

# A Practice-Based Clinical Evaluation of a Bulk Fill Restorative Material

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## ABSTRACT

*Objective:* To evaluate the handling, by a group of practice-based researchers, of a recently introduced bulk fill resin-based composite restorative material, Filtek Bulk Fill Restorative (3M ESPE). *Methods:* The twelve selected evaluators were sent explanatory letters, a pack of the material under investigation to use for 8 weeks, and a questionnaire. *Results:* The evaluators rated the ease of use of the bulk fill restorative the same as the previously used posterior composite material. The provision of one shade only for evaluation may have compromised the score for aesthetic quality. No post-operative sensitivity was reported. *Conclusions:* The bulk fill material was well received as indicated by the high number of evaluators who would both purchase the material and recommend it to colleagues. *Clinical relevance:* A recently introduced bulk fill restorative material achieved a rating for handling which was similar to the evaluators' previously used resin composite, although there were some concerns regarding the translucency of the material.

## INTRODUCTION

### PRACTICE BASED RESEARCH

The value of practice-based research has been previously discussed,<sup>1</sup> 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. In this regard, a wide variety of research projects may be considered to be appropriate to general dental practice, including<sup>1</sup> assessment of materials, devices and techniques, clinical trials of materials, assessment of treatment trends and, patient satisfaction with treatment.

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, with one in mainland Europe.<sup>2</sup> The group have completed over 70 projects – “handling” evaluations of materials & techniques, and more recently, clinical evaluations (n=8) of restorations placed under general dental practice conditions, with the restorations being followed for periods of one to five years.<sup>2</sup>

### BULK FILL DENTAL MATERIALS

The goal of manufacturers of dental materials could be considered to be the development and production of the ideal dental material. In this regard, not only should the material produce good clinical results – a goal of

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importance not only to the manufacturer, but also to the clinician and the patient, but it should also be simple to handle as it could be considered that a material which is simple to handle is one which will produce better results in the hands of the clinician.<sup>3</sup> This may also involve the speed by which a restoration utilising the material can be placed, given that clinicians may suppose that patients do not wish to sit in their dental chair for any longer than necessary. Resin composite restorations for posterior teeth are becoming increasingly popular,<sup>4</sup> but may require an incremental placement technique in order to overcome the problems associated with polymerisation shrinkage stress, this also being dependent upon the depth of the cavity, its configuration and the depth of cure of the material being used. In addition, incremental placement may lead, as discussed by El-Safty and colleagues,<sup>5</sup> to the incorporation of voids, a risk of contamination between layers and extended chair time. A dental material which fulfils the goals of clinical effectiveness, ease of placement and reduced time of placement might therefore be considered to be of value. These factors may be considered to have been facilitated the introduction of bulk-fill resin composite materials, these materials being defined as “composites that can be properly cured in a single layer of 4mm thickness”.<sup>6</sup> These materials may be subdivided into two groups, the bulk fill base materials, and the bulk fill restorative materials.

### **(a) Bulk Fill Base materials**

The first bulk-fill resin composite material was introduced by SDR (Dentsply, Weybridge, UK). This material was designed to be placed in bulk, in depths of up to 4mm and was shown to have low levels of polymerisation contraction stress in a cuspal deflection experiment.<sup>7</sup> Most recently, good three-year clinical performance has been reported when restorations formed in SDR were capped with Ceram X (Dentsply, Weybridge, Surrey),<sup>8</sup> although questions could be asked whether the study was actually testing the SDR material or its Ceram X capping. In this regard, when the material was introduced, the wear resistance of SDR was not deemed sufficient for the occlusal surface of restorations, along with other similar materials, and it was necessary to “cap” the bulk fill material with a later of conventional resin composite. Nevertheless, the idea that a restoration could be placed quickly using this material seemed to be attractive to dental clinicians, and a variety of manufacturers have produced materials of similar characteristics to SDR. This group of materials could be termed Bulk Fill Base Materials. Examples of these materials have been tested by Jang and colleagues,<sup>9</sup> with the results indicating that two of the bulk fill flowables that they tested (SDR [Dentsply] and Venus Bulk fill [Hereaus]) cured properly at 4mm depth but shrank more than conventional non-flowable composites. However, a highly filled flowable (G-aenial Universal Flo [GC]) which has been considered to be an “injectionable composite”, demonstrated a higher polymerisation shrinkage than the other materials with which it was compared.<sup>9</sup>

