Brazilian Dental Science
Ciência Odontológica Brasileira
unesp
UNIVERSIDADE ESTADUAL PAULISTA "JÚLIO DE MESQUITA FILHO"
Instituto de Ciência e Tecnologia
Campus de São José dos Campos



ORIGINAL ARTICLE

doi: 10.14295/bds.2018.v21i3.1593

# Clinical performance of class I occlusal composite resin restorations: a multicenter double-blinded randomized clinical trial

Performance clínica de restaurações oclusais classe I em resina composta: ensaio clínico randomizado duplo-cego e multicêntrico

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## ABSTRACT

**Objective:** To evaluate the 6-month clinical performance of class I occlusal composite resin restorations through a multicenter, randomized, double-blind, clinical trial. **Material and Methods:** Two hundred and eighty class I occlusal restorations were performed in 70 patients (aged between 17 to 50 years). The restorations were divided into four groups: G1 (Filtek P60/3M ESPE); G2 (Rok/SDI); G3 (Filtek™ P90/3M ESPE); G4 (Evolux/Dentsply). Two pre-calibrated dental practitioners performed and evaluated the restorative procedures regarding to color match, marginal discoloration, recurrent caries, wear (anatomic form) and marginal integrity according to the USPHS criteria. **Results:** In 85.8% of the evaluated restorations was observed the ideal score (A) for color match; 91.4% for marginal discoloration; 100% for recurrent caries; 87.7% for wear (anatomic form) and 99.3% for marginal integrity. **Conclusion:** The composite resins used in this study presented satisfactory and similar clinical performance in a 6-month clinical evaluation.

## KEYWORDS

Dentistry; Composite resins; Permanent dental restoration; Molar; Bicuspid.

## RESUMO

**Objetivos:** Avaliar através de um ensaio clínico randomizado duplo-cego e multicêntrico o desempenho clínico de restaurações classe I oclusais realizadas em dentes posteriores. **Material e Métodos:** Foram realizadas duzentas e oitenta restaurações em 70 pacientes dos gêneros masculino e feminino (entre 17 e 50 anos). As restaurações foram divididas em 4 grupos: G1 (Filtek P60/3M ESPE); G2 ( Rok/SDI); G3 Filtek TM P90/3M ESPE); G4 (Evolux/Dentsply). Dois operadores précalibrados avaliaram os procedimentos restauradores em relação a reprodução da cor, descoloração marginal, incidência de cárie, desgaste e integridade marginal de acordo com os critérios da USPHS. **Resultados**: De um total de restaurações avaliadas, 85,8% receberam score ideal (A) para reprodução da cor; 91,4% para descoloração marginal; 100% para incidência de cárie; 87,7% para contorno e 99,3% para integridade marginal. **Conclusão**: Os materiais empregados neste estudo apresentaram desempenho clínico satisfatório e semelhante após avaliação clínica de 06 meses.

## PALAVRAS-CHAVE

Odontologia; Restauração dentária permanente; Resinas compostas; Dente molar; Dente pré-molar.

## INTRODUCTION

The constant improvement of the characteristics, restorative techniques, and aesthetic appeal are responsible for the increased popularization of composite resins among dentists and patients. In order to achieve success with composite resin restorations, knowledge of the adhesive restorative materials and the use of suitable techniques are necessary, otherwise, failures may occur [1,2].

The major causes of failure in composite resin restorations are attributed to the properties of the material itself, such as low wear resistance, high polymerization shrinkage, marginal infiltration and difficulty in obtaining a tight proximal contact, or to the operator (due to the sensitivity of the technique). Wear and marginal infiltration associated with recurrent caries are among the main causes for replacement of restorations [3-5].

Since that the earliest scientific investigations identified the deleterious effects of the polymerization shrinkage of the composite resins in restored cavities, much effort was made to develop composite resins with lower polymerization shrinkage. The magnitude of the shrinkage depends on the resin matrix composition, the viscoelasticity of the composite and the insertion technique [6,7].

The condensable composite resins were marketed as a possible alternative to amalgam in posterior tooth restorations. They are characterized by high filler content, lower polymerization shrinkage and ease of handling [3].

Hybrid composite resins indicated for posterior teeth have adequate compressive and wear resistance. The association of the microparticle resins (indicated for anterior teeth) and the increase of the filler content to the hybrid resin promoted the development of micro-hybrid resins. The better aesthetics, the smoother surface obtained after polishing and higher wear resistance (<10M/year), led to the recommendation of these composites for anterior and posterior teeth [2,8].

