CLINICAL EVALUATION OF CLASS II COMPOSITE RESIN RESTORATIONS USING TWO DIFFERENT BULK-FILL TECHNIQUES

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Abstract

The purpose of the present study was to compare the clinical performance of class II composite resin restorations using two different bulk fill techniques according to the United States Public Health Service criteria (USPHS) over 12 months follow-up.

Sixty class II restorations were placed in 60 patients, 20-50 years old. The patients were divided into three groups according to the applied restoration technique. In all cavities, etching (N Etch, Ivoclar Vivadent) was applied for 15 seconds and then rinsed. After that bonding was applied and cured for 20 seconds (N Bond, Ivoclar Vivadent). In group 1, Tetric Evo Ceram (Ivoclar Vivadent) was placed in 2 mm increments. In group 2, Tertic N Ceram Bulk Fill (Ivoclar Vivadent) was placed in single increment. In group 3, SonicFill™ (Kerr, Kavo) was placed in single increment by sonic vibration. The restorations were evaluated using modified USPHS criteria at baseline and then after 3, 6, 9 and12 months.

After 12 months, 58 class II restorations were evaluated. Two cases were dropped out. All the restorations in the three groups showed acceptable clinical performance according to the modified USPHS criteria. The differences between the techniques weren't statistically significant. Overall success was 91.3%. Five restorations failed, one in the first group and four in the second group.

Both bulk fill techniques performed well over the 12 months observation period. The bulk fill composite resin performed equally to the conventionally layered resin composite during the 12 months of the present clinical study.

Keywords: Bulk fill - composite resin – sonic vibration - USPHS.

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ÉVALUATION CLINIQUE DES RESTAURATIONS EN COMPOSITES UTILISANT DEUX TECHNIQUES DIFFÉRENTES DE REMPLISSAGE EN « BULK »

Résumé

Le but de la présente étude était de comparer la performance clinique des restaurations classe II en résine composite en utilisant deux techniques différentes de remplissage en vrac selon les critères du « United States Public Health Servicee (USPHS) » sur une durée de suivi de 12 mois.

Soixante restaurations ont été placées chez 60 patients âgés de 20 à 50 ans. Les patients ont été répartis en trois groupes selon la technique de restauration appliquée. Pour toutes les cavités, un traitement à l'acide (N Etch, Ivoclar Vivadent) a été réalisé pendant 15 secondes, suivi d'un rinçage. Puis le «bonding» a été appliqué et polymérisé pendant 20 secondes (N Bond, Ivoclar Vivadent). Dans le groupe 1, Tetric Evo Ceram (Ivoclar Vivadent) a été placé par couches de 2 mm. Dans le groupe 2, Tertic N Ceram Bulk Fill (Ivoclar Vivadent) a été placé en une seule couche. Dans le groupe 3, SonicFill™ (Kerr, Kavo) a été placé en couche unique par vibration sonique. Les restaurations ont été évaluées en se basant sur les critères modifiés du service de santé publique aux Etats-Unis au moment de la restauration, puis à 3, 6, 9 et 12 mois.

Après 12 mois, 58 restaurations de classe II ont été évaluées. Deux cas ont été éliminés. Toutes les restaurations dans les trois groupes ont démontré une performance clinique acceptable selon les critères USPHS modifiés. Les différences entre les techniques ne sont pas statistiquement significatives. Le succès global était de 91,3%. Cinq restaurations ont échoué, une dans le groupe 1 et quatre dans le groupe 2. Les deux techniques de restauration étaient satisfaisantes après 12 mois.

Mots-clés: restauration en composite – longévité – polymérisation – contraction.

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Introduction

Polymerization shrinkage of composite resin restorations has been widely investigated [1, 2]. Much of the studies focused on attempts to reduce polymerization shrinkage in order to improve marginal integrity, insure better adaptation to the cavity walls, reduce cusp deflection and enhance the restoration longevity [3].

Polymerization shrinkage must be distinguished from contraction stress. Visible light-cured composite resin contains multifunctional reactive molecules called monomers. When exposed to light, these monomers link together to create large molecules called polymers, which, in turn, link together to form a continuous network. The polymerization process requires that monomers physically move closer together to chemically reactivate a free radical process. This process results in a net loss of volume referred to as polymerization shrinkage if not restricted by bonding to a cavity. When this shrinkage process is restricted, stress builds up in the material [4].