### **(b) Bulk Fill Restorative materials**

Post-operative sensitivity following placement of posterior composite restorations has been reported to vary between 2% and 7%,<sup>10</sup> and this could be considered to present a challenge for the clinician, notwithstanding the fact that the patient may find such symptoms unacceptable. In this regard, a cause of such sensitivity is the stressing of weakened cusps by the stresses of polymerisation contraction, this, in turn, being a function of the actual polymerisation contraction, the modulus of elasticity of the material (with a stiffer material being more likely to cause stresses than one which is less stiff) and the degree of resin conversion.<sup>11</sup> One material which achieved very low levels of polymerisation contraction stress was 3M ESPE’s Filtek Silorane, with very low levels of post-operative sensitivity being reported.<sup>12</sup> However, the material, although, anecdotally, was highly regarded by clinicians because of its handling characteristics and low reported levels of post-operative sensitivity, it was perceived as being less than ideal clinically and slow to place because of a (low) 2.5mm depth of cure, the need to use its own dedicated bonding system (which had two stages and was therefore time consuming to place), the similarity of its shades (which led to restorations of less than ideal aesthetics in some cases) and the quartz filler system (which made polishing difficult/time consuming). In addition, the manufacturing system was difficult. As a result, the manufacturers deleted this material from their portfolio in early 2015 and introduced Filtek Bulk Fill Restorative. Other manufacturers have introduced bulk fill restorative materials, including Tetric Evo Ceram Bulk Fill Restorative from Ivoclar-Vivadent (Schaan, Liechtenstein), Beautifil Bulk Fill Restorative from Shofu (Kyoto, Japan) and Admira Fusion Extra from VOCO GmbH (Cuxhaven, Germany), with these materials having been found to perform better, in a study from Trinity College, Dublin, in terms of cusp movement on polymerisation than conventional composite materials that they were tested against.<sup>13</sup> In this regard, in work by Benetti and co-workers,<sup>14</sup> Tetric Evo-Ceram Bulk Fill, when compared with two conventional composites, exhibited a small but significant increase in depth of cure, but also an increased polymerisation contraction, whereas three low viscosity bulk fill materials, x-tra base, Venus Bulk Fill and SDR, (i.e. the type which require a cap) exhibited significantly larger depth of cure and polymerisation contraction. It could be surmised, from these limited data, that increasing the depth of cure adversely affects the wear resistance, thereby necessitating the need for a cap at the occlusal surface.

Sonic Fill from Kerr (Orange, CA, USA) has also been introduced as a bulk fill material with 4mm depth of cure, in conjunction with a handpiece which imparts sonic energy to the uncured material to make it less viscous when activated, with the material increasing in viscosity when the sonic energy is removed.

Central to good performance of dental materials are, not only, their physical properties, but also their ease of use, since it could be suggested that a device or material which handles easily will be more likely to produce an optimally performing restoration than one which is difficult to use.<sup>3</sup> The assessment of the handling of a recently introduced dental material, one of a new range of bulk fill materials, Filtek Bulk Fill Restorative by 3M ESPE (Seefeld, Germany), may therefore be considered to be of relevance to dental clinical practice. It is therefore the aim of this article to describe how a group of practice-based researchers assessed the handling of Filtek Bulk Fill Restorative (3M ESPE).

## METHODS

### SELECTION OF PARTICIPANTS

All 33 members of the practice-based research group, the PREP Panel, were sent an email communication asking if they would be prepared to be involved in the "handling" evaluation of a new bulk fill restorative material. Of those who agreed to participate, twelve were selected at random.

### Questionnaire design

A questionnaire was designed by the PREP Panel co-ordinators and the manufactures of the material under evaluation in order to provide background information on the ease of use of resin composite materials previously by the participating practitioners and to compare the ease of use of these with the material Filtek Bulk Fill Restorative (FBFR). The majority of answers were made on visual analogue scales (VAS).

### Instructions to evaluators

Explanatory letters, questionnaires and a pack of 20 shade A3 capsules of FBFR were sent to the evaluators in February 2015, along with the instructions for use. The practitioners were asked to use the material until the end of April and return the questionnaire for analysis. The data from the returned questionnaires were collated as below.

## RESULTS

Of the twelve evaluators from the PREP panel, two were female and the average time since graduation was 24 years, with a range of 9 to 35 years. A variety of techniques was used by the evaluators used for the placement of posterior composite restorations, but these were principally the use of a dentine bonding agent (10 evaluators), a flowable composite base (5 evaluators) and a glass ionomer base/sandwich (4 evaluators).

A variety of resin composite materials was used by the evaluators for posterior teeth, with the most commonly used material being Filtek Supreme XTE (3M ESPE), which was used by six evaluators. Reasons given for the use of their materials were primarily ease of use and good aesthetics.