However, restorative composite systems created with the use of nanotechnology are capable of offering high translucency and polishing similar to microparticulate composites, maintaining the physical and wear properties equivalent to several hybrid composites. They combine the aesthetic properties required for anterior restorations and the mechanical properties required for restorations on posterior teeth [8,9].

The polymerization shrinkage observed in the composite resins, that presents methacrylates in the matrix in which the resin molecules move towards one another generating the polymer network and resulting in a significant volume contraction (1.5-5%), is a challenge for direct restorations. Moreover, the limitations of these materials are still questioned, especially the tensions generated during this polymerization, which can lead to cusp deflection and increase the risk of enamel fractures and postoperative sensitivity, microleakage, marginal discoloration and cracking formation [6,10,11].

Different from the polymerization shrinkage of the linear reactive groups of the methacrylates, the development of a silorane-based composite resin (Filtek P90, 3M ESPE), in which the ring-opening compensates the volume loss that occurs during the bonds generating a contraction of about 0.7%, is promising for increasing the longevity of direct restorations [6,11]. The silorane is derived from the combination of the basic components of the epoxy siloxanes and oxiranes groups, the siloxanes being known for their hydrophobicity, while oxiranes are known for their low contraction and stability [12].

The objective of the present study was to evaluate and to compare the clinical performance of class I occlusal restorations of premolars and molars performed with four different composite resins: one hybrid (Rok/SDI), one nanohybrid (Evolux/Dentsply) and two micro-hybrids (Filtek P60/3M ESPE and Filtek TM P90/3M ESPE), being the Filtek TM P90 of low shrinkage according to the manufacturer.

## MATERIAL & METHODS

This multicenter, double-blinded and randomized clinical trial was approved by the Research Ethics Committee of CISAM (approval number: 002/10) and registered in the Brazilian Registry of Clinical Trials (Registration No: RBR-6fsy6z). The clinical study was developed following the CONSORT recommendations.

Two hundred and eighty occlusal cavity restorations were performed in 70 male and

female patients, over 17 years of age, selected from the Dental Clinics of the Federal University of Pernambuco - UFPE and the Centro Integrado de Saúde Amaury de Medeiros (CISAM) (n = 80); Federal University of Piauí - UFPI (n = 100) and Centro Universitário UNINOVAFAPI (n = 100). Sample size was calculated according to previous studies [13,14,15], and the centers were chosen by convenience and interest in carrying out the study.

Inclusion criteria were: patients over 17 years of age; in need restorative treatment on the occlusal surfaces of at least four posterior teeth and the antagonistic teeth should be healthy or satisfactorily restored. Patients with dental elements antagonistic to non-healthy restorations, missing or not satisfactorily restored, restored with ceramic material and with removable denture were excluded. Periapical and interproximal radiographs were taken with the purpose of assisting the diagnosis of cavity depth.

The teeth indicated for treatment were preferable of the same group (pre-molars or molars), and may or may not be in the same dental arch, and the restorations with the materials to be studied were randomly distributed among the elements. All teeth possessed the same chance of being restored with any of the groups to be studied. Patients and examiners were unaware of this allocation to guarantee a double-blind study.

Before the restoration procedures, patients underwent a counseling session regarding diet, oral hygiene and treatment motivation. The patients read and agreed to a consent form, which described the risks and benefits associated with the treatment. No patient was aware of the materials that would be inserted in each restoration (blinding).

### Clinical Procedures

All clinical procedures were performed by a single operator at each center. They were previously calibrated and were knowledgeable about the materials used in the restorations, as they should follow all manufacturers' recommendations. The color selection was performed under natural light and rubber dam isolation was used for all restorative procedures.

The cavity preparations were performed with #1014, #1015 and #1046 carbide burs (KGSorensen, Cotia, São Paulo, Brazil) in high speed and #1, #2 and #3 in low speed. To obtain conservative cavities, being limited to the removal of carious tissue (the procedure was guided with the use of a 0.5% basic fuchsin) or pre-existing defective restoration.

The pulp capping procedures followed the guidelines of the Brazilian Group of Operative Dentistry Professors (Table 1), depending on the cavity depth.

