# Clinical Challenges and Longevity of Bulk-Fill Materials

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Vesna Miletic

## 9.1 Introduction

Clinical application of composites in increments thicker than 2 mm began in 2003, when QuiXfil (Dentsply) appeared on the market and in dental practice. The manufacturer's recommended increment thickness for this material was 4 mm. The true clinical era of "bulk-fill" composite materials began when Smart Dentin Replacement (SDR, Dentsply) was launched in 2009.

Scientific evidence has shown comparable polymerization shrinkage and stress [1], depth of cure [2, 3], physico-mechanical properties [4–6] and marginal adaptation [6–8] of bulk-fill and universal composites. In vitro data indicate that these materials may be used as recommended for dentin replacement in posterior teeth in increments up to 4–5 mm (flowable bulk-fill) or as full restorations (sculptable bulk-fill) in posterior cavities without cusp replacement [9].

Within the last decade, all major manufacturers have at least one bulk-fill composite in their portfolio, and many have several types of bulk-fills (flowable and sculptable) as well as second "generation" of the original material. Bulk-fill composites were expected to reduce clinical working time as fewer increments are needed to restore posterior cavities compared to universal composites recommended for 2 mm increments. Indeed, a recent meta-analysis by Bellinaso et al. [10] confirmed that sculptable ("full-body") bulk-fill composites shorten restorative time in posterior teeth compared to conventional composites. The same, however, was not found for flowable bulk-fill composites. The true value of these findings should be verified in further research, as only three studies with moderate to substantial heterogeneity were included in the above meta-analysis [10]. Nevertheless, scientific

V. Miletic (✉)
Faculty of Medicine and Health, Sydney Dental School, The University of Sydney, Sydney, NSW, Australia
e-mail: vesna.miletic@sydney.edu.au



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and clinical interest in these materials and continuous improvements reflect the potential of bulk-fill composites to alter clinical practice related to posterior restorations.

## 9.2 Criteria for Clinical Evaluation of Restorative Materials

Clinical performance of bulk-fill composites, as well as restorative materials in general is evaluated using either of the following sets of criteria: (1) modified USPHS[1] and (2) FDI.[2]

Modified USPHS are based on evaluation criteria published by Cvar and Ryge [11] in 1971, which initially used five categories of esthetic and functional performance: color match, cavosurface marginal discoloration, anatomic form, marginal adaptation and caries. The ratings, as originally presented by Cvar and Ryge, include a series of bipolar decisions as "Yes"/"No" answers to questions specific for a certain criterion until a code is reached. The Cvar and Ryge criteria were expanded in 1980 by a panel of researchers to include more categories, such as post-operative sensitivity, occlusion, fracture and retention. These criteria are known as "modified USPHS" criteria [12]. The ratings or scores in modified USPHS criteria indicate progressively less acceptable performance from "Alpha"—clinically ideal situation, "Bravo"—minor deviations from norm but clinically acceptable, "Charlie"—unacceptable deviation from norm requiring re-intervention to prevent future damage to "Delta"—unacceptable deviation from norm requiring immediate replacement. Some studies use numerical scores (e.g., 0–4) to indicate ratings, with 0 corresponding to an ideal clinical situation to 4 indicating clinically unacceptable rating [13, 14]. Definitions of each score for each evaluation criterion vary in different clinical trials [15–20]. Confusion may be further created when referencing the original Cvar and Ryge criteria and claiming that modified USPHS criteria were used as the latter is a broader set. This is especially so when a non-original criterion (e.g. surface roughness/texture) is used without proper score definition [21, 22]. Therefore, it is recommended to state the criteria and define the scores/ratings when reporting clinical trials because of the lack of uniformity in modified USPSHS criteria [12]. A summary of variations in score definitions in clinical trials on bulk-fill composites using modified USPHS criteria is presented in a recent meta-analysis by Veloso et al. [23].

A more comprehensive and discriminatory evaluation system, known as FDI clinical criteria, was introduced in 2007 [24] and updated in 2010 [25]. This system is based on three sets of criteria: esthetic, functional and biological. Each set contains a subset of criteria (16 in total) with 5 scores: (1) clinically excellent/very good—ideal clinical situation; (2) clinically good—minor deviation from the norm; (3) clinically sufficient/satisfactory—minor shortcomings, no unacceptable effects but not adjustable without damage to the tooth; (4)—clinically unsatisfactory but repairable and (5) clinically poor—replacement necessary. Scores 4 and 5 are

[1] United States Public Health Service.

[2] World Dental Federation (Fédération Dentaire Internationale).

considered relative and absolute failures, respectively [25]. The former score indicates repaired existing restorations while the latter indicates replacement as the existing restoration is beyond repairable. Hickel et al. [25] recommend that selected FDI criteria may be used in clinical trials instead of the entire set of 16 criteria, depending on the trial objective. Furthermore, they recommend that five scores may be reduced to 4 or even 2, depending on the purpose of the study and the tested material or procedure. This should be carefully considered as reduced scores may result in lower discriminatory power of evaluation, similar to modified USPHS criteria. A recent randomized clinical trial (RCT) comparing two bulk-fill composites to a conventional control composite found significant differences between modified USPHS and FDI scores in that FDI scores were mostly "success" while USPHS were mostly "acceptable" [16].

Both "modified USPHS" and "FDI criteria" rely on subjective examiners' judgment. To reduce the risk of bias and ensure consistency, clinical evaluation is conducted independently by at least two trained or calibrated examiners. Consistency in judgment is of critical importance for valid evaluation. Inter-examiner agreement is agreement between different examiners and intra-examiner agreement relates to agreement of one examiner's judgment on different occasions. An inter-examiner and intra-examiner agreement of at least 85% is considered acceptable [11]. For training purposes, photographs, radiographs and models are useful in anchoring definitions related to specific characteristics. In the internet era, online databases may serve as excellent training and calibration resources. One example was e-calib.info, an online database developed in 2008, which contained about 300 high quality clinical photographs. This database was used to train and calibrate examiners in 8 of 16 FDI criteria. Unfortunately, e-calib database is no longer accessible. Another potential solution is development of digital and laser-based evaluation techniques to improve standardization and avoid bias. Expansion of intraoral scanners and software solutions allow high quality reproduction of teeth and restorations and could be used for, at least, some aspects of clinical evaluation, e.g. luster, staining, color match and translucency, anatomic form, marginal adaptation, contour and wear.

## 9.3 Clinical Performance of Bulk-Fill Composites

One of the first randomized control trials (RCTs) compared performance of an early sculptable bulk-fill material (QuiXfil, Dentsply) to a hybrid composite (Tetric Ceram, Ivoclar) with their respective adhesive systems. Comparable results between the two composites were reported at 3 years with significantly worse results for marginal discoloration and integrity of QuiXfil and marginal discoloration of Tetric Ceram [26]. At 10 years, 26 QuiXfil and 30 Tetric Ceram restorations were evaluated out of the initial 46 and 50, respectively. The main reasons for failure were secondary caries and marginal discoloration, followed by tooth fracture, restoration fracture, post-operative sensitivity and deterioration of the marginal integrity [27]. Overall, the control material Tetric Ceram performed slightly better than the bulk-fill QuiXfil in terms of the overall annual failure rate (1.6% vs. 2.5%, respectively)

and success rate (86.7% vs. 76.9%, respectively) but the difference did not reach statistical significance [27]. Statistical significance was related to cavity/restoration size, i.e. large restorations failed significantly more often than small restorations [27]. To date, this is the only RCT comparing bulk-fill and conventional composites with 10 years follow-up.

### 9.3.1 Systematic Reviews and Meta-Analyses

Clinical trials on bulk-fill composites increased as of 2014, with annual numbers of published clinical trials rising steadily over the past couple of years. Beside randomized clinical trials (RCTs), several systematic reviews and meta-analyses were published in the last 3 years, comparing clinical effectiveness of bulk-fill to conventional methacrylate-based composites [1, 10, 23, 28, 29].