The ease of use of the previously used posterior composite restorative was stated to be (on a VAS where 5 = easy to use and 1 = difficult to use) as follows:

Difficult to use 1	5 Easy to use
4.6	

The aesthetic quality of posterior restorations placed using the current composite materials was stated to be (on a VAS where 5 = excellent and 1 = poor) as follows:

Poor 1	5 Excellent
4.6	

Thirty three per cent (n=4) of the evaluators knew the % shrinkage of the composite that they were currently using and stated it to be: 1) <3%, 2) 2.2%, 3) 1%, 4) 2 – 2.5%. All of the evaluators felt that a composite with minimal shrinkage stress would be advantageous. The reasons given for this were:

- "Less post-operative sensitivity" (6)
- "Less microleakage and staining" (4 similar)
- "Less cuspal flexure" (2 similar)
- "Shrinkage stress = problems = stress for the dentist"

The most commonly used dentine/enamel bonding system was Scotchbond Universal (3M ESPE), which was used by seven evaluators.

### EVALUATION OF FBFR

The number of direct placement restorations placed during the evaluation was 183, comprised of 23% Class I, 37% Class II, 27% MOD and a variety of restorations in primary teeth, core build up restorations and cusp replacements.

Ninety-two per cent (n=11) of the evaluators stated they were satisfied with FBFR.

Comments included:

- "Handling & convenience OK, shade A3 too translucent, so, in shallow cavities any discolouration shows through"
- None of the evaluators encountered any post-operative sensitivity.
- The evaluators rated the ease of use of FBFR (on a VAS where 5 = easy to use and 1 = difficult to use) as follows:

Difficult to use 1	5 Easy to use
4.6	

- None of the evaluators stated they experienced difficulty with FBFR sticking to instruments.
- All the evaluators (100%) stated that the viscosity of FBFR was satisfactory and rated the viscosity (on a VAS where 1 = not viscous enough and 5 = too viscous) as follows

Not viscous enough 1	5 Too viscous
3.1	

- The working time was rated by the evaluators (on a VAS where 1 = too short and 5 = too long) as follows:

Too short 1 5 Too long  


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2.7

Comments:

- “You have to work fast!!!” “It set too rapidly”
- “FBFR will cure under operating light – need to turn light down & then OK” (2 similar)
- The rating (on a VAS where 1 = difficult to polish and 5 = Easy to polish) for ease of finishing and polishing using the evaluators usual system was as follows:

Difficult 1 5 Easy  


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4.4

- When the evaluators were asked to rate the overall aesthetic quality of the restorations of FBFR (on a VAS where 1= poor and 5 = excellent), the result was as follows:

Poor 1 5 Excellent  


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3.6

Comments:

- “Only shade provided - A3 – looked greyish sometimes” (3 similar)
- “Quite translucent” (4 similar)
- “Translucent because of curability need?”
- “Best restorations were over Biodentine which improved depth of colour”

Additional shades suggested were A1, A2 and B2.

- 100% (n=12) of the evaluators stated that the restorations of FBFR maintained their shape prior to curing.

Finally, 75% (n=9) of the evaluators stated they would purchase FBFR if available at an average price and 92% of the evaluators (n=11) would recommend FBFR to colleagues.

Further comments regarding the performance/handling and overall acceptability of FBFR were:

- “Doesn’t slump, good depth of cure and no post-operative sensitivity”
- “Initially I didn’t think there was a need for a Bulk Fill material but the longer I used it, the better I felt about complete curing. Less shrinkage than Filtek Supreme – I have found an alternative!”
- “Great material, looks great. Very convenient to place in 4mm increments – a good time saver. I would definitely buy!”
- “Aesthetics good but heavily stained dentine shows through – problem to leave remove more dentine or leave and opaque out”
- “Nice material – less than ideal aesthetics”
- “Possible to create excellent contact points with FBFR. I think placement technique is great – easier than increments & restoration will have less voids & imperfections”

- “Despite 5mm depth of cure, I still placed 2mm increment in boxes of Class II restorations”
- “Would like to try other shades to test if colour OK or the translucency an issue”
- “This material seems to be targeted at those who want an easy to use amalgam replacement & where time issues are an important factor. In the eye of the patient inferior aesthetics is probably not a major factor but for those who like to achieve ‘lifelike’ posterior composites this is a system I would not use”

When the evaluators were asked if the fact that they could use any adhesive system with FBFR was advantageous, 92% (n=11) stated that it was.

## DISCUSSION

Posterior composite restorations are becoming increasingly important as the phase down of amalgam suggested by the Minamata Agreement gathers momentum. Posterior composite restorations in adults have been found to perform well in a recent systematic review by Astvaldsdotir and colleagues,<sup>15</sup> which found the survival proportion, with a minimum follow up time of four years, to be high. However, they have been demonstrated to take longer to place,<sup>16</sup> hence the introduction of materials which may be placed in larger increments, the Bulk Fill Restorative materials which do not need a capping. In this regard, it is of interest to note that two evaluators did not fully utilise the 5mm depth of cure provided by the material under test, as they stated a preference for placing a 2mm increment in the gingival box of a class II restoration which they could then check.