**Table 1 -** Pulp capping procedures according to cavity depth

| Cavity Classification | Cavity Depth | Pulpal Protection |
|---|---|---|
| Shallow | 0.5 - 1.0 mm of the amelodentinal junction | Adhesive system for dentin (Hybrid layer) |
| Medium | » 1.0 mm of the remaining dentin between the cavity floor and the pulp | Adhesive system for dentin (Hybrid layer) |
| Deep | Up to 0.5 mm of the remaining dentin between the cavity floor and the pulp | Glass Ionomer Cement (GIC) + Adhesive System |
| Very deep | ≤ 0.5mm the remaining dentin between the cavity floor and the pulp | Ca(OH)2 Cement + GIC + Adhesive System |
| Pulp exposition | _____ | CA(OH)2 Solution + Ca(OH)2 Powder + Ca(OH)2 Cement + GIC + Adhesive System |

After cavity preparation and rubber dam isolation of the operative field, prophylaxis with pumice (SSWhite, Juiz de Fora, Minas Gerais, Brazil) and water with the aid of a Robinson brush (KGSorensen, Cotia, São Paulo, Brazil) was performed. After washing and drying, the cavity was etched with 37% phosphoric acid gel (30 seconds in enamel and 15 in dentin). The restorative procedure followed the recommendations of the manufacturers regarding the use of the adhesive system and the composite resin (Table 2). Table 3 shows the composition of the restorative materials and table 4, the information about the adhesive systems employed in this study.

**Table 2 -** Distribution of the restorative materials

| Group | Composite Resin | Ahesive System |
|---|---|---|
| G1 | Filtek P60 | 3M ESPE Self-etch adhesive |
| G2 | Rok | GO! Self-etch adhesive |
| G3 | Filtek P90 | 3M ESPE Silorane-Based |
| G4 | Evolux | Primer & Bond 2.1 Self-etch adhesive |

**Table 3 -** Composition of the restorative materials

| Group | Particle type and size | % volume / weight | Organic Matrix | Classification |
|---|---|---|---|---|
| G1 | 0.6 μm Zircony and Silica | 83.0% in weight 61% in volume | Bis-GMA. UDMA. Bis-EMA | Micro-hybrid |
| G2 | 40nm-2.5 μm Quartz | 82.3% in weight 67.7% in volume | Bis-GMA. UDMA. Bis-EMA | Hybrid |
| G3 | 0.4 μm quartz and yttrium fluoride | 76.0% in weight 55.0% in volume | Silorane | Micro-hybrid |
| G4 | 0.02 - 3.0 μm (Mean =0.8) Sílica. BABG. BAFG | 58% in weight 77% in volume | Bis-EMA. TEGDMA | Nano-hybrid |

**Table 4 -** Composition of adhesive systems

| Group | Organic matrx | Filler Particles | Solvent |
|---|---|---|---|
| G1 | UDMA, TEGDMA and TMPTMA | - | Water |
| G2 | Monomethacrylate, Dimethacrylate | Silicon dioxide | Water and acetone |
| G3 | - | Silica particles | Water and alcohol |
| G4 | - | - | Acetone |

After the restorations were completed, occlusal analysis and adjustment, with the aid of a carbon paper (Angelus, Londrina, Paraná, Brazil), were performed. Interferences were removed with #2200 and #2112 diamond burs (KGSorensen, Cotia, São Paulo, Brazil). The finishing and polishing of the restorations were carried out after 24 hours with the same diamond burs and Enhance finishing points (Dentsply, Pensilvânia, EUA) with polishing pastes (Diamond – FGM, Joinville, Santa Catarina, Brazil). No surface sealant was applied.

## Evaluation

The restorations were evaluated through direct methods immediately after the finishing and polishing procedures (baseline) and in six months period. The direct clinical evaluation is characterized by collecting information inherent to the restorations directly in the oral cavity of the patient and subsequent registration in specific forms. The USPHS (United States Public Health Service) evaluation method [16] was used under natural light and with the aid of a dental mirror and explorer to analyze the other parameters.

The clinical performance of restorative materials was evaluated according to the following parameters: color match, margin discoloration, recurrent caries, wear (anatomic form) and marginal integrity. Satisfactory restorations receive A (ideal) and B (acceptable) scores. Scores C and D are attributed to unsatisfactory restorations (Table 5).