Arbildo-Vega et al. [28] included 16 unique RCTs with follow-up periods from 6 months to 10 years in which sculptable bulk-fill, flowable and sculptable two-step restorations were compared to conventional incremental composites. Clinical effectiveness of bulk-fills was found to be similar to conventional composites, regardless of the type of restoration (class I, II, or non-carious cervical lesions), the type of tooth restored (primary or permanent teeth), or the restoration technique used (incremental, bulk, or two-step bulk) [28]. In terms of fractures, marginal staining and adaptation, secondary caries, color stability and translucency, surface texture and anatomical form, no significant differences were found between conventional and bulk-fill composites. In terms of post-operative sensitivity, the meta-analysis found no difference between conventional and two-step bulk restorations. However, reduced or no post-operative sensitivity was associated with conventional materials in non-carious cervical lesions as well as incremental technique in permanent dentition.

Cidreira Boaro et al. [1] included 11 RCTs spanning from 12 months to 10 years. No significant difference in clinical performance of bulk-fill and conventional composites was reported. In addition to RCTs, this meta-analysis included 137 other in vitro studies comparing an array of material properties. Polymerization stress and cusp deflection were found to be significantly lower in bulk-fill composites. No differences were found between bulk-fill and conventional composites regarding flexural and fracture strength. As for volumetric shrinkage, microhardness and degree of conversion, the results varied depended on material viscosity and specimen thickness. Differences in the above-mentioned properties detected in vitro did not result in differences in clinical performance of bulk-fill and conventional composites. It should be highlighted that only 1 RCT was evaluated for each of the follow-up periods of 5, 6 and 10 years with the majority of RCTs reporting for 1-year follow-up [1].

Veloso et al. [23] included 10 RCTs with follow-up periods between 1 and 6 years. No significant difference in clinical performance was found between bulk-fill and conventional composites, irrespective of the viscosity of the bulk-fill material (sculptable or flowable requiring a capping layer). Failure rates were 5.57% (29

of 520) in bulk-fill and 3.32% (14 of 421) in conventional composites. The causes of restoration failure were reported to be secondary caries (23%), tooth and resin fractures (19% each), post-operative sensitivity (9%), anatomical shape and marginal adaptation (7%), marginal discoloration (9%), caries associated with tooth fracture (5%) and retention (2%).

Kruly et al. [29] conducted a meta-analysis on various types of composites, comparing non-conventional (ormocer, silorane and bulk-fill) to conventional methacrylate-based composites. Bulk-fills were investigated in three studies of the 21 studies included in the review with 1–3 years follow-up periods. All non-conventional composites were grouped when evaluating post-operative sensitivity, secondary caries, retention, marginal adaptation and discoloration, so no conclusion was made specifically for bulk-fill materials as a separate group. Restorations conducted with low polymerization shrinkage composites, such as silorane, ormocer and bulk-fill type showed clinical performance similar to restorations with conventional methacrylate-based composites [29].

According to Hickel et al. [24] restoration failures are classified as early (0–6 months), medium time frame (6–24 months) and long-term (beyond 18 or 24 months). The majority of RCTs evaluated in meta-analyses reported findings at 12 months follow-up with progressively fewer studies reporting after longer follow-up periods [1, 23, 28], hence detecting to a greater extent only short- to medium-time failures.

All meta-analyses expressed the need for long-term properly designed RCTs following the CONSORT 2010 statement [30]. This 25-item checklist and a flow diagram ensure transparency and completeness in reporting RCTs. Though CONSORT only focuses on reporting with no specific recommendations on study design, conduct and data analysis, it indirectly affects design and implementation by including specific items such as participant eligibility criteria, sample size calculation, allocation sequencing, primary and secondary outcomes with information on how and when they were assessed.

Sample size calculation, randomization, allocation concealment and blinding have been identified in meta-analyses on bulk-fill composites as characteristics that increase the risk of bias. Operator blinding is not possible due to different clinical protocols for bulk-fill and conventional composites, but patient and outcome assessment blinding should be implemented to avoid bias.

In reporting interventions in restorative dentistry additional factors need to be considered in study design and reporting. These were summarized in Hickel et al. [24]:

1. Patient's oral status (including pre-existent damage to the tooth), attitudes, habits.
2. Participant selection reflective of population at large.
3. Limit the split-mouth design to one test and one control restoration.
4. Detailed description of the restorative procedure (cavity type and size, bevelling, lining, adhesives, composites, light-curing, finishing and polishing procedures).
5. Evaluation to be performed by calibrated evaluators independent of personal or situational bias.

6. Confounding factors to be controlled by inclusion/exclusion criteria (for patients, teeth, operators), randomization, matching the confounding variable and/or including it in statistical analysis.

### 9.3.2 Recent Randomized Clinical Trials and Other Clinical Trials

Several randomized clinical trials (RCTs) were published around or after the latest meta-analysis [28] and, hence, were not included in this review. The same search strategy as the one used in the most recent meta-analysis by Arbildo-Vega et al. [28] was applied to identify more recent RCTs, i.e. those published around the same time or after the latest systematic review and meta-analysis [28]. The same databases (PubMED, CENTRAL, Web of Science, Scopus and EMBASE) were searched using the same keywords: ("dental caries" or "dental restoration, permanent") AND ("bulk fill" or "bulk fill" or "bulk-fill" or "bulk") AND ("composite resins" or "composite resin" or "resin composite" or "resin composites" or "resin restoration" or "composite restoration" or "composite restorations").

A total of 1230 studies were retrieved from database search up until July 2021. The search was then modified to include the keyword "clinical" in all fields to narrow the search and avoid unnecessary screening of non-clinical trials. It is self-evident that any type of clinical trial, especially RCTs, must contain this word in either title, abstract or the keywords. This resulted in 642 results. After screening for duplicates and removal of studies that were not clinical trials, 51 studies were assessed for eligibility based on inclusion and exclusion criteria.

Inclusion criteria were: (1) Studies carried out on permanent vital teeth in human participants; (2) RCTs comparing bulk-fill and conventional composites and (3) Prospective clinical studies evaluating bulk-fill composites. These inclusion criteria allowed inclusion of not only RCTs but also other prospective clinical trials as the aim was to provide a comprehensive narrative review and not conduct another meta-analysis. This approach allowed wider inclusion of studies, some of which would be excluded in a meta-analytical approach, despite presenting relevant clinical information.

Exclusion criteria were: (1) Studies on primary teeth; (2) Studies involving pulpotomy or root canal treatment; (3) Retrospective studies; (4) Insights, letters to editor, article review; (5) The same studies at different times; (6) Studies already included in meta-analyses; (7) Studies in a language other than English and where full text was unavailable.

Finally, 16 studies were found eligible and included in further analysis. Literature review and selection process are shown in Fig. 9.1.

Table 9.1 summarizes the main characteristics of these reviewed clinical trials (See Appendix 1). Eight studies are RCTs comparing bulk-fill and conventional incremental composites in a split-mouth design [16, 17, 21, 31–35], five are RCTs evaluating only bulk-fill composites with a different test group [36–40], one is an RCT that compared bulk-fill and incremental composites but in parallel-group