Shrinkage stress exerts forces on bonded interfaces to which the composite resin is attached. This transfer of polymerization stress to tooth structure is the cause of many clinical problems such as enamel fracture, cuspal movement and cracked cusps [5]. In less well-bonded restorations, polymerization stress has the potential to initiate failure of the composite-tooth interface (adhesive failure). The resulting gap between the composite and cavity walls may produce post-operative sensitivity, microleakage, and/or secondary caries [6].

Therefore, if the magnitude of polymerization stress due to shrinkage can be reduced, the clinical success of composite resin systems might be improved.

Several factors have been identified as influencing the shrinkage stress of a restoration: the size (depth and diameter) and the geometry of the restoration (C-factor), the materials used and the curing protocol [7].

Composite resins with a lower modulus of elasticity or slower curing rate can reduce the polymerization stress [8]. Therefore, several modified insertion and light- curing techniques have been introduced during the past few years to decrease the marginal stress [9]. Extensive efforts have also been made to develop low shrinkage composite resins by changing filler amount, size, shape, monomer structure or chemistry, and by modifying the polymerization reaction [10].

Several restorative techniques have been used to minimize the polymerization shrinkage and stress, such as multiple increment techniques, the use of ceramic inserts, and replacement of the dentin with glass ionomer cement in the sandwich technique [11].

Incremental filling techniques have been proposed as a mean to reduce shrinkage stress of composite restorations. The results were controversial. Despite contradictory conclusions, incremental filling techniques are generally recommended, and dentists may choose to restore composite resin restorations on the basis of additional factors such as acceptable depth of cure, proper adaptation, and adequate bond formation [12].

The conventional increment technique is time-consuming and complicated when it is used to fill large and voluminous cavities in posterior teeth. As a result, many dentists eagerly anticipate the arrival of an alternative to this highly sensitive, multiple layering technique. The bulk fill composite resins have been developed in response to this growing demand for more efficiency. Bulk fill materials can be placed in increments of 4 to 5 mm thickness [13]. That might be done by enhanced translucency of the composite resin which permits an increased depth of cure per layer. Optimizing the photo-initiator system of the light-curing composite can cause shorter curing times and increased depth of cure. Also, the use of low-shrinkage composite resins with minimal stress build-up can help in applying thicker layers. Finally, the use of low viscosity composite resins improves their adaption to the internal wall of the cavity [13].

The aim of the present study was to compare the efficiency of two different bulk fill techniques used to restore class II cavities and compare them intra- individually with conventionally layered technique (Tetric Evo Ceram). The null hypothesis tested was that there would be no difference between the techniques under investigation.

Materials and methods

The current study is a prospective, controlled clinical trial conducted at the University of Damascus, Department of Operative Dentistry between July 2014 and October 2015. The protocol of the study was approved by the Council of Scientific Research and Postgraduate Studies, and followed FDI recommendations.

The original study sample included 60 patients. The sex distribution, withdrawals and distribution of the experimental restorations are showed in tables 1 and 2. All patients were informed about the study protocol.

The inclusion criteria were: good oral hygiene, permanent premolars and molars requiring class II for treating, primary carious lesions, and the presence of caries degree D3-D4 according to DIAGNOdent.

The exclusion criteria were: the presence of unerupted or partially erupted tooth, poor oral hygiene, heavy bruxism habits, periodontal problems, pathologic pulpal diagnosis with pain (non vital tooth), and fractured or visibly cracked teeth.

Sample size considerations

The sample size was calculated on the basis of previous sample size calculations performed in similarly designed studies of posterior restoration evaluations. Based on previous investigations, a power analysis determined that for an alpha value of 5% and a power of 80%, a sample size of 16 per group would be required. Accordingly, assignment continued until 20 patients

	Group1			Group 2			Group 3			Total sample		
	Male	female	Total	Male	female	Total	Male	female	Total	Male	female	Total
Initial sample	9	11	20	5	15	20	9	11	20	23	37	60
Dropouts	0	1	1	1	0	1	0	0	0	1	1	2
Final sample	9	10	19	4	15	19	9	11	20	22	34	58

Table1: Study sample: sex distribution and withdrawals.

Class II		Premolar	Molar	Total
Group1	Maxilla	10		10
	Mandible		10	10
Group2	Maxilla	6	3	9
	Mandible	4	7	11
Group3	Maxilla	5		5
	Mandible	5	10	15
Total		30	30	60

Table 2: Study sample: distribution of the experimental restorations.

