©Operative Dentistry, 2014, **39-6,** 588-594

Resin Composite Class I Restorations: A 54-month Randomized Clinical Trial

AKM de Andrade • RM Duarte • FDSC Medeiros e Silva
AUD Batista • KC Lima • GQM Monteiro
MAJR Montes

Clinical Relevance

Restorations in Class I cavities of posterior teeth restored with nanofilled and nanohybrid resin composites showed satisfactory results after 54 months.

Ana Karina Maciel de Andrade, DDS, PhD, Department of Restorative Dentistry, Universidade Federal da Paraíba (UFPB), Cidade Universitária, João Pessoa, Brazil

Rosângela Marques Duarte, DDS, PhD, Department of Restorative Dentistry, Universidade Federal da Paraíba (UFPB), Cidade Universitária, João Pessoa, Brazil

Fábia Danielle Sales Cunha Medeiros e Silva, DDS, PhD, Department of Restorative Dentistry, Universidade Federal da Paraíba (UFPB), Cidade Universitária, João Pessoa, Brazil

André Ulisses Dantas Batista, DDS, PhD, Department of Restorative Dentistry, Universidade Federal da Paraíba (UFPB), Cidade Universitária, João Pessoa, Brazil

Kenio Costa Lima, DDS, PhD, Department of Dentistry, Universidade Federal do Rio Grande do Norte (UFRN), Natal, Brazil

Gabriela Queiroz de Melo Monteiro, DDS, PhD, Dental Materials, School of Dentistry, Universidade de Pernambuco (UPE), Camaragibe, Brazil

*Marcos Antônio Japiassú Resende Montes, DDS, PhD, Dental Materials, School of Dentistry, Universidade de Pernambuco (UPE), Camaragibe, Brazil

*Corresponding author: Faculdade de Odontologia de Pernambuco–UPE, Disciplina de Materiais Dentários, Av. Gen. Newton Cavalcanti, 1650, Camaragibe - PE, 54753-220, Brazil; e-mail: majrm@uol.com.br

DOI: 10.2341/14-067-C

SUMMARY

The objective of this longitudinal clinical randomized trial was to evaluate the clinical performance of a nanofilled and a nanohybrid resin composite in Class I occlusal restorations of posterior teeth over the course of 54 months. Forty-one adolescents participated in the study. The teeth were restored with Adper Single Bond 2 (3M ESPE) and nanofilled (Filtek Z350, 3M ESPE), nanohybrid (Esthet-X, Dentsply) and microhybrid Filtek Z250 (3M ESPE) used as a control. After 54 months, the restorations were evaluated in accordance with the modified United States Public Health Service criteria. The McNemar and Friedman tests were used for statistical analysis, at a level of significance of 5%. Five failed restorations were observed during the follow-up. A change to unacceptable restoration occurred for one Esthet-X, two Filtek Z350, and two Filtek Z250 restorations, which received the clinically unacceptable score, Charlie, for both anatomic form and marginal adaptation. Secondary caries and postoperative sensitivity occurred in one Filtek Z250 and one Filtek Z350 restoration. When the five

evaluation periods (baseline and six, 12, 30, and 54 months) were compared, significant differences were found in the marginal adaptation of Filtek Z250 and Filtek Z350. Significant differences in the roughness criteria (p=0.005) were also observed when the three composites were compared after 54 months (Filtek Z350 > Filtek Z250 > Esthet-X), always within clinically acceptable limits. The materials investigated showed acceptable clinical performance for Class I restoration after 54 months. Long-term reevaluations are necessary for a more detailed analysis of these composites.