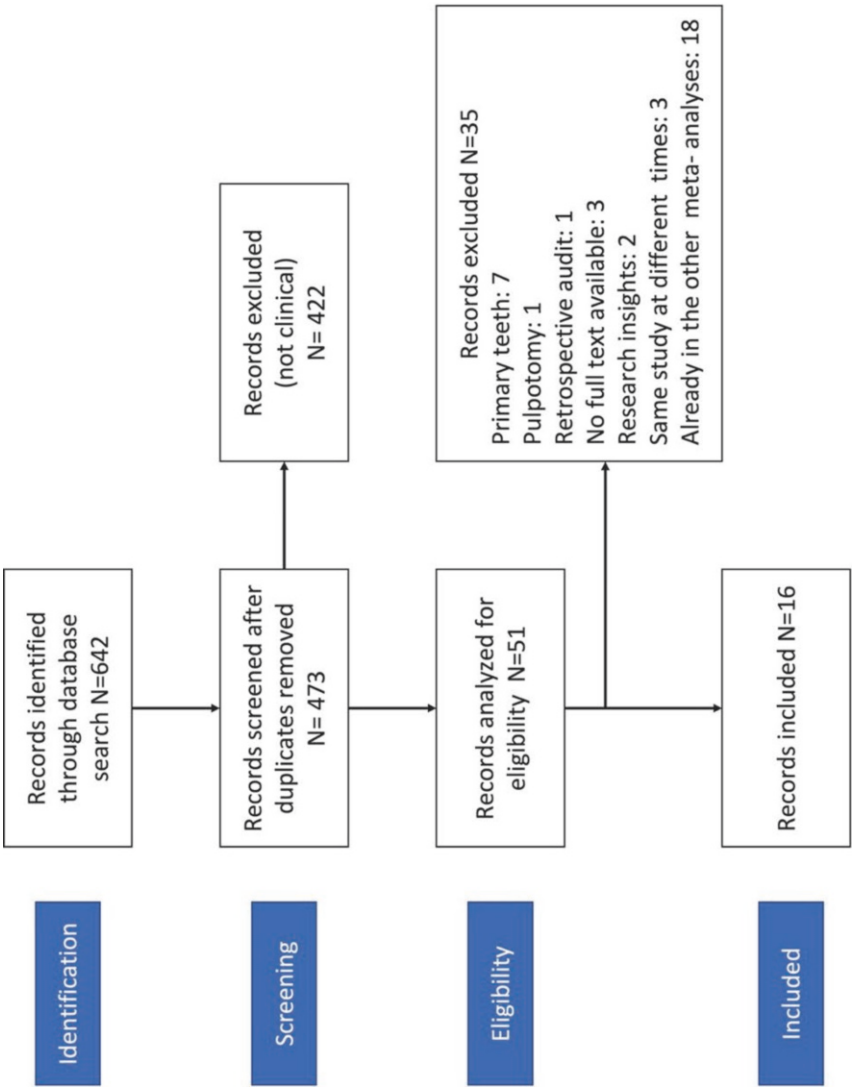


**Fig. 9.1** PRISMA search flow diagram

design and only evaluating post-operative sensitivity [25] and two studies were prospective clinical trials with only a bulk-fill test group without a control group [15, 20].

The overall success or survival rate of bulk-fill composites ranged from 100% [18, 32, 33, 36, 39] and 97.1% [17] to 88.1% [37] at 12 months, 100% [40] to 99.1% at 2 years [15], 100% [38] to 94.44% with an annual failure rate of 1.26% at 3 years follow-up [16], 94.28% [21] to 93.9% with annual failure rates of 0.95% [21] to 1% [14] at 6 years. At 10 years, overall success rates of a bulk-fill and conventional composite were 76.9% and 86.7%, respectively, with an overall annual failure rate of 2.5% for the bulk-fill and 1.6% for the conventional composite [27]. Reasons for failure were recurrent caries, unacceptable marginal adaptation [16], pulpal or periapical inflammation [15, 17], crown replacement (no reason provided) [21] and "lost restoration" (no reason provided) [37].

Similar clinical performance in terms of esthetic, functional and biological FDI criteria was reported for ormocer bulk-fill composite (Admira Fusion x-tra, Voco) compared to the conventional, incremental ormocer (Admira Fusion, Voco) at 2 years [35]. Placement of sculptable bulk-fill composites required less chair time than incremental placement [34, 35].

In most randomized clinical trials (RCTs), the majority of criteria were comparable irrespective of the evaluation method (modified USPSH or FDI). There were little differences between bulk-fill and conventional control composites, somewhat lower incidence, intensity and duration of post-operative sensitivity [31], lower pain and marginal discoloration in the bulk-fill group at 12 months [33], lower marginal discoloration in the bulk-fill at 6 years though both bulk-fill and conventional composite exhibited significant deterioration in marginal discoloration compared to baseline [21], surface luster in one of the two tested bulk-fills compared to a conventional control at 3 years [41], marginal integrity but worse in color match than conventional composite onlays [17]. The overall risk for post-operative sensitivity was found to be 4% and significantly greater within the first 48 h post-restoration [34]. This overall risk for post-operative sensitivity was found to be independent of material (bulk vs. conventional), adhesive strategy (total-etch vs. self-etch) or delivery method (capsule vs. syringe) but was found to be significantly higher in cavities deeper than 4 mm [34]. Similarly, post-operative pain was mostly recorded within the first 48 h post-restoration in another study that compared different placement and bonding techniques and only used one bulk-fill composite [42]. This is the same study as [38] but only reporting on post-operative sensitivity. However, unlike in [34], Costa et al. [42] reported an overall risk of post-operative sensitivity of 20.3%. Cavities with 3–4 surfaces were significantly more at risk of post-operative pain that 1–2 surface cavities. Adhesive strategy or composite placement technique had no effect on incidence or intensity of post-operative pain. Differences between these studies in the risk of post-operative sensitivity warrant further research, especially taking into account factor operator.

Several RCTs compared clinical performance of bulk-fill composites in both the test and control group, but with different placement techniques (bulk vs. incremental) [38, 39], bonding techniques (wet vs. dry bonding of a 2-step total-etch [36] or

total-etch vs. self-etch adhesive [38]), with or without a lining material [40] or cured with a high-intensity vs. low-intensity light-curing units [37]. In general, comparable performance was reported in short- and medium-time frame of 12–36 months. Significantly greater percentage of marginal discontinuity involving occlusal margins at 12 months was reported for "high-intensity" than "low-intensity" light-curing group [37]. In another study, marginal staining and adaptation at 36 months were found to be significantly worse when a bulk-fill composite was used with a self-etch than total-etch adhesive [38].

Distinct, statistically significant differences were found in an RCT comparing a sculptable bulk-fill composite (Filtek One Bulk Fill, 3M) and a self-adhesive bulk-fill composite (SABF, 3M) with more unfavorable scores for the latter in terms of surface luster, marginal staining and color match already at 12 months [32]. The self-adhesive bulk-fill composite is intended for use without an adhesive system due to the presence of a phosphoric acid functionalized methacrylate. Manufacturer's instructions recommend mixing for 15 s, placing in one bulk increment in unconditioned cavities and light-curing albeit the material is dual-curing and hence allows only limited sculpting time during auto-polymerization. These initial results indicate inferior esthetic performance of the self-adhesive bulk-fill to other bulk-fill and conventional composites. Its unfavorable marginal staining as early as 12 months post-restoration indicates inability of the phosphoric acid functionalized methacrylate in this self-adhesive composite to substitute an adhesive system.

Recent RCTs present a positive trend in that the split-mouth design is a predominant form of clinical trials evaluating bulk-fill composites. When appropriately designed and conducted, RCTs represent a gold-standard in evaluating healthcare interventions [30]. The split-mouth approach eliminates a number of factors potentially affecting the restorations, i.e. caries risk, oral hygiene, dietary habits, masticatory characteristics, bruxism, etc. In the majority of studies, the split-mouth design involved placement of 1 test and 1 control restoration [17, 21, 32, 33, 35–37, 39, 40, 43], albeit in some cases more than 1 pair of restorations was placed per patient [16, 31, 34, 38].

Progress can be seen in recent clinical trials on bulk-fill composites with regard to study design characteristics identified as limitations in previous meta-analyses. Sample size calculation, randomization, allocation concealment and blinding were all included in study design and reported in the majority of studies [16, 17, 21, 31, 34–36, 38, 40]. In these studies, adherence to CONSORT 2010 Statement was explicitly mentioned. Several studies partially addressed these characteristics. Allocation concealment was missing in three studies [32, 37, 39], and allocation concealment and blinding were not addressed in another study [25]. Interestingly, CONSORT 2010 Statement was followed in these studies [25, 32, 39] indicating that the authors were aware of the checklist items. A recent RCT study only mentioned randomization but without clear explanation of the procedure, and did not report on sample size, allocation concealment and blinding [33]. A prospective clinical trial did not report on any of the four important study design features [15]. As expected, the latter two studies contain no reference to CONSORT 2010 Statement [15, 33]. Despite the fact that CONSORT 2010 Statement specifically

addresses reporting of RCTs, authors of other types of clinical trials are encouraged to report their studies following CONSORT 2010 Statement [30].