Material	Composition	Consistency	Application step	Manufacturer
TetricEvo Ceram	Dimethacrylates 16.8%(Bis-GMA, Bis-EMA,UDMA, Ethoxylated Bis-EMA) Fillers 82.0% (Barium glass, Ytterbium trifluoride, Mixed oxide, sio2).	Sculptable	2 mm incremental filling	Ivoclar Vivadent, Schaan, Liechtenstein
Tetric N-Ceram Bulk Fill	Dimethacrylates 21.0% (Bis-GMA,Bis-EMA,UDMA) Polymer Filler 17.0% (Barium glass filler, Ytterbium trifluoride) Mixed oxide 61.0% Additive, Initiators, Stabilisers, Pigments, 1.0%	Sculptable	4 mm bulk-filling without capping	Ivoclar Vivadent, Schaan, Liechtenstein
SonicFill™	Dimethacrylates 15% (EBADMA, Bis-GMA TEGDMA,UDMA) Glass, oxide, chemicals 75% Silicon dioxide 10%.	Flowable, sound activated, sculptable	5 mm bulk-filling without capping	Kerr, Orange, CA, USA
N Bond	Dimethacrylates (Bis-GMA).		Apply one layer	Ivoclar Vivadent, Schaan, Liechtenstein
N Etch	Phosphoric acid 37%		Apply etch 15sec. then rinse and dry	Ivoclar Vivadent, Schaan, Liechtenstein
UDMA, urethane dimethacrylate; EBADMA, ethoxylated bisphenol A dimethacrylate; TEGDMA, triethyleneglycol dimethacrylate; Bis-GMA, bisphenol A diglycidyl ether dimethacrylate.				

Table 3: Composite resin and adhesive systems used.

Category	Score		Criteria
	Acceptable (alpha+bravo)	Unacceptable (charlie)	
Marginal discoloration	1 2	3	No discoloration on the margin Superficial discoloration on the margin Deep discoloration penetrated in a pulpal direction
Secondary caries	1	2	Caries absent Caries present
Wear (anatomic form)	1 2	3	Anatomy resembles original restoration Anatomy shows change in contour but not requiring replacement Excessive wear with dentin exposure requiring replacement
Marginal integrity	1 2	3	Continuity at the margin (no ledge or ditch) Slight discontinuity detectable with explorer but not requiring replacement Marginal ledge or crevice requiring replacement
Postoperative sensitivity	1 2	3	Normal Low sensitive for limited period of time. Sever sensitive to temperature changes and pressure
Surface roughness	1 2	3	Smooth surface Slightly rough or pitted Rough and surface pitting cannot be refinished
Fracture	1	2	Absent Present
Color stability	1 2	3	Absent Slight difference Severe difference

Table 4: Modified USPHS criteria for direct clinical evaluation.

(20 restorations) were enrolled in each group to compensate for any unexpected dropouts. It has been possible to determine significant differences between material groups in similarly designed intra-individual comparison evaluations with this sample size in previous studies [15].

Clinical procedure

Materials used in this study are listed in table 3. Caries degrees were measured by DIAGNOdent device. Existing caries were removed under constant water cooling, no bevel was prepared, and the operative field was carefully isolated with rubber dam. None of the cavities received Ca(OH)2 or other base materials. In all cavities etching (N Etch , Ivoclar, Vivadent) was applied for 15 seconds then rinsed. After that bonding (N Bond, Ivoclar, Vivadent) was applied and cured for 20 seconds. Ring matrix (Palodent, Dentsply) was used. Polymerization was performed with the LED unit Light Hemao (Hemao Medical Instrument Co. Ltd, China); the output was measured using a curing radiometer.

Group 1: Tetric Evo Ceram (Ivoclar, Vivadent) was placed in 2 mm increments, and each increment was light-cured for 20 seconds.

Group 2: Tetric N Ceram Bulk Fill (Ivoclar,Vivadent) was placed in single increment, and was light-cured for 40 seconds.

Group 3: SonicFill™ (Kerr, Kavo) was placed in single increment by sonic vibration, and was light-cured for 40 seconds.

The occlusion and articulation were checked and adjusted, and then the composite restorations were finished with fine-grit diamond instruments and polished with polishing disks, brushes and finishing strips (OptiDisc, Kerr).