INTRODUCTION

Resin-based composites have been used extensively over the past decade to restore posterior teeth.[1] Many clinicians have used this class of materials in posterior stress-bearing areas quite successfully for the last five to 10 years.[2] However, there are some problems associated with resin-based composites in posterior teeth, including occlusal and proximal wear, marginal leakage, discoloration, polymerization shrinkage, and postoperative sensitivity.[3]

Nanotechnology has recently been introduced in dentistry.[4] Nanofillers can be prepared by various techniques, such as flame pyrolysis, flame spray pyrolysis, and sol-gel processes.[5] They can increase the overall filler level as a result of the small size of the particles. In several newer nanocomposites, nanofillers have been included in order to obtain high fracture toughness, longer-lasting polish retention and esthetics, and higher wear resistance.[6,7] As a consequence, manufacturers now recommend the use of nanocomposites for both anterior and posterior restorations.[8]

Nanocomposites comprise nanofilled and nanohybrid materials. While the former is based on nanosized fillers and/or nanofiller clusters, the latter contain the traditional glass filler particles found in hybrid resin composites and smaller concentrations of nanosized fillers and/or nanofiller clusters.[9,10]

Clinical trials are important to verify the performance of composites under actual conditions of use.[11] Focusing solely on the longitudinal clinical performance, this study evaluated the clinical performance of a nanofilled, a nanohybrid, and, as a control, a conventional microhybrid composite in Class I occlusal restorations of posterior teeth over the course of 54 months. The null hypothesis to be tested was that there was no difference in the clinical performance among the three resin composites after 54 months.

METHODS AND MATERIALS

This was a clinical study with a controlled and randomized design and it followed the guidelines published by Consolidated Standards of Reporting Trials.[12] This research was approved by the Research Ethics Committee of the Health Science Center (CEP: # 1252) of the Federal University of Paraíba (Brazil). Written informed consent was obligatory for each patient.

1. Population and Sample

The patients in this study were selected from among male and female students at public schools in the municipality of João Pessoa, Paraíba (Brazil). Our sample was restricted to students in public schools who lived in the suburbs. These patients were adolescents (mean age ± standard deviation, 13.44 ± 2.22 years).

The sample size was calculated based on an expected difference in survival of the three composites of 15%, a power of 0.8, and a significance level of 0.05. In agreement with the recommendations of Hickel and others,[13] there should not be more than one restoration per group per patient, therefore leading to a final sample composed of 123 permanent molars of 41 volunteers, who were divided into three groups (Figure 1).

2. Eligibility Criteria, Randomization, and Blinding

The inclusion criteria were as follows: the presence of three molars requiring replacement of Class I restorations or with primary caries on the occlusal surface; occlusal contact with the antagonist tooth; and a patient who was in a good state of general health.[14] The following were excluded from the study: patients with intense bruxism, observed as abnormal wear patterns of the occlusal surface, abfractions, and fractures in the teeth; molars that presented a carious lesion on a surface other than the occlusal surface and in continuity with the occlusal cavity; pulp exposure during caries removal or cavities with imminent risk of pulp exposure; or spontaneous pain or sensitivity to percussion.

To ensure randomness, a drawing was held using sealed envelopes to establish in which group a certain tooth would be placed, as follows:

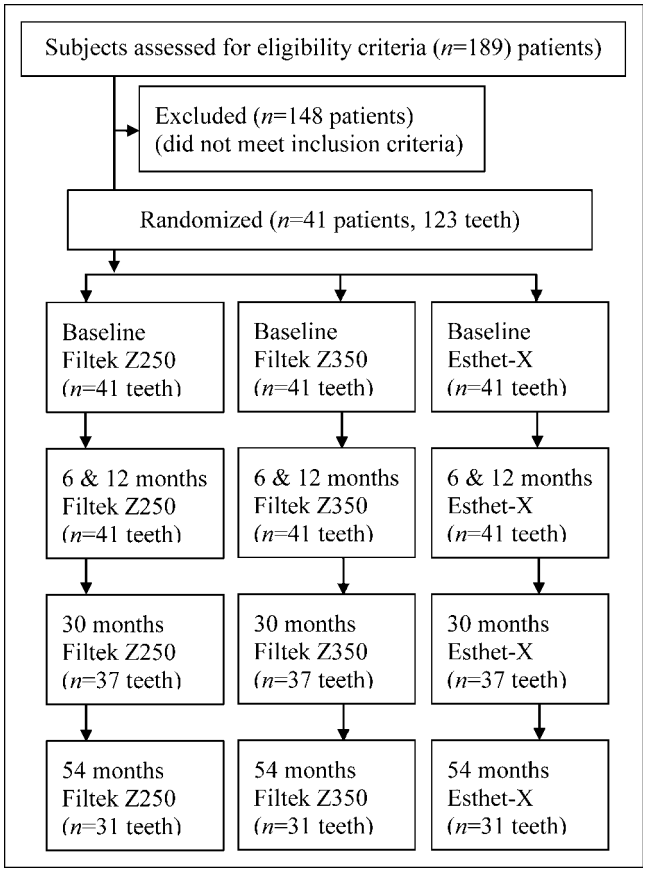

Figure 1. *Flowchart of the trial.*

- Group I: microhybrid resin composite Filtek Z250 (3M ESPE, St Paul, MN, USA), representing the control;
- Group II: nanofilled resin composite Filtek Z350 (3M ESPE); or
- Group III: nanohybrid resin composite Esthet-X (Dentsply/Caulk, Milford, DE, USA).

Neither the patients nor the examiners knew which commercial brand of composite was used in each tooth, thus resulting in a double-blind study.

3. Clinical Procedure

Treated teeth were isolated with rubber dam, and cavity preparations were performed with 245 carbide burs (SS White, Rio de Janeiro, Brazil) using high speed with light intermittent pressure. Tissue removal was limited to that required for access to carious tissue. Residual caries were removed with a spherical bur at low speed. In cases of unsatisfactory restorations, these and any remaining carious tissues were removed. In deep cavities, resin-modified glass ionomer cement (Vitrebond; 3M ESPE) was used. In shallow and medium cavities, only dentin hybridization was performed. One-step total-etch adhesive system, Adper Single Bond 2 (3M ESPE), was applied following the manufacturer's instructions. The composite was inserted using the incremental technique, with a maximum of 2 mm in each layer, and photo-activated with an LED curing light (Optilight LD Max; Gnatus, Ribeirão Preto, São Paulo, Brazil), depending on the manufacturer's recommendations. Irradiance of 600 mW/cm^2 was verified using a radiometer. Occlusion was adjusted with a multibladed bur (FG7714F, KG Sorensen, Brazil) at high speed. The restorations received final finishing and initial polishing with rubber cups and points (Flexicups and Flexipoints, Cosmedent Inc, Chicago, IL, USA). Final polishing was performed using Enamelize paste (Cosmedent Inc) and a diamond felt disk (FGM Joinville, Santa Catarina, Brazil). All of the procedures were performed by the same operator, and all of the patients received individual oral hygiene instructions, tooth brushes, and toothpaste with fluoride.

4. Sample Characteristics

The characteristics of the samples are shown in Table 1. After performing the statistical tests to verify the homogeneity of the sample, it was found that the distribution of the variables was homogeneous in the three groups ($p>0.05$).

5. Evaluations

The restorations were clinically evaluated by two examiners, who had been previously trained and whose performance had been calibrated. Kappa varied from 0.8 to 1. When disagreements arose during the evaluations, consensus among examiners was obtained. The evaluations were made one week after the restorations were performed (baseline) and after six, 12, 30, and 54 months, in accordance with the criteria (Table 2) established by Dresch and others[14] and the modified US Public Health Service criteria (Ryge Criteria).[15] Radiographs (bitewings) and periapicals in teeth with deep cavities were taken and vitality tests were performed. Postoperative sensitivity was evaluated at all sessions by questioning the patients and applying an air spray for three to five seconds from a syringe at a distance of 3-5 mm.

The restorations were classified as Alpha, Bravo, and Charlie. Alpha and Bravo scores corresponded to excellent and clinically acceptable results; a Charlie score corresponded to a clinically unacceptable result and served as an indication to replace the restoration to prevent future damage or to repair the present damage.[11]

6. Statistical Analysis

The Statistical Package for the Social Sciences (version 13.0, SPSS, Chicago, IL, USA) was used for the statistical analysis. The McNemar and Friedman nonparametric tests were used at a level of significance of 5%. The McNemar test was applied to verify the homogeneity of the sample, and the Friedman test was applied to assess and evaluate differences between time periods for each composite and differences between composites at the end of each time period.