Further progress in conducting clinical trials on bulk-fill composites is evidenced in increased use of rubber dam for moisture control. Rubber dam was reported in the majority of recent clinical trials with only a few using rubber dam selectively or entirely relying on cotton rolls and suction (Appendix 1, Table 9.1). This is unlike the finding of previously mentioned meta-analyses in which cotton rolls were found to be the main moisture control tool [23, 28]. Though this is a positive trend in conducting clinical trials, it may alienate clinical trials in university settings from general practice as the majority of dentists still opt not to use rubber dam for restorative procedures [44, 45] similar to the observations in general practice more than 10 years ago [46].

### 9.3.3 Clinical Challenges of Bulk-Fill Composites

Clinical challenges for bulk-fill composites are similar to composites in general. This is evidenced in the same main reasons for restoration failure: secondary caries, tooth and restoration fractures, post-operative sensitivity and inflammation, anatomical shape, marginal adaptation and discoloration and loss of retention.

Secondary caries was shown to be partly material dependent as it was significantly more associated with composite than amalgam [47, 48]. Technique sensitivity, no antimicrobial properties, affinity for bacterial growth and presence of gaps were identified as contributing factors to secondary caries related to composite restorations [47]. Gingival margins of Class II restorations are particularly vulnerable to secondary caries. In terms of patient's status, high caries risk and smoking were identified as significant contributing factors to secondary caries [48].

A variety of factors may contribute to secondary caries at gingival margins, such as improper moisture control, poor adhesive bonding to dentin, material adaptation and light-curing. The same challenges apply for bulk-fill composites, both sculptable and flowable, though the latter may not be associated so much with material adaptation as the former.

Rubber dam and proper moisture control is *condicio sine qua non* for proper composite polymerization which is, in turn, responsible for optimal material properties and ultimately clinical longevity. Various stakeholders, dental schools, manufacturers, insurance companies should put more effort in increased use of rubber dam in restorative dentistry. Patients should be better educated so they can develop and express expectation that their dentist uses rubber dam during restorative procedures.

Marginal adaptation may be improved with flowable materials. However, it is unknown whether flowable bulk-fill composites would be prone to defects in the area of proximal contacts similar to those found in glass ionomer restoratives [49, 50]. It is further unknown if these proximal defects occur due to material's chemical composition and/or inferior mechanical properties. It seems prudent that flowable composites are used for improved gingival adaptation but restricted to the area under proximal contacts and covered with sculptable universal or bulk-fill

composites due to their generally better mechanical properties. Marginal adaptation of sculptable composites may be improved by material preheating [51]. A problem with preheated composites is that they cool down rapidly [52], so placement should occur as soon as the material is removed from the heater. Gap formation in the gingival margin in bulk-fill composites seems to be comparable to conventional composites [6]. Flowable bulk-fill composite SDR was found to induce smaller gap formation in dentin compared to sculptable materials [53]. It remains unclear if gap formation in bulk-fill composites contributes to secondary caries, but the risk seems no greater than that associated with conventional composites.

Adhesive bonding to dentin remains a challenge in contemporary adhesive dentistry and is not associated with composite material but rather with adhesive system, its composition, application mode and biodegradability. Current evidence supports three-step full etch-and-rinse (total-etch) approach and the preferred three-step combined selective enamel total-etch with two-self-etch bonding route for increased longevity of the adhesive-dentin bond [54].

Light-curing of bulk-fill composites should follow the same recommendations as for light-cured materials in general. Proper light-curing source and technique (diameter and positioning of the light tip and curing time) should ensure that sufficient energy is delivered to the material to maximize polymerization [55].

Tooth and restoration fracture risk should be addressed in the treatment planning phase. It is widely known that increased risk of tooth fracture is associated with insufficient cusp resistance, e.g. in endodontically treated teeth. Cuspal reduction of 2 mm and coverage with resin composite in MOD cavities of endodontically treated premolars and molars improves fracture resistance of such teeth [56, 57]. The remaining cavity wall thickness, even in the range of 1–1.5 mm does not seem to reduce significantly fracture resistance of teeth when proper cuspal protection is performed [58]. A clinical study on cusp-replacing complex composite restorations reported an annual failure rate of 0.9% over 96 months, the reasons for failure being endodontic complications, cusp fracture and inadequate proximal contact [59]. Composite materials with filler content above 74 vol% (compact composites [60]) may be suitable for complex composite restorations involving cusp replacement as their flexural modulus approaches 20 GPa which is expected for load-bearing restorations [61]. Sculptable bulk-fill composites do not exhibit such mechanical properties as compact composites [9, 62] and hence should not be used for complex composite restorations. Annual failure rates of Class I and II bulk-fill restorations in the available RCTs did not exceed the annual failure rate of composites in general [63] indicating that bulk-fill composites may be used for posterior restorations without cusp involvement.

Fiber-reinforced bulk-fill composite (introduced as Xenius, later rebranded as everX posterior, GC) is recommended for large cavity defects to replace dentin as a base material especially for high-stress bearing restorations [64]. In addition to the conventional filler particles in the BisGMA/TEGDMA-based resin matrix, this composite contains 1–2 mm glass fibers for improved fracture toughness and mechanical properties in general [65]. At 3 years, a somewhat lower clinical success rate was found for fiber-reinforced bulk-fill composite group (78.3%) compared to an incremental microhybrid composite restoration (91.3%) in endodontically treated

molars of 24 patients, with fracture as the main reason for failure [66]. Another prospective clinical study following only the fiber-reinforced composite in posterior restoration in vital and non-vital molars and premolars reported an overall success rate of 88.9% for a period ranging from 1.3 to 4.3 years [67]. This is generally in line with findings for other composite materials, suggesting that fiber-reinforced bulk-fill may be a suitable base material for large cavities in posterior teeth.

Additionally, factor operator with regard to previous training and experience has not been investigated. It is unknown how the outcome of bulk-fill composite restorations might be influenced by the age of operator with older dentists trained in amalgam techniques. This challenge is not unique for bulk-fill composites, but for all innovations in dental practice. This highlights the importance of hands-on training and continuing professional development courses. The fact is that bulk-fill composites are applied to the cavity and sculpted in much the same way as universal composites, which have become materials of choice for posterior restorations and taken over amalgam. It is reasonable to expect that dentists primarily trained in amalgam techniques have already mastered universal composites over the course of their practice and that including bulk-fill composites in their everyday work should not present a challenge.

Appendix 2 shows clinical cases of teeth restored with different types of bulk-fill composites and followed at various periods of time ranging from 3 to 10 years. The restorations were placed by the same operator (JS) using different adhesive systems and illustrate the different failures reported in the literature such as secondary caries, fracture of the restoration, wear of composite and loss of esthetics, in general for composite materials [68] as well as for bulk-fill composites in this chapter.

As stated earlier, similar clinical performance in terms of esthetic, functional and biological FDI criteria was reported for bulk-fill composites as for conventional microhybrid composites. Failures occur at different periods of time, short term (1–3 years), medium term (3–6 years) and long term (6 years and above) (Appendix 1, Table 9.1). Management of those failures depends on the type of defect or problem, and can include monitoring, repair or total replacement of the restoration [69].

The clinical evaluation of bulk-fill composites (sculptable, flowable or fiber-reinforced) in Appendix 2 followed the same criteria as mentioned earlier in this chapter—FDI criteria set out in Hickel et al. [25] Evaluation of flowable and fiber-reinforced bulk-fill composites is only possible through radiography that may reveal some imperfections, voids or secondary caries.

### 9.3.4 Challenges in Clinical Evaluation of Bulk-Fill Composites

The main challenges in clinical evaluation of bulk-fill composites are no different from other restorative dental materials. Dental research community still has not adequately responded to these challenges.

*University vs. general practice setting*—The majority of clinical trials are conducted in university settings with one or a few operators involved. In the reviewed clinical trials on bulk-fill composites, the number of operators did not exceed five

[35, 40] with the majority of trials involving only one operator [16, 17, 20, 21, 25, 31, 33, 37, 39]. The conditions are more strictly controlled with relatively narrow inclusion criteria in university clinical settings compared to general practice. This inevitably means that results from such clinical trials may not necessarily reflect a material's true performance in general practice.

