectiveness. It was therefore the aim of this study to assess the performance of Silorane restorations placed in load-bearing situations in patients attending five UK dental practices.

2. Methods

2.1. Ethical standards

The study was conducted in accordance with the Declaration of Helsinki (1964) as revised in Venice in 1983. Multicentre Research Ethics Committee approval was obtained from Southampton and South West Hampshire Research Ethics Committee (REC Ref: 08/H502/93) prior to commencing the study, as too was an additional ethical requirement (peculiar to the UK) for each practice, Site Specific Assessment. Informed written consent was obtained from all patients prior to registration for participation in the evaluation. Implicit in giving informed written consent was the right of patients to withdraw from the study at any time.

2.2. Selection of clinicians

Five members of the PREP Panel, who had previous experience in clinical evaluations of dental materials, were asked if they would be prepared to evaluate the performance of restorations placed in Filtek Silorane. Their practices were located in Abingdon, England, Birmingham, England (2), Burton-on Trent, England and Coleraine, N. Ireland. Each practice was asked to recruit sufficient patients to provide a minimum of 20 restorations per center. Sequential patients attending these practices, who required a Class I or II restoration and fulfilled the inclusion criteria, were informed about the study and were given a Patient Information Leaflet (PIL) describ-

Table 2 – Inclusion and exclusion criteria.

To be considered appropriate for inclusion in the study a patient must:

- Have been over 18 years of age
- Have a molar supported permanent dentition free of any clinically significant occlusal interferences
- Have well maintained dentitions free of any active, untreated periodontal disease
- Have a maximum of three Filtek Silorane™ restorations
- Be a regular dental attender who agrees to return for assessments.

Patients will be 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 are pregnant or have medical and/or dental histories which could possibly complicate their attendance for the assessment of the restorations and/or influence the behavior and performance of the restorations in clinical service
- They were irregular dental attenders

ing their potential involvement. They were given two weeks to decide whether they were happy to be involved. Patients paid the "normal" amount for their restoration(s) but were reimbursed for attending for the clinical evaluation(s) of their restorations. The participating dentists were also reimbursed for the surgery time.

2.3. Operative procedures for Silorane

The practitioners were asked to place the Silorane restorations in situations where it was indicated (i.e. for the restoration of cavities in posterior teeth) and as described in the manufacturers' instructions. Inclusion and exclusion criteria are shown in Table 2.

The protocol stated that teeth to be included should be in occlusal function and should be free of signs and symptoms of periapical pathology both clinically and radiographically.

Clinical procedures employed for placement of restorations in Silorane are similar to those used for conventional materials [37,38], although cavity outlines with minimal retention were also considered appropriate (Fig. 1). The following cavity preparations were suggested:

- Rounded line and point angles.
- Resistance and retention form to be achieved in the usual way from remaining tooth tissues.
- The tooth shade was selected using the Silorane shade guide, appropriate isolation obtained, and the restoration placed in accordance with the manufacturer's instructions in increments of a maximum depth of 2.5 mm, given that the product profile suggests a depth of cure of 2.5 mm [17]. In this respect, in contrast to "traditional" resin composite materials in which it has been advised that increments should touch only one cavity wall at a time [38], increments in Silorane may be placed horizontally. Silorane has its own dedicated bonding agent, because the hydrophobicity of the material makes it inappropriate for use with conventional methacrylate-based bonding agents. There are two stages in bonding: the application of a self-etch adhesive, followed by the application of a more hydrophobic resin.
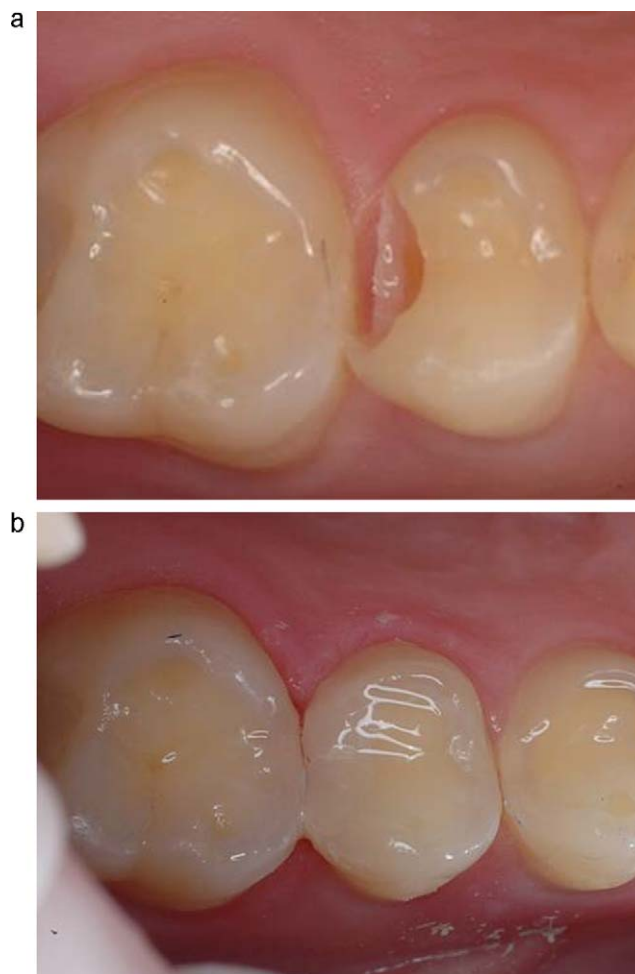