RESULTS

In total, 123 restorations were placed in 41 patients. However, after 30 and 54 months, four and 10 patients, respectively, were lost to follow-up because they had moved and could not be located. After 54 months, 31 patients were reevaluated (a total of 93 restorations were available). The results are shown in Table 3. The overall success rate at 54 months was 94.62%. Five failed restorations (5.37%) were observed during the follow-up: two Filtek Z250 (6.45%), two Filtek Z350 (6.45%), and one Esthet X (3.22%). This resulted in annual failure rates of 1.61% for the Filtek Z250 and Filtek Z350 groups and a failure rate of 0.80% for the Esthet X group.

In some restorations, a decline was observed for evaluated criteria in the performance of the restoration from category Alpha to Bravo. An exception occurred for one Esthet-X, two Filtek Z350, and two Filtek Z250 restorations, which received the clinically unacceptable score Charlie for both anatomic form and marginal adaptation. Secondary caries as well as postoperative sensitivity occurred in one Filtek Z250 and one Filtek Z350 restoration. When the five evaluation periods (baseline and six, 12, 30, and 54 months) were compared, there were significant differences in the marginal adaptation of Filtek Z250 and Filtek Z350 ($p<0.05$). Significant differences were also observed in the roughness of Filtek Z250, Filtek Z350, and Esthet-X ($p<0.05$).

There were significant differences in the roughness criteria ($p=0.005$) when the three composites were compared after 54 months. The roughness of Filtek Z350 was greater, followed by that of Filtek Z250 and that of Esthet-X, but all were always within clinically acceptable limits.

Table 1: *Sample Characteristics*

	n	%
Gender		
Male	27	65.9
Female	14	34.1
Dental element		
Maxillary molar	43	35
Mandibular molar	80	65
Dental condition		
Primary caries	93	75.6
Replacement of restoration	30	24.4
Cavity width		
Larger than 1/3	22	17.9
Less than 1/3	101	82.1
Cavity depth		
Shallow	17	13.8
Medium	76	61.8
Deep	30	24.4
Dentin consistency		
Soft	30	24.4
Leathery	93	75.6
Dentin color		
Yellow	43	35.0
Light brown	54	43.9
Brown	26	21.1
Pulp protection		
Adhesive system	93	75.6
Glass ionomer cement and adhesive system	30	24.4

DISCUSSION

In general, early failures, which are encountered after weeks or months, must be distinguished from late failures, which occur after several years of clinical service. Early failures are a result of treatment faults, selection of an incorrect indication for the restorative material, or postoperative symptoms of pain and discomfort. Late failures are predominantly caused by fractures, secondary caries, and wear or deterioration of the materials.[3] After 12 months, all groups presented failures (Charlie rating) for anatomic form and marginal adaptation. At 54 months, the number increased by one for Filtek Z250 and Filtek Z350 restorations. Esthet-X maintained the same number of restoration failures. Secondary caries was first observed at the 36-month evaluation for Filtek Z350. After 54 months, a Filtek Z250 restoration also presented secondary caries.

The loss of marginal adaptation due to fracture and loss of retention and the presence of secondary caries are the main cause of failures of posterior resin-based composites, resulting in restoration replacement. According to Mjör,[16] development of secondary caries is not only due to the material itself. The clinical environment, the patients' history

Table 2: *Modified USPHS Evaluation Criteria*

Criterion	Code	Definition
Anatomic form	Alpha	Restoration continuous with existent anatomic form
	Bravo	Restoration discontinuous with existent anatomic form, but loss of material is not sufficient to expose the dentin base
	Charlie	Loss of material sufficient to expose the dentin or base
Marginal adaptation	Alpha	Restoration completely adapted to the tooth; no visible gap; no explorer catch at the margins or in any direction
	Bravo	Explorer catch; there is no visible evidence of a gap into which the explorer could penetrate
	Charlie	Explorer penetrates into a deep gap that exposes dentin or base
Marginal discoloration	Alpha	No discoloration along the cavo-superficial margin
	Bravo	<50% of the cavo-superficial margin affected by stain
	Charlie	>50% of the cavo-superficial margin affected by stain
Color match	Alpha	Restoration with color and translucency similar to those of the adjacent dental structure
	Bravo	Change in color and translucency within an acceptable standard
	Charlie	Change in color outside the acceptable standard
Surface roughness	Alpha	Restoration surface is smooth
	Bravo	Restoration surface is slightly rough or has scratches but can be refinished
	Charlie	Surface deeply rough, with irregular scratches; cannot be refinished
Secondary caries	Alpha	Absent
	Charlie	Present
Postoperative sensitivity	Alpha	Absent
	Charlie	Present