Practice-based dental research (PBRNs) is not a new concept in dentistry and is considered to be a "real world" setting [70]. Dental PBRNs involve mostly private practitioners willing to conduct research within their practice. The main objective of this approach is to increase knowledge base for clinical decision-making by testing clinical approaches and effectiveness of strategies for the prevention, management and treatment of oral diseases and conditions [70]. A recent scoping review identified 24 dental PBRNs worldwide, from USA and Canada to Europe to Japan, Australia and New Zealand [71]. Material testing, clinical and in vitro, is the sole focus of the oldest PBRN, found in 1976, the CRA (Clinical Research Associates). However, dental restorative materials are included in many research projects by various networks. The National Dental Practice-Based Research Network, the largest PBRN in the world, involved 226 practitioners in evaluating 6218 direct composite and amalgam restorations in 3855 patients over 2 years [72]. The failure rate was 6.2% with no difference between material types, but with higher incidence of failures in patients over 65 years of age, in large restorations, in female clinicians and those practicing part-time. Among the most frequent reasons for failure were recurrent caries, loss of retention, tooth fracture, however the most frequent reason was found to be a repair/replacement of a restoration by another dentist [72].

A large retrospective PBRN-based study compared the longevity of nearly 360.000 composite, amalgam, glass ionomer and compomer restorations in more than 75.000 patients placed by 67 general dental practitioners [63]. The mean annual failure was 4.6% over 10 years, with the annual failure rate being 4.4% for composites, 5.1% for amalgam, 7.5% for compomer and 11.1% for glass ionomer cement restorations. Generally, the annual failure rate was found to increase in patients over 65 years of age (6.9%), in large 4+ surface restorations (6.0%), in molars (5.2%) and, especially, endodontically treated teeth (11.0%) [63]. Greater annual failure rate was reported for Class II than Class I restorations involving bulk-fill composite, 1.4% and 0% at 6 years, respectively [14], which is in line with findings for composite restorations in general [63, 72].

Only one study involving a bulk-fill composite in a PBRN setting was found in the literature [73]. In this study, a group of 12 dentists was asked to evaluate a sculptable bulk-fill composite in their practice. Handling of the material was found to be similar to composites previously used by the dentists, but its esthetic appearance was less favorably accepted. Despite the lack of PBRN-based clinical trials on the performance of bulk-fill composites, it is reasonable to expect similar results as for composites in general. This assumption is based on the findings from clinical trials in university settings which show similar clinical performance of bulk-fill and conventional incremental composites.

There is obvious strength in large numbers analysis, which is not possible to achieve in university-based clinical trials in a similar time frame, if ever. Yet, PBRNs

have a number of limitations such as evaluator calibration [70], unbalanced test groups (multiple confounding factors) [72], inconsistencies in treatment protocol [74] and decision-making [75], operator- and practice-related differences (experience, skills, workload, practice size, location, type) [63, 72, 74], drop-out of practitioners throughout a trial [72]. One way of addressing limitations of PBRN-based clinical trials is implementing RCT study design. This would reduce the number of patients involved in such trials but would allow better control of variables and ultimately more meaningful results. Additionally, high quality calibration material and rigorous evaluator calibration would increase consistency and improve validity of results.

*Low recall rate in long-term studies*—A significant negative correlation was observed between the recall rate and observation period, suggesting the longer the trial, the lower the recall rate [76]. The same finding was seen in recently reported randomized clinical trials (RCTs) on bulk-fill composites [16, 21, 27] albeit there are examples of high recall rates [14]. Patient relocation, unavailability for contact and loss of interest in participating in the study were cited as the reasons for drop-out [16, 21]. Although the same decreasing trend can be found in PBRN-based studies [77], patients in private practices may be more inclined to be regular attendees of the same practice and attend regular follow-ups [63, 74] resulting in higher recall rates compared to university settings. Increase in PBRN-based research in general, proper selection of participating practices, data-sharing between different geographical locations and increased patient awareness of benefits in participating in clinical trials may improve recall rates in long-term clinical trials.

*Low participant numbers*—As seen in meta-analyses and recent RCTs, the number of patients per group remains below 50 in most cases. The number of participants per group is determined so that there is a high probability (at least 0.8), also known as "power," to detect a statistically significant difference between the study and control group based on the expected effect size between the test groups. The expected effect size or difference between the test groups can be estimated from published data, pilot trials or empirically. The problem with sample size calculation is this expected effect difference between the test groups. The true expected difference between groups may be rather small that it requires a large number of participants (large sample size). A large number of participants may be difficult to enrol in a university-based clinical trial with one or few operators performing the treatment. Conversely, participant numbers feasible for a university-based study may prove to be sufficient only to detect as statistically significant an unrealistically large difference between the test groups which makes the study not worth performing. A consequence of low participant numbers is that a difference between groups may be found not significant even though there may be clinical relevance in it. As university-based clinical trials struggle with sample size, this is a not an issue in PBRN-based studies. Moreover, pooling of restorations is a common practice in university-based studies, e.g. Class I and Class II or premolar and molar teeth, for statistical analysis. Tooth type, cavity size and the number of involved surfaces are significant factors determining the restoration annual failure rate [63, 72]. Unbalanced groups in this respect may affect statistical analysis.

*Insufficient number of clinical trials*—It is often stated that more clinical research on the performance of dental materials, especially newly launched materials, is required. The same is true for bulk-fill composites and recent meta-analyses clearly express the need for more, especially long-term, clinical trials [1, 23, 28]. This is true for clinical research in general, but more importantly for properly designed, conducted and reported RCTs. Short-term studies often cannot detect differences between bulk-fill and conventional composites as it may take long time for these differences to develop. Moreover, evaluation criteria, especially modified USPHS may be rather insensitive to slight differences in materials' performance.

Clinical trials in restorative dentistry are demanding in design and execution, take long time, have a number of confounding factors and progressively higher drop-outs and rely on subjective evaluators' assessment. Despite all efforts, it is difficult or impossible to overcome these limitations. Confounding factors, low recall rate and evaluators' subjectivity may be mitigated at best. Both university- and PBRN-based trials have their strengths and weaknesses. Both approaches are required to reach balance and improve the validity of findings to a degree that can strongly affect clinical practice.

## 9.4 Conclusions

Bulk-fill composites have shown similar clinical performance to conventional incremental composites in clinical trials. Restoration survival and annual failure rates are similar to conventional incremental composites. The main reason for restoration failure is secondary caries. Occasional differences in individual characteristics do not affect their overall clinically acceptable performance. Sculptable bulk-fill composites reduce restoration time, but the same has not been confirmed for flowable bulk-fill materials, likely due to the required capping layer of a sculptable composite. Clinical performance of bulk-fill composites is not influenced by the placement technique, adhesive system or technique and lining material. Challenges in clinical placement of bulk-fill composites are the same as for composites in general and include moisture control, proper adhesive placement technique, material adaptation and light-curing. Caution should be taken when restoring large cavities, especially in molar teeth. There is no clinical evidence to support the use of sculptable bulk-fill composites for cusp replacement in complex restorations and in vitro studies indicate their inferior mechanical properties for this indication. More well-designed, conducted and reported long-term randomized control trials are required to further elucidate clinical performance of bulk-fill composites. Conducting randomized clinical trials in practice-based network settings allows greater participant numbers, ability to detect smaller differences between test groups and better "real-life" research context.

**Acknowledgments** The author would like to express sincere gratitude to Professor Joseph Sabbagh for his clinical cases presented in Appendix 2 to illustrate clinical longevity of bulk-fill composites. The author is grateful to Professor Joseph Sabbagh and Professor Robert McConnell for their critical review of this chapter.