Fig. 1 – (a and b) Silorane restoration placed in saucer-shaped cavity with minimal retention.

These two materials are designed to "bridge the gap" between the hydrophilic bonding resin and tooth and the hydrophobic resin in Silorane.

2.4. Assessment procedures

The restoration reviews were undertaken by one trained and calibrated examiner (RJC) with the assistance of the clinician who placed the restorations. Modified USPHS criteria were used [39]. In the event of a restoration being unsatisfactory, details of the mode of failure were recorded and the necessary remedial work carried out.

The primary end points were:

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

Secondary end points:

- Health of gingival tissues surrounding the restored teeth
- Color match

Table 3 – Gingival status codes used for assessment of gingival health.

1. Healthy gingivae
2. Mild inflammation—slight color change, slight edema, no bleeding on probing
3. Moderate inflammation—redness, edema and glazing, bleeding on probing
4. Severe inflammation—marked redness and edema, tendency to spontaneous bleeding

- Stain resistance
- Surface quality

2.4.1. Recalls

The reviews of the restorations were to be completed at one year ± 3 months, two years ± 3 months and three years ± 3 months from the placement of the restoration.

2.4.2. Patient compensation

The patients received £30 financial compensation for each recall visit made.

3. Results

At the two year recall, 100 restorations, of the 122 originally placed (82%) [40], were available for examination. Their mean age was 25.7 months (range 18–33 months) in 64 patients (39 female and 25 male) of mean age 46.7 years. The 100 restorations composed of 30 Class I and 70 Class II restorations, distributed as shown in the table below.

	Molar	Pre-molar	Total
Upper	38	17	55
Lower	35	10	45

Of the restorations examined, 29% (n = 29) involved the replacement of one or more cusps and 75% (n = 76) were placed under rubber dam isolation.

Results of the criteria assessed were as follows:

Retention and lack of fracture: 100% of the restorations were present and intact.

Anatomic form: 97% of the restorations examined were rated optimal for anatomic form, with no unacceptable scores. All contact points of Class II restorations were considered acceptable.

Margin integrity and discoloration: 84% of the restorations were rated optimal for marginal integrity and no restorations were rated unacceptable. 77% of the restorations were rated optimal for marginal discoloration and none were scored unacceptable.

Secondary caries: No secondary caries was detected.

Gingival health: Three surfaces (mesial, facial and distal) of the teeth involved were scored for gingival health according to the criteria in Table 3. The scores, shown in Table 4, included those for Class 1 restorations with no restoration surfaces adjacent to gingivae.

Color match: 99% of the restorations were rated optimal for color match. The one restoration rated B was also rated the

Table 4 – Health of gingival tissues adjacent to restorations.

	Baseline	One-year	Two-year
Facial	1. 97%	1. 96%	1. 96%
	2. 3%	2. 4%	2. 4%
Mesial	1. 97%	1. 93%	1. 96%
	2. 3%	2. 7%	2. 4%
Distal	1. 97%	1. 96%	1. 94%
	2. 3%	2. 4%	2. 6%

Fig. 2 – Two Silorane restorations in maxillary premolars at two year recall.

same at placement i.e. no change of color match since baseline was recorded.

Stain resistance: No staining of the restoration surface was recorded.

Surface quality: 93% of the restorations were rated optimal for surface quality, with no unacceptable scores.

No patient complained of post-operative sensitivity, either post-operatively or at either review.

Illustrations of a representative sample of restorations are presented in Figs. 2–5.

4. Discussion

This assessment was a practice-based cohort study, with patients being selected in the five participating practices according to their need for one or more restorations which fulfilled the inclusion criteria. All patients who fulfilled these criteria were approached and given a PIL, and, a high proportion (*circa* 95%) agreed to participate in the study. Tooth and patient selection was therefore governed by the attendance of patients and no effort was made to select a given percentage of premolar or molar teeth, patients of a certain age, restorations including cusp replacements, and so forth. The present study may therefore be considered to lack some of the control which may be built in to certain hospital-based studies, but has the benefit of involving "real" patients and "real" dentists, with all the pressures which pertain to general dental practice, with the patients paying the "normal" fee for their treatment. The practice base for the study may also account for the variation in the age of the restorations, since not all practices commenced the study at the same time and may

Fig. 3 – Silorane restoration at two year recall.