Clinical evaluation

Modified USPHS criteria [14-15-19] were used to evaluate post-operative sensitivity, marginal integrity and marginal discoloration, surface texture, color stability, wear, fracture and secondary caries (Table 4) at baseline, then after 3, 6, 9, and 12 months. The baseline rating was carried out immediately after finishing and polishing procedures.

Statistical analysis

Statistical analysis was carried out with Statistical Package for the Social Sciences (SPSS 16.0 for Windows) software. Since the assessment of the restorations yielded clearly ordinal structured data, only non-parametric statistical procedures were used. Kruskal-Wallis test was used to explore significant differences between groups for the criteria listed in table 3. Wilcoxon Signed Ranks test was used to explore significant differences of the results at baseline and after 12 months.

Results

Sixty restorations were evaluated at baseline; only 58 restorations were evaluated after 12 month. Two restorations (one from group1 and the other from group 2) could not be evaluated because the patients moved away and could not come for final recalls. All restorations were judged as alpha at the baseline evaluation. The numbers of restorations judged as bravo rating at the recall visit were seven for marginal discoloration, six for surfaces texture, eight for wear of restoration, seven for marginal integrity, twenty-three for postoperative sensitivity and seven for color stability. The numbers of restorations judged as charlie rating at the recall visit were three for marginal discoloration, two for postoperative sensitivity. Table 5 summarizes the results of clinical evaluation of the restorations at baseline and after12 months. Overall success was 91.3%. Five restorations failed, one in group1(1 marginal discoloration) and four in group 2 (2 marginal discoloration, 2 persisting hypersensitivity), resulting in a 100% success rate for Sonic Fill , 94.7% for and 78,9% for Tetric N Ceram Bulk Fill ($p>0.05$).

Discussion

Composite resin bulk fill technology has undergone major advancements over the last decade. However, these developments have been so rapid that long-term clinical data on specific products are rarely available. Laboratory tests might provide useful information on the potential performance of a filling material and its handling, but such tests cannot adequately evaluate the clinical performance of the material or its clinical characteristics. Besides, in vitro studies cannot answer questions about in vivo longevity of tooth colored restorations [16]. Clinical studies of bulk fill materials are lacking and there is insistent need for long-term studies evaluating the clinical performance of these newly developed materials.

The present prospective controlled clinical study compared the clinical performance of class II direct composite resin restorations placed using two different bulk fill techniques (flowable composite resin by sonic vibration and sculptable composite resin) according to the modified US PHS criteria. The latter is the most commonly used direct method for quality control of restorations, applied in many clinical trials [11-14-15-17].

The results of the present study supported the null hypothesis that there are no significant differences in the clinical performance between the two bulk fill techniques, also between the bulk fill technique and the multi-layering technique.

According to these results, it is possible to clinically apply thicker increments as determined in other similar studies [17-18]. This procedure can help overcome the problems associated with multi-layering technique such as air incorporation between the layers and time wasting. Also, some authors indicated that incremental layering induced high stresses at the interfacial margins [19-21].

Bulk-fill composites do not constitute a uniform class of materials. Considerable differences exist between the individual products with regard to

Categories	Group	Baseline			12 months		
		a*	b*	c*	a	b	c
Marginal discoloration	Tetric Evoceram Tetric N Ceram Bulk Fill SonicFill™	20 20 20			15 13 18	3 2 2	1 2
Secondary caries	Tetric Evoceram Tetric N Ceram Bulk Fill SonicFill™	20 20 20			20 20 20		
Wear (anatomic form)	Tetric Evoceram Tetric N Ceram Bulk Fill SonicFill™	20 20 20			15 14 19	4 3 1	
Marginal integrity	Tetric Evoceram Tetric N Ceram Bulk Fill SonicFill™	20 20 20			17 13 19	2 4 1	
Postoperative sensitivity	Tetric Evoceram Tetric N Ceram Bulk Fill SonicFill™	12 10 13	8 8 7	2	19 17 20		
Surface texture	Tetric Evoceram Tetric N Ceram Bulk Fill SonicFill™	20 20 20			16 15 19	3 2 1	
Fracture	Tetric Evoceram Tetric N Ceram Bulk Fill SonicFill™	20 20 20			19 17 20		
Color stability	Tetric Evoceram Tetric N Ceram Bulk Fill Sonic™ Fill	20 20 20			17 14 18	2 3 2	

*a: alpha, b: bravo, c: charlie
Table 5: The results of clinical evaluation of the restorations at baseline and after 12 months.

the composition and the size of the filler particles. Also, they differ in the way of clinical application and the built-up technique [22].