## Appendix 1

**Table 9.1** summarizes the main characteristics of clinical trials that were not included in recent meta-analyses for not meeting the inclusion criteria or for being published at later dates

| Authors | Year | Type of study | Setting | Groups | Np-Nr (per group) | Follow-up | Class/ tooth type | Evaluation criteria | Rubber dam | Intervention group | Control group | Observation |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Torres et al. [35]** | **2021** | **RCT split-mouth double blind** | **University 5 operators** | **Ormocer vs bulk-fill ormocer** | **30–30** | **2 years** | **Class II/ molar** | **FDI** | **Yes** | **Futurabond U (self-etch mode) + Admira fusion xtra** | **Futurabond U (self-etch mode) + Admira fusion** | **No sig. differences. Bulk-fill material required significantly shorter chair time** |
| **Hardan et al. [33]** | **2021** | **RCT split-mouth** | **University 1 operator** | **Bulk-fill vs incremental** | **30–30** | **12 months** | **Class I/ premolar and molar** | **Reduced FDI** | **Yes** | **Adper SingleBond (2-step total-etch) + Filtek bulk fill posterior** | **Adper SingleBond (totat-etch) + Filtek Z250XT** | **Initially no post-op pain in both groups, lower pain and marginal discolor-ation in bulk at 12 month than incremental. No caries** |
| **Cieplik et al. [32]** | **2021** | **RCT split-mouth blinded examiners** | **University 3 operators** | **SABF vs. sculptable bulk-fill** | **30–30** | **12 months** | **Class II/ premolar and molar** | **FDI** | **If possible** | **No adhesive, light cured 20s** | **ScotchBond universal (self-etch mode) + Filtek bulk fill one** | **All clinically acceptable scores; BF sign. better surface luster, marginal staining, color match than SABF, no diff. in other scores** |
| Suneelku-mar et al. [39] | 2021 | RCT split-mouth double blind | University 1 operator | Bulk-fill incremental vs. bulk technique | 42–42 | 12 months | Class I/ unstated | FDI | Yes | Single bond universal (self-etch mode) + Filtek bulk fill posterior, bulk technique | Single bond universal (self-etch mode) + Filtek bulk fill posterior, incremental technique | All restorations "excellent" or "clinically good" FDI scores. No sig. differences between two techniques |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Yazici et al. [21] | 2021 | RCT split-mouth double blind | University 1 operator | Bulk-fill vs. incremental composite | 50–50 | 6 years | Class II/ premolar and molar | Modified USPHS | Yes | Excite (total-etch) + Tetric Evoceram bulk fill (TEC BF) | Adper single bond (total-etch) + Filtek ultimate (FU) | Sig. lower marginal discoloration for TEC BF than FU. Other criteria no sig. diff. Sig. worse marginal discoloration of FU than at baseline. Both sig. worse marginal adaptation than at baseline. No failure due to caries at 6 years |
| Durão et al. [16] | 2021 | RCT split-mouth double blind | University 1 operator | 2 bulk-fill vs 1 incremental composite | 46–46 | 3 years | Class I and II/ molar and premolar | Modified USPHS and FDI | Yes | 1. Clearfil SE bond (selective-etch mode) + Tetric Evoceram bulk fill (TEC BF); 2. Clearfil SE bond (selective-etch mode) + Filtek bulk fill (FBF) | Clearfil SE bond (selective-etch mode) + Filtek Z250 | TEC BF sig better surface luster than FBF and Z250 at 3 years. high-viscosity bulk-fill composites comparable to conventional incremental composite in a high caries incidence population. Sig. diff. Between USPHS and FDI criteria (surface roughness, marginal adaptation and staining). FDI more "success" scores, USPHS most "acceptable" scores |

(continued)

**Table 9.1** (continued)

| Authors | Year | Type of study | Setting | Groups | Np-Nr (per group) | Follow-up | Class/ tooth type | Evaluation criteria | Rubber dam | Intervention group | Control group | Observation |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Torres et al. [40] | 2020 | RCT split-mouth double blind | University 5 operators | Bulk-fill composite with/without liner | 30–30 | 2 years | Class I and II/molar and premolar | FDI | Yes | Ionoseal liner + Futurabond U (self-etch mode) + Admira fusion xtra | Futurabond U (self-etch mode) + Admira fusion xtra | No clinically "unsatisfactory" scores. No sig. diff. in criteria between two groups. 1 restoration per group "satisfactory" color match; 4 (liner) vs. 3 (no-liner) "satisfactory" marginal adaptation |
| Castro et al. [36] | 2020 | RCT split-mouth double blind | University 3 operators | Wet vs. dry bonding technique of a 2-step TE adhesive and 1 bulk-fill composite | 45–45 | 12 months | Class I and II/molar and premolar | Reduced FDI | Yes | Wet-bonding Adper single Bond2 (total-etch) + Filtek bulk fill posterior | Dry-bonding Adper single Bond2 (total-etch) + Filtek bulk fill posterior | Ni sig. diff. in post-op sensitivity between groups. A sig. higher risk up to 48 h in both groups. No sig. diff. in marginal discoloration and adaptation, fracture and secondary caries. No effect of cavity type, depth or number of restored surfaces |
| **ElAziz et al. [17]** | **2020** | **RCT parallel blinded examiners** | **University 1 operator** | **Direct everX vs indirect onlays in complex restorations** | **38–38** | **12 months** | **Class II complex/ molars** | **Modified USPHS** | **Yes** | **Gaenial bond (selective-etch) + everX posterior + Gaenial posterior** | **Immediate dentin sealing (Futurabond 2-step self-etch) + dual cure adhesive cement (BifixQM) + GrandioSO** | **Marginal integrity of everX group sig. better than onlay. Color match sig. better in onlay group. No sig. diff. in other criteria** |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Afifi et al [31]** | **2019** | **RCT split mouth and parallel double blind** | **University 1 operator** | **Post-op sensitivity 1 month** | **30–15** | **1 months** | **Class II/ premolar and molar** | **VAS** | **No (cotton rolls + suction)** | **1. Total-etch adhesive (unspecified) + Tetric EvoCeram bulk fill; 2. Self-etch adhesive (unspecified) + Tetric EvoCeram bulk fill** | **1. Total-etch adhesive (unspecified) + Tetric EvoCeram; 2. Self-etch adhesive (unspecified) + Tetric EvoCeram** | **No sig. diff between the groups. Low sample size. Post-op sensitivity in bulk-fill initially and 1 week (total-etch), conventional occurred at 1 month (total-etch)** |
| **Tardem et al. [34]** | **2019** | **RCT split mouth double blind** | **University 4 operators** | **Self-etch vs. selective etch & bulk-fill vs. incremental** | **81–49 restora-tions** | **1 week** | **Class I and II/ premolar and molar** | **Numeri-cal rating scale (NRT) and visual analog scale (VAS)** | **Yes** | **1. ScotchBond universal (SBU selective-etch) + Filtek one bulk fill (F1BF); 2. SBU (self-etch) + F1BF; 3. SBU (selective-etch) + FBF posterior; 4. SBU (self-etch) + FBF posterior** | **1. ScotchBond universal (selective-etch) + Filtek supreme ultra; 2. ScotchBond universal (self-etch) + Filtek supreme ultra** | **Twelve restorations in 6 patients post-op sensitivity (mild-moderate) to mastication/ air up to 48 h. overall risk of post-op sensitivity was 4%. Deeper cavities than 4 mm sig. more post-op sensitivity than shallower. Bulk-fills less time-consuming than incremental** |
| Fahim et al. [37] | 2019 | RCT, examiners blinded | University 1 operator | High-inten-sity vs. conventional LED (1 bulk-fill) | 36 patients and 44 restora-tions in total | 12 months | Class II/ premolar and molar | Modified USPHS | Yes | Futurabond U (selective-etch) + x-traFill (high-intensity 1400 mW/cm2 for 5 s) | Futurabond U (selective-etch) + x-traFill (low-intensity 650 mW/cm2 for 20s) | No sig. diff in criteria between groups. Significant increase in the % of marginal discontinuity of occlusal margins (impressions, SEM) at 12 m, more in "high-intensity" than "control" group |

(continued)