Table 3: *Results of the Clinical Evaluation of the Restorations*

Evaluation Criteria	Score	Baseline, n (%)			12 mo, n (%)			30 mo, n (%)			54 mo, n (%)		
		Z250 (n=41)	Z350 (n=41)	Esthet-X (n=41)	Z250 (n=41)	Z350 (n=41)	Esthet-X (n=41)	Z250 (n=37)	Z350 (n=37)	Esthet-X (n=37)	Z250 (n=31)	Z350 (n=31)	Esthet-X (n=31)
Anatomic form	A	41 (100)	41 (100)	41 (100)	40 (97.6)	40 (97.6)	40 (97.6)	35 (94.6)	35 (94.6)	35 (94.6)	29 (93.5)	29 (93.5)	29 (93.5)
	B	—	—	—	—	—	—	1 (2.7)	1 (2.7)	1 (2.7)	—	—	1 (3.2)
	C	—	—	—	1 (2.4)	1 (2.4)	1 (2.4)	1 (2.7)	1 (2.7)	1 (2.7)	2 (6.5)	2 (6.5)	1 (3.2)
Marginal adaptation	A	41 (100)	41 (100)	41 (100)	31 (75.6)	32 (78)	35 (85.4)	32 (86.5)	29 (78.4)	30 (81.1)	28 (90.3)	26 (83.9)	26 (83.9)
	B	—	—	—	9 (22)	8 (19.5)	5 (12.2)	4 (10.8)	7 (18.9)	6 (16.2)	1 (3.2)	3 (9.7)	4 (12.9)
	C	—	—	—	1 (2.4)	1 (2.4)	1 (2.4)	1 (2.7)	1 (2.7)	1 (2.7)	2 (6.5)	2 (6.5)	1 (3.2)
Marginal discoloration	A	41 (100)	41 (100)	41 (100)	41 (100)	41 (100)	41 (100)	37 (100)	36 (97.3)	36 (97.3)	30 (96.8)	31 (100)	31 (100)
	B	—	—	—	—	—	—	—	1 (2.7)	1 (2.7)	1 (3.2)	—	—
	C	—	—	—	—	—	—	—	—	—	—	—	—
Color match	A	39 (95.1)	38 (92.7)	39 (95.1)	37 (90.2)	33 (80.5)	35 (85.4)	32 (86.5)	32 (86.5)	32 (86.5)	27 (87.1)	29 (93.5)	26 (83.9)
	B	2 (4.9)	3 (7.3)	2 (4.9)	4 (9.8)	8 (19.5)	6 (14.6)	5 (13.5)	5 (13.5)	5 (13.5)	4 (12.9)	2 (6.5)	5 (16.1)
	C	—	—	—	—	—	—	—	—	—	—	—	—
Surface roughness	A	41 (100)	41 (100)	41 (100)	32 (78)	25 (61)	37 (90.2)	28 (75.7)	22 (59.5)	34 (91.9)	15 (48.4)	12 (38.7)	24 (77.4)
	B	—	—	—	9 (22)	16 (39)	4 (9.8)	9 (24.3)	15 (40.5)	3 (8.1)	16 (51.6)	19 (61.3)	7 (22.6)
	C	—	—	—	—	—	—	—	—	—	—	—	—
Secondary caries	A	41 (100)	41 (100)	41 (100)	41 (100)	41 (100)	41 (100)	37 (100)	36 (97.3)	37 (100)	30 (96.8)	30 (96.8)	31 (100)
	C	—	—	—	—	—	—	—	1 (2.7)	—	1 (3.2)	1 (3.2)	—
Postoperative sensitivity	A	41 (100)	41 (100)	41 (100)	41 (100)	41 (100)	41 (100)	37 (100)	37 (100)	37 (100)	30 (96.8)	30 (96.8)	31 (100)
	C	—	—	—	—	—	—	—	—	—	1 (3.2)	1 (3.2)	—

of previous caries, the criteria for replacements, and different handling characteristics also seemed to affect the clinical results. In addition, Bernardo and others[17] reported that the overall risk of failure due to secondary caries was 3.5 times higher in composite restorations than in amalgam restorations.