Bulk-fill composite resins are generally more translucent than multi-layers composite resins; shade and translucency levels influence the depth of cure of composites [23]. This observation partially explains why thick increments of bulk-fill composite resins cure are just as effective as thin two-millimeter layers of conventional composite resins. Ilie et al. found that high translucency reduces light scattering and improves light penetration which enhance the light polymerization of thick restoration layers [24]. Nevertheless, individual products can differ quite considerably in this respect [24-25]. Tetric N Ceram Bulk Fill features a photo-initiator called Ivocerin, which is highly reactive to incoming photons and therefore enables the restorative material to cure to a depth of 4mm [26]. SonicFill™ had enhanced the depth of cure by increasing levels of photo-initiators in the composite material which allows achieving a full 5mm depth of cure [27-28].

The satisfactory clinical results obtained in this study for Tetric N Ceram Bulk Fill and SonicFill™ regarding the fracture and recurrent caries (100% alpha) might be related to the improvements in the structure of the materials. Minimization of the polymerization shrinkage and the shrinkage stress are particularly important in a material that is applied in increments up to 4-5mm. [26-28]. Tetric N Ceram Bulk Fill contains polymer filler considered as shrinkage stress reliever with a low modulus of elasticity that attenuates the forces generated during shrinkage [26]. SonicFill™ depends on using low shrinkage resin; in addition, sonic activation of the composite resin dramatically lowers the viscosity during placement, providing superior adaptation to the cavity walls [28].

Even though the differences in the clinical efficacy between the techniques tested in the present study were not statistically significant, the scores recorded for SonicFill™ restorations were better than Tetric N Ceram Bulk Fill.

According to the present results, Tetric N Ceram Bulk Fill exhibited 82% alpha scores after 12 months regarding restorations wear and 88% alpha scores regarding surface texture (roughness). Whereas SonicFill™ exhibited 95% alpha scores regarding both wear and surface texture: SonicFill™ has higher filler load of the material (83.5 % in weigh) than Tetric N Ceram Bulk Fill (75% in weigh) which gives the material these good properties [26-28].

Also, the three composite resin types of restorations demonstrated similar results in regard to color stability; the three materials have relatively small filler particles that provide an advantage in terms of color properties [29]. Also they have a Urethane Dimethacrylate (UDMA) polymer matrix, which provides better resistance to color change as Bayne et al. found in their study [30].

Marginal discoloration usually results from defects present between tooth-colored restorations and cavity margins [31]. In the present study, Tetric N Ceram Bulk Fill exhibited 76% alpha scores after 12 months in regard to marginal discoloration and integrity, whereas SonicFill™ recorded 90-95% alpha scores. Sonic vibration lowers the viscosity of the SonicFill™ composite resin, allowing the material to flow and possess a good wetting ability. That favors their adaptation to the cavity walls, allowing better marginal properties than Tetric N Ceram Bulk Fill.

In the present one-year clinical study, postoperative sensitivity was recorded only at baseline (56% alpha score for the three groups) and disappeared after 12 months. Postoperative sensitivity seemed to be a problem related to resin composite restorations. Many studies [32, 33] have indicated that up to 30% of the studied populations have reported postoperative sensitivity following the placement of a posterior resin restoration. In the current study, postoperative sensitivity was seen in premolar teeth more than molar teeth and in Tetric N Ceram Bulk Fill group more than SonicFill™ group. Two failed class II premolars restorations in Tetric N Ceram Bulk Fill group were recorded. The patients suffered from severe postoperative sensitivity to temperature changes and pressure during the first three weeks after treatment and needed pulp treatment. That may be due to lack of monomer conversion in deep cavities especially in premolar teeth which usually have less thickness of dentine above pulp chamber, causing leakage of monomer to the pulp and resulting in an irreversible irritation.

Conclusion

Within the limits of the present study, the following observations were retained:

-The two bulk fill techniques showed acceptable clinical results and were similar to the conventional layering technique over 12 months evaluation period.

- The bulk fill restorations can overcome the difficulties with multi-layers technique, saving time and efforts with satisfactory clinical outcomes.

-Low viscosity sonic fill was better Tetric N Ceram Bulk Fill in terms of depth of cure and marginal integrity; sonic energy is applied through the handpiece, increasing the flowability of the SonicFill™ and enabling quick placement and precise adaptation to the cavity walls.

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