**Table 9.1** (continued)

| Authors | Year | Type of study | Setting | Groups | Np-Nr (per group) | Follow-up | Class/ tooth type | Evaluation criteria | Rubber dam | Intervention group | Control group | Observation |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Loguercio et al. [38] | 2019 | RCT split-mouth double blind | University 4 operators | Bulk-fill composite placed incrementally vs. bulk AND in total-etch vs self-etch adhesive | 59–59 | 3 years | Class I and II/ premolar and molar | FDI | Yes | 1. Tetric N-bond (total-etch) + Tetric EvoCeram bulk fill (as bulk); 2. Tetric N-bond SE (self-etch) + Tetric EvoCeram bulk fill (as bulk) | 1. Tetric N-bond (total-etch) + Tetric EvoCeram bulk fill (as increm.); 2. Tetric N-bond SE (self-etch) + Tetric EvoCeram bulk fill (as increm.) | All restorations "acceptable" at 3 years. no caries after 3 years. 48 restorations (10–14 per group) immediate post-op sensitivity, no sig diff between groups. Marginal staining and adaptation sig worse in self-etch groups. No sig diff in other criteria |
| *Akalın* et al. [15] | *2018* | *Prospective clinical trial* | *University 2 operators* | *1 bulk-fill Sonicfill* | *52 patients in total, 111 restorations* | *2 years* | *Class II/ premolar and molar* | *Modified USPHS* | *No (cotton rolls + suction)* | *ScotchBond universal (selective-etch) + SonicFill NB:2%CHX applied after rinsing the acid and before adhesive. Rubbed in for 10s, left for 10s and air-dried.* | */* | *1 failure due to periapical inflammation, required RCT. Survival rate 99.1%. All received "acceptable" scores for color match, marginal staining and adaptation, anatomic form, surface roughness. Post-op sensitivity 0 at baseline, but 2 at 2 years recall. No secondary caries. Color match, marginal discoloration and surface roughness start to deteriorate within 6 m* |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Hickey et al. [43]** | **2016** | **RCT parallel** | **General dental practice 1 operator** | **Bulk fill vs. incremental post-op sensitivity** | **72–36** | **2–30days** | **Class I and II/ premolar and molar** | **Question-naire** | **Yes** | **ScotchBond NT (total-etch) + SDR + Filtek Z250** | **ScotchBond NT (total-etch) + Filtek Z250** | **At day 2, 18 (25%) teeth-postop pain, sig more in SDR group. At day, 7 *(11%) teeth- postop pain, no diff between groups. At day 30, 2 (3%) teeth-postop pain. Not unclear whether pain was spontaneous/cold/air. More class I tender to biting than class II** |
| *Sarret* et al. [20] | *2006* | *Prospec-tive clinical trial* | *University 1 operator* | *Bulk-fill* | *32 patient, 57 restora-tions* | *3 years* | *Class II/ premolar and molar* | *Modified USPHS* | *Yes* | *OptiBond solo (total-etch) + prodigy* | */* | *<50% recall rate. Clinically unacceptable score requiring replacement 8% marginal adaptation and proximal contact, 4% caries, anatomical form and retention* |

References in **Bold**—RCTs with Conventional Composite as Control; References in Normal Font—RCTs with Bulk-Fill in both Test Groups with Control Related to, e.g., Bonding, Placement Technique, Lining, Light-Curing; References in *Italic*—Prospective Clinical Trials with no Control Group

## Appendix 2: Clinical Examples

**Case 1**

A class II SDR and Ceramex restoration at 8.5 years, the restoration is considered "clinically unsatisfactory but repairable" (too weak (open) contact, 100 micron metal blade can pass, inadequate proximal contour and potential soft tissue damage due to food impaction). The space between the molar and the premolar is due to a generalized periodontal problem. The radiography shows no secondary caries, a perfect adaptation of the composite on the cavity walls and a porosity in the middle of the restoration which indicates an air-bubble trapped during injection of flowable composite (Fig. 9.2).

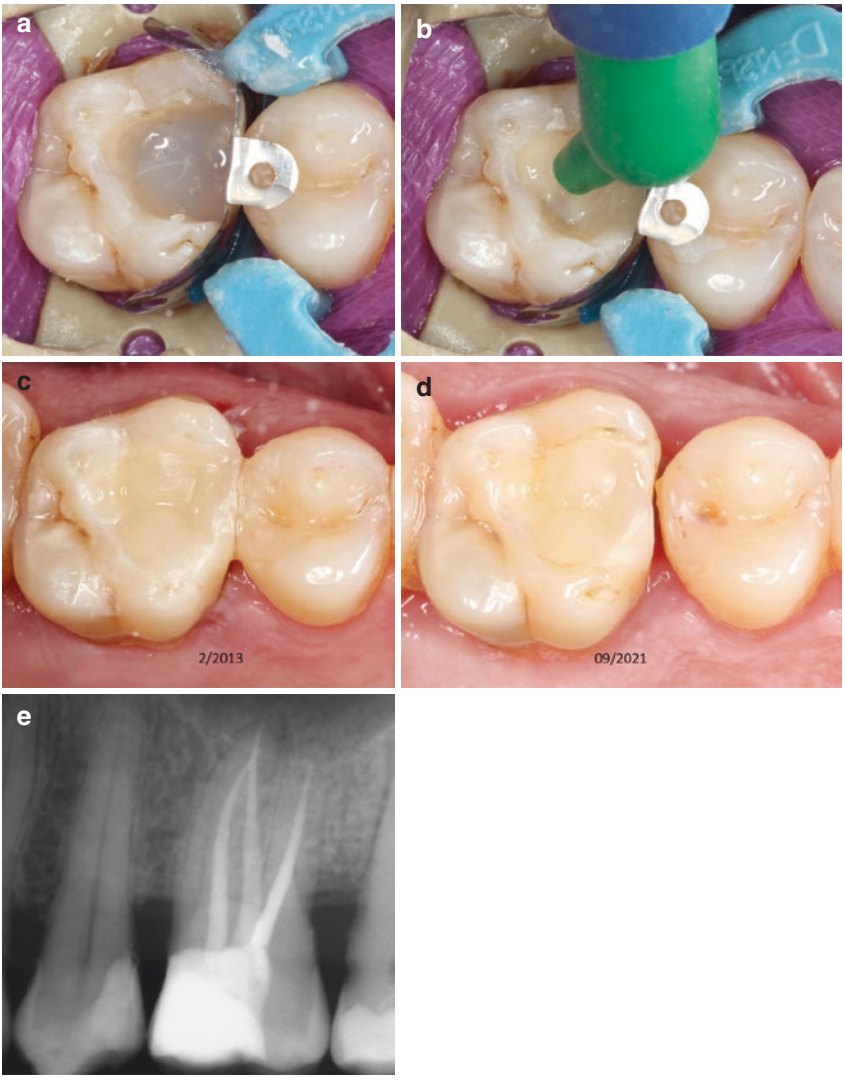


**Fig. 9.2** SDR and Ceramex at 8 years

**Case 2**

The use of flowable bulk-fill composite Xtra Base (Voco) in a deep class I cavity, covered by Amaris (Voco).

At 5 years, the restoration is considered excellent/very good from a functional and esthetic point of view. The form is ideal and the luster similar to that of enamel. The radiography shows no pathology (secondary caries) and a harmonious transition between restoration and tooth (Fig. 9.3).