Bulk Fill restorative materials which do not need a capping comprise a new generic group of resin composite materials. Several manufacturers have introduced these, with the bulk fill being achieved by one or more amendments to previous composite technology. Among these are:

- More potent/efficient initiator systems
- Increasing the translucency of the filler
- Improved resin systems.

The material under evaluation in this study has employed two of these, a translucent filler and a novel low stress resin (Palin and Watts unpublished data: personal communication, Feb.2015).

The 3M ESPE Filtek Bulk Fill Restorative posterior composite system (one shade supplied – A3) has been subjected to an extensive evaluation by eleven members of the PREP panel in which 183 restorations were placed. Principal comments related to the aesthetics of the material, but these comments may not be completely relevant, given that only one shade was provided to the evaluators. In this regard, however, the 5mm depth of cure has to be achieved somehow, and the use of a translucent filler is one way to achieve that. This, in turn, leads to shine through of, for example, dentine stained by a previous amalgam resto-

ration or by arrested caries. In this regard, FBFR scored 3.6 (on a VAS where 1= poor and 5 = excellent) compared with 4.6 for the currently used posterior composite material. Indeed, some evaluators (n= 3) recognised that to achieve the depth of cure of the bulk fill material some degree of translucency was to be expected, possibly a necessary evil. Capping the material with a more aesthetic composite was also suggested by two evaluators.

The evaluators rated the ease of use of FBFR (on a VAS where 5 = easy to use and 1 = difficult to use) the same as the pre-evaluation posterior composite (4.6), indicating that this new material was considered as acceptable to use as the material chosen previously by the evaluators. The viscosity was rated as ideal (3.1 on a VAS where 1 = not viscous enough and 5 = too viscous). The working time was rated slightly on the short side of ideal (2.7 on a VAS where 1 = too short and 5 = too long) and comment was made by three evaluators that the material cured under the operating light.

Despite these minor criticisms, the excellent handling and ease of use of FBFR resulted in 75% (n= 9) of the evaluators stating they would purchase the system, at an average cost, and 92% (n=11) would recommend the system to colleagues.

Of significance is the reported lack of post-operative sensitivity, given that this is a problem previously associated with placement of posterior composite restorations.<sup>10</sup> Bulk placement, rather than incremental placement, might also be considered to predispose to this problem, so it is reassuring that this was not reported by evaluators. The low polymerisation shrinkage stress of Filtek Bulk Fill Restorative material reported by Palin and Watts (unpublished data: personal communication, Feb.2015) may be of relevance here.

Figures 1 to 4 present restorations placed by three of the evaluators



**Figure 1a-b:** (a) Disto-occlusal Cavity in tooth 16. (b) Cavity in fig 1a restored with Filtek Bulk Fill Restorative (evaluator DP)



**Figure 2:** Class II in tooth 36 restored with Filtek Bulk Fill Restorative (Evaluator PR)



**Figure 3:** Class II restorations in Filtek Bulk Fill Restorative in teeth 45 & 46 (Evaluator PS)



**Figure 4:** Class II restoration in tooth 35 in Filtek Bulk Fill Restorative (Evaluator PS)

## CONCLUSIONS

The Filtek Bulk Fill Restorative material has been well received, achieving high scores for ease of use and handling. Only one shade (A3) was provided so the aesthetic quality score may have been compromised. However, the high number of evaluators who would purchase the material, and recommend it to colleagues indicates a positive reception.

## MANUFACTURER'S COMMENTS

3M ESPE wish to thank the PREP Panel for their comments regarding our recently introduced Filtek Bulk Fill Posterior Restorative material. We are pleased by their positive responses, other than the translucency of the material, which is a necessary evil in order to produce the 5mm depth of cure. Several findings were helpful to us, such as the lack of post-operative sensitivity. The creation of stress during the polymerisation of traditional methacrylate composites is an issue that has been associated with posterior composites for many years. Despite the use of flowables, and the adoption of a herring bone style layering configuration, sensitivity has always been an issue. Systems that create significantly lower levels of stress should combat post-operative sensitivity.

As found by the evaluators, the material has been designed to be easy to use. With no requirements for a capping layer, extra hardware or a specific adhesive, Filtek Bulk Fill Posterior Restorative is quick and straight forward to use. Available in 5 shades (A1, A2, A3, B1 and C2), the material is ideal for any posterior restoration.

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## CONFLICT OF INTEREST

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

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