A blinded clinical evaluation was performed independently by two pre-calibrated evaluators from each center. The evaluators were not involved in the restorative procedures. In case of disagreement, a final decision was made through immediate reexamination and discussion. The data were submitted to descriptive and inferential statistical analysis (Fisher's exact test) with a level of significance of 95%.

**Table 5 -** Clinical evaluation through the USPHS method

| PARAMETERS | SCORES |
|---|---|
| Color match | Alpha (A) - Matches tooth |
| | Bravo (B) - Acceptable mismatch. |
| | Charlie (C) - Unacceptable mismatch. |
| | Delta (D) – could not be scored without the aid of the dental mirror. |
| Marginal Discoloration | Alpha (A) – No discoloration. |
| | Bravo (B) – Superficial staining (without axial penetration). |
| | Charlie (C) – Deep staining (with axial penetration). |
| Recurrent Caries | Alpha (A) – No caries present. |
| | Charlie (C) – Caries present |
| Wear (Anatomic form) | Alpha (A) – Continuous |
| | Bravo (B) – Visible crevice, explore will penetrate |
| | Charlie (C) – Crevice in which dentin is exposed |
| Marginal Integrity | Alpha (A) – Closely adapted, no visible crevice. |
| | Bravo (B) – Discontinuous, no dentin exposed |
| | Charlie (C) – Discontinuous, dentin exposed |

Score: Alpha – ideal clinical situation; Bravo – clinically acceptable; Charlie - clinically unacceptable situation

## RESULTS

Out of the 280 restorations, a total of 268 (95.7%) was evaluated after the end of the study period. Three patients did not attend the reevaluation. Tables 6 and 7 show the results of the baseline evaluation and after six months, respectively, in which color match, marginal discoloration, recurrent caries, wear (anatomic form) and marginal integrity did not present a significant statistical difference.

Two restorations (0.7% of the total) received a D score for color match at the end of six months: one of the G1 (Filtek P60/3MESPE) and one of the G3 group (Filtek P90/3MESPE). Also, it was observed that six restorations of group G1 changed from Score A to B in the same criterion in the period of the final evaluation. Eighteen restorations changed from Score A to B in the final evaluation considering the marginal discoloration.

The wear (anatomic form) showed that 27 restorations before categorized with Score A, went to Score B, totaling 33 restorations (12.3% of the total) with Score B in this evaluation.

**Table 6 -** Baseline evaluation

| Group | Group | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | P60 | | ROK | | P90 | | Evolux | | Total Group | | p-value |
| | N | % | N | % | N | % | N | % | N | % | |
| **TOTAL** | **67** | **100.0** | **67** | **100.0** | **67** | **100.0** | **67** | **100.0** | **268** | **100.0** | |
| **Color match** | | | | | | | | | | | |
| A | 60 | 89.6 | 62 | 92.5 | 60 | 89.6 | 64 | 95.5 | 246 | 91.8 | p= 0.3778* |
| B | 6 | 9.0 | 5 | 7.5 | 7 | 10.4 | 2 | 3.0 | 20 | 7.5 | |
| C | - | - | - | - | - | - | 1 | 1.5 | 1 | 0.4 | |
| D | 1 | 1.5 | - | - | - | - | - | - | 1 | 0.4 | |
| **Marginal discoloration** | | | | | | | | | | | |
| A | 65 | 97.0 | 66 | 98.5 | 15 | 88.2 | 66 | 98.5 | 262 | 97.8 | p = 1.000* |
| B | 2 | 3.0 | 1 | 1.5 | 2 | 11.8 | 1 | 23.5 | 6 | 2.2 | |
| C | - | - | | - | - | - | - | - | - | - | |
| **Recurrent caries** | | | | | | | | | | | |
| A | 67 | 100.0 | 67 | 100.0 | 67 | 100.0 | 67 | 100.0 | 67 | 100.0 | ** |
| C | - | - | - | - | - | - | - | - | - | - | |
| **Wear (anatomic form)** | | | | | | | | | | | |
| A | 67 | 100.0 | 66 | 98.5 | 65 | 97.0 | 64 | 95.5 | 262 | 97.8 | P = 0.522* |
| B | - | - | 1 | 1.5 | 2 | 3.0 | 3 | 4.5 | 6 | 2.2 | |
| C | - | - | - | - | - | - | - | - | - | - | |
| **Marginal integrity** | | | | | | | | | | | |
| A | 67 | 100.0 | 67 | 100.0 | 66 | 98.5 | 66 | 98.5 | 266 | 99.3 | p = 1.00* |
| B | - | - | - | - | 1 | 1.5 | 1 | 1.5 | 2 | 0.7 | |
| C | - | - | - | - | - | - | - | - | - | - | |