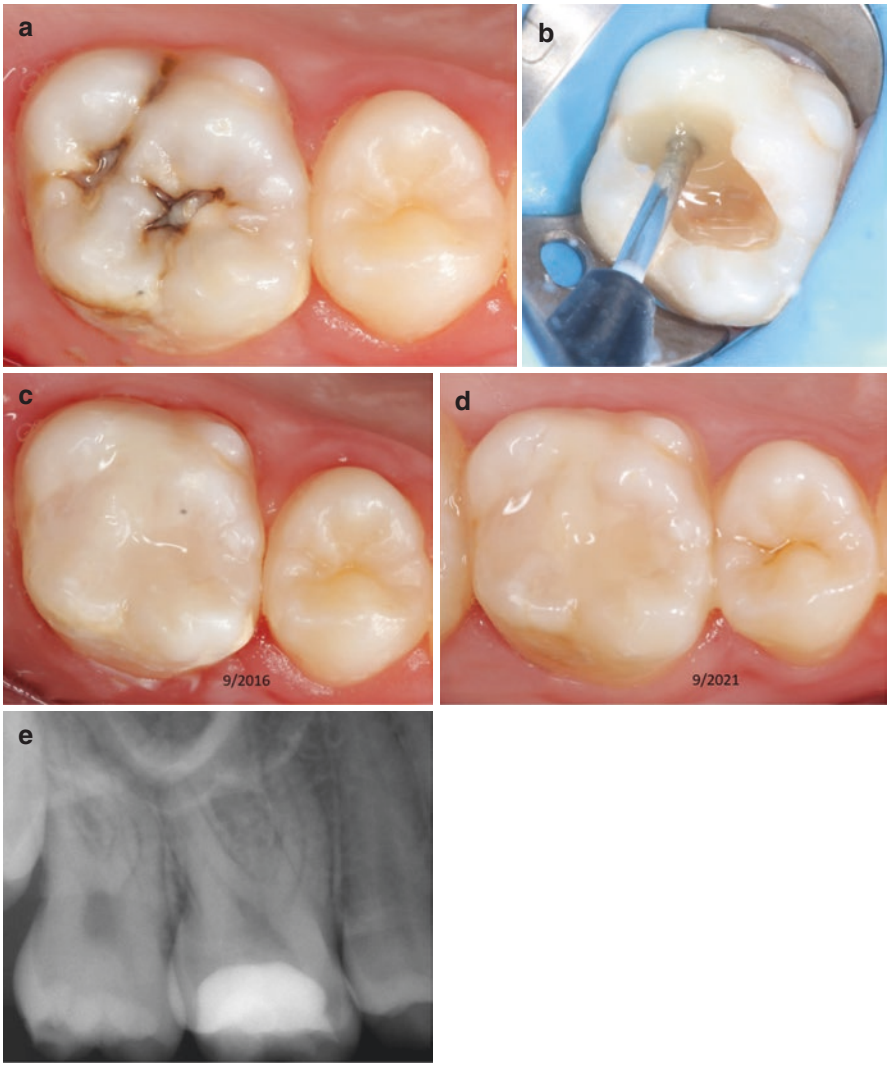


**Fig. 9.3** Xtra Base + Amaris

**Case 3**

Restoration of a class II (OD) and a class I using Sonicfill 1, a sculptable and sonically activated bulk-fill resin composites with Optibond FL. At 9 years, the restorations show good marginal adaptation and anatomical shape but a loss of surface luster.

It is considered clinically sufficient/satisfactory from an esthetic point of view since the surface is dull but acceptable if covered with saliva film. From a functional point of view, it is considered clinically good with a slight visible margin on the lingual cusp of the first molar (Fig. 9.4).

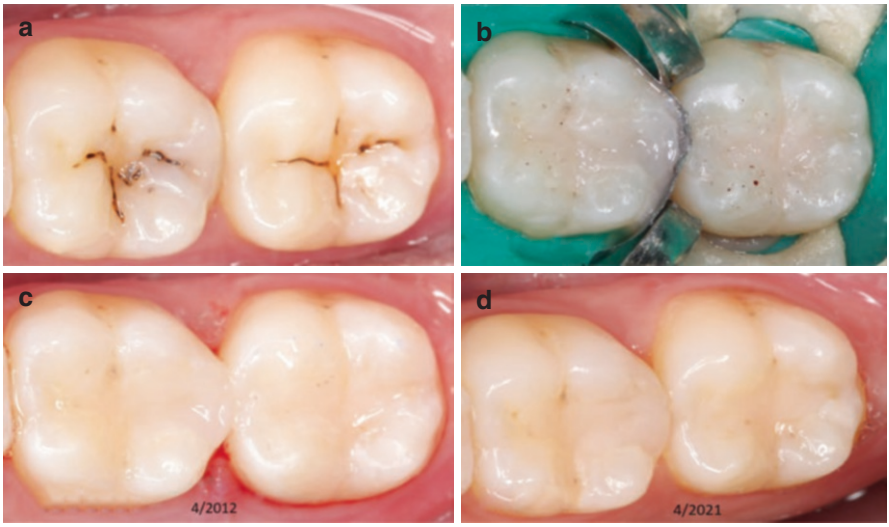


**Fig. 9.4** Sonicfill restoration

**Case 4**

Restoration of a class II (OM) using Sonicfill 1, a sculptable and sonically activated bulk-fill resin composites with Optibond XTR. At 8 years, the restoration shows severe wear and loss of anatomical shape and surface luster. It is considered clinically sufficient/satisfactory from a functional and esthetic point of view with gaps <250 μm (Fig. 9.5).

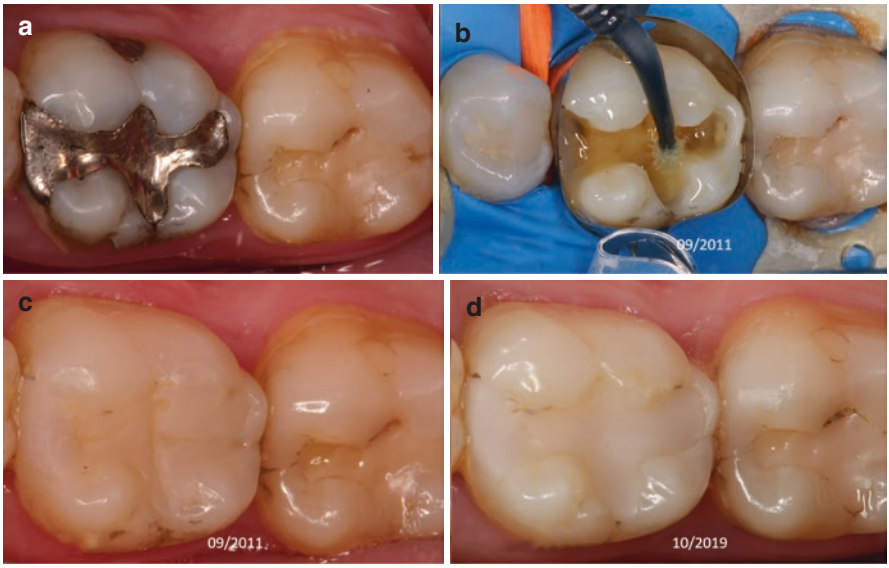


**Fig. 9.5** Sonicfill 1 + Optibond XTR

**Case 5**

Sonicfill 1 at 9 years shows marginal fracture and secondary caries (tooth 46), and moderate surface staining 9 (tooth 48)—clinically sufficient/satisfactory (Fig. 9.6).

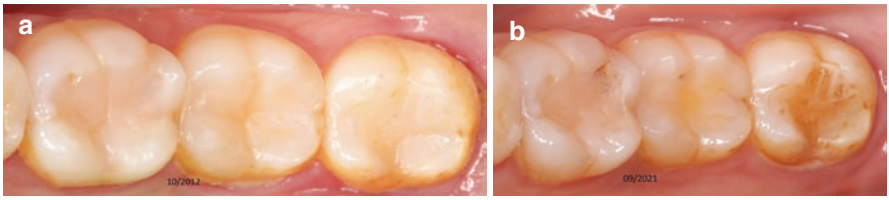


**Fig. 9.6** Sonicfill Three class I cavities

**Case 6**

At 8 years, a class II Sonicfill restoration shows caries and cavitation and is considered "clinically unsatisfactory/poor" and too weak contact point with food impaction and requires replacement (Fig. 9.7).

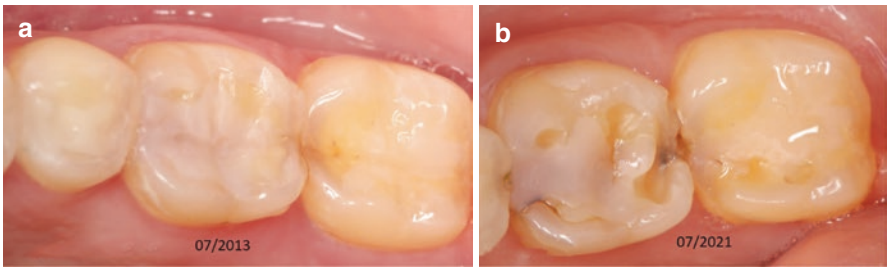


**Fig. 9.7** Sonicfill: Secondary caries and fracture at 8 years

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