Fig. 4 – Silorane restoration at two year recall. Small area of marginal staining at interproximal surface.

represent difficulties encountered in patient attendance at the specific times arranged for the assessment of restorations.

Patient appreciation of the esthetic health of their posterior teeth may be considered to be increasing, given the trend away from amalgam restorations worldwide [41], and the fact that patients, once they have received a tooth colored restoration in their posterior tooth, may be unlikely to return to receiving amalgam restorations [42]. The assessment of tooth-colored materials designed for placement in stress-bearing restorations in posterior teeth may therefore be considered to be of clinical relevance. In this regard, the results of the present study may be considered to indicate good performance of the material under evaluation, especially when it is noted that 29% ($n = 29$) of the restorations involved the replacement of one or more cusps. There was little change from the assessment at

Fig. 5 – Silorane restoration replacing distobuccal cusp of mandibular molar at two year recall.

one year in respect of anatomic form, gingival health, color match, stain resistance and surface quality. Margin Integrity showed a decrease from 90% optimal at year 1 to 84% at year 2, while marginal discoloration showed an increase from 96% optimal at year 1 to 77% at year 2. However, no margins were rated as unacceptable and the staining, when present, affected only small areas of the restoration margins rather than being generalized.

One and two year evaluations may be considered to provide timely information on the performance of restorations, particularly in terms of catastrophic failure and may be considered to be particularly appropriate for newly introduced materials such as that used in the present study. 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 is therefore the intention to continue to examine the restorations assessed in this study for a period of at least a further year.

The use of a recently introduced material will necessarily be without the benefit of clinical trials since the "evidence" that such evaluations produce takes time to accumulate. Clinicians may therefore commence use of a new material such as Silorane because they consider its benefits, in terms of reduced polymerization contraction stress, to outweigh the disadvantages of a paucity of research. Additional benefits include the simplified placement procedure, since the techniques utilized to negate the effects of polymerization contraction stress, such as placement of a flowable composite layer, increments touching only one wall, ramped curing and/or pulse activation, need not be employed.

In the case of the material described in this paper, the clinicians involved, all of whom were experienced users of conventional resin composite materials for restoration of posterior teeth, considered the reduced shrinkage of Filtek Silorane to be a clinical advantage which justified its use. In this respect, results of a recent evaluation on the handling

of Silorane have been positive [43]. This handling evaluation also indicated post-operative sensitivity of *circa* 0.6%, a lower value than that reported by Burrow and colleagues [44], in whose study 4% of restorations exhibited sensitivity in daily function and similar to the value (0%) for post-operative sensitivity reported by Opdam and co-workers [45], although these researchers reported that 19% of the teeth in their study were sensitive to loading, a potential indication of stressed cusps. Other studies have reported 10–20% incidence of post-operative sensitivity at one week and one month recalls [46,47], while Auschill and colleagues have recently reported 6% overall post-operative sensitivity in a study of 600 teeth with different classes of cavity, restored with resin composite. In their study, cavity depth was significantly associated with the occurrence of post-operative sensitivity [48]. These studies [44–48] employed conventional resin composite materials and the zero value for post-operative sensitivity in the present study could be attributed to the lower values for cuspal deflection reported for an early version of Silorane [13] and research that highlights its reduced polymerization contraction [27] and reduced polymerization contraction stress [28]. This low level of post-operative sensitivity could be considered to be a substantial clinical advantage, especially if found to be associated with a high expectation of clinical success.

There are few published papers which may allow comparison of the results of the present work with those from other practice-based studies. However, a large retrospective study, carried out in practice in The Netherlands, may be of relevance. In this study, two clinicians placed a total of 2867 amalgam and resin composite (912 amalgam, 1955 composite) Class I and II restorations between 1990 and 1997, with longevity and reasons for failure being recorded in 2002 [49]. The results, using life table analysis, indicated that 82.2% of the resin composite and 79.2% of the amalgam restorations had survived at 10 years, with no significant differences being found between the materials or the operators. Examination of the Kaplan–Meier survival curve presented in the paper shows *circa* 2% failure at one year. Furthermore, a compilation of the data on longevity of direct posterior composite restorations has indicated annual failure rates within the range of 0–9% [50]. The results of the present paper may therefore be considered to present favorable early performance of Silorane restorations when compared with previously published work on "conventional" resin composite restorations in posterior teeth.

5. Conclusion

Within the limitations of the present study, the two year assessment of restorations placed in a novel low shrink resin composite material, Filtek Silorane, has indicated satisfactory clinical performance of the restorations which have been assessed. Longer term clinical evaluations are required to fully assess the performance of this novel material.

Disclosures

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