In the study of Stefanski and van Dijken,[10] no secondary caries was observed contiguous to the evaluated Class II nanofilled restorations, despite the frequency of high caries risk in the participants, which may indicate a good marginal seal. On the other hand, a two-year evaluation is far too short to observe the formation of secondary caries. This develops mainly after four to six years of intraoral aging, as shown in longer follow-ups.[18]

Marginal discoloration usually results from defects present between the composite restoration and the cavity margins. These defects may be caused by inadequate restoration placement and finishing procedures, by unsatisfactory bonding, and by subsequent stress fatigue.[19,20] The use of the incremental technique with a maximum of 2 mm in each layer likely contributed to a lower incidence of marginal discoloration.

Polymerization shrinkage can generate high stresses at bonded surfaces in confined cavity preparations.[21] The configuration factor of the restoration, the ratio of bonded to nonbonded surfaces in the cavity, has been reported to play an important role during the development of contraction stress. Despite the high C-factor of the cavities, a high durability for the evaluated Class I restorations was observed. Van Dijken[22] observed clinical results with excellent durability after a 12-year evaluation period of incrementally filled cavities. The influence of polymerization shrinkage stress on the longevity of the Class I resin composite restoration was far less than expected and indicated the role of other factors.

Sadeghi and others[21] evaluated bulk filled restorations in small cavities with a high C-factor for 18 months. Despite their good clinical results, the authors highlight that caution should be exercised when restoring such situations and that the use of incremental placement techniques is encouraged where reasonably possible.

The durability of a restoration is multifactorial, and other factors, such as the handling of the material by the operator, the bonding capacity of the restorative system, the application and curing technique used, and several patient-dependant factors during aging (like temperature and pH cycles in the mouth, degree of occlusal loading, and hydrolytic degeneration of the material), may all play a role.[22]

The surface roughness of the resin composites changed over the course of 54 months. However, these changes occurred from the Alpha to Bravo ratings, maintaining restorations as clinically acceptable. This difference was found when comparing the three composites (Filtek Z350 > Filtek Z250 > Esthet-X) and for the same composite over the course of time. Our results are supported by the laboratory investigations of Mayworm and others,[23] who reported that Filtek Supreme has larger particles and/or particle agglomerates and larger interparticle spacing. Moreover, wear tests caused larger and deeper voids on the surface of Filtek Supreme than on the surface of Esthet-X, caused by the removal of particles and possibly of particle agglomerates. However, other clinical trials[24,25] have shown significantly better or equal polishability for Filtek Supreme compared with microhybrid restorations. This divergence of results is not worrisome, because all restorations were classified as clinically acceptable in terms of roughness.

Despite the proposed advantages for nanofilled and nanohybrid composites, their clinical performance was not superior to that of the control group, which was restored with Filtek Z250, a microhybrid composite that has been on the dental market for a longer period of time. The study of Palaniappan and others[26] does not appraise the claimed advantages of nanometer-size particles on the clinical wear performance of resin composites because of the lack of any significant differences between the nanocomposites and microhybrid restoration groups. Similar to this observation, nanocomposites were reported to perform no better than the conventional microfills and microhybrids in recent *in vitro* wear studies.[27] Others studies[9,24] are in agreement with our results. There is a need to evaluate restorations over a longer timescale to determine the long-term clinical performance of these resin composite materials.

CONCLUSIONS

The materials investigated showed acceptable clinical performance in Class I restorations after 54 months. Continuous reevaluations are necessary for a more detailed long-term analysis of these composites. Furthermore, other long-term clinical trials are necessary to confirm our results.

Acknowledgments

The authors thank 3M ESPE and Dentsply/Caulk for the kind donation of materials for this investigation. The authors received no financial support and declare no potential conflicts

of interest with respect to the authorship and/or publication of this article.

Conflict of Interest

The authors of this manuscript certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

(Accepted 31 March 2014)

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