*Fisher's Exact Test, ** Can not be determined due to occurrence in only one category

**Table 7 -** Six-month evaluation

| Group | Group | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | P60 | | ROK | | P90 | | Evolux | | Total Group | | p-value |
| | N | % | N | % | N | % | N | % | N | % | |
| **TOTAL** | **67** | **100.0** | **67** | **100.0** | **67** | **100.0** | **67** | **100.0** | **268** | **100.0** | |
| **Color match** | | | | | | | | | | | |
| A | 53 | 79.1 | 60 | 89.6 | 56 | 83.6 | 61 | 92.5 | 230 | 85.8 | p= 0.357* |
| B | 12 | 17.9 | 7 | 10.4 | 10 | 14.9 | 5 | 6.0 | 34 | 12.7 | |
| C | 1 | 1.5 | - | - | - | - | 1 | 1.5 | 2 | 0.7 | |
| D | 1 | 1.5 | - | - | 1 | 1.5 | - | - | 2 | 0.7 | |
| **Marginal discoloration** | | | | | | | | | | | |
| A | 62 | 92.5 | 61 | 91.1 | 61 | 91.1 | 60 | 89.6 | 244 | 91.4 | p = 0.991* |
| B | 5 | 7.5 | 6 | 9.0 | 6 | 9.0 | 7 | 10.4 | 24 | 9.0 | |
| C | - | - | - | - | - | - | - | - | - | - | |
| **Recurrent caries** | | | | | | | | | | | |
| A | 67 | 100.0 | 67 | 100.0 | 67 | 100.0 | 67 | 100.0 | 67 | 100.0 | ** |
| C | - | - | - | - | - | - | - | - | - | - | |
| **Wear (anatomic form)** | | | | | | | | | | | |
| A | 62 | 92.5 | 57 | 85.1 | 56 | 83.6 | 60 | 89.6 | 235 | 87.7 | p = 0.338* |
| B | 5 | 7.5 | 10 | 14.9 | 11 | 16.4 | 7 | 10.4 | 33 | 12.3 | |
| C | - | - | - | - | - | - | - | - | - | - | |
| **Marginal integrity** | | | | | | | | | | | |
| A | 67 | 100. | 67 | 100. | 66 | 98.5 | 66 | 98.5 | 266 | 99.3 | p = 0.345* |
| B | - | - | - | - | 1 | 1.5 | 1 | 1.5 | 2 | 0.7 | |
| C | - | - | - | - | - | - | - | - | - | - | |

*Fisher's Exact Test, ** Can not be determined due to occurrence in only one category.

## DISCUSSION

The evaluation of the composite resins in relation to the USPHS criteria did not show significant statistical difference in the baseline evaluation and after six months. This fact is not surprising given that several studies evaluating composite resins for periods shorter than three years confirm the tendency of good behavior of these restorative materials in posterior teeth [3,7,8].

The performance of a restorative material depends not only on its physicochemical properties but also on a series of factors ranging from the restorative technique to characteristics inherent to the patient, such as diet, hygiene, pH of saliva and its buffer capacity, and occlusal factors [5].

We believe that some of the exclusion criteria of this study, which considered the presence of defective or unsatisfactory restorations in the opposing teeth, ceramics and presence of prosthetic appliances, associated with dietary advice and motivation, besides the respect to a meticulous restorative technique

with the use of rubber dam, incremental insertion, finishing and polishing carried out in a later session and calibration of the operators, have contributed to the positive results obtained in the observed period.

Regarding the color match, it was observed in the baseline evaluation that one restoration presented C score, one D score, 20 restorations (7.5% of the total) presented B score and that this amount was superior (N = 34; 12.7% of the total) during the 6-month evaluation.

Although not statistically significant, the results of the baseline evaluation were probably influenced by the limited number of available colors of some of the material, which makes it difficult to correctly adjust the aesthetic restorative material to the dental element. This difficulty has already been mentioned in the literature [17]. Impregnation of metallic ions in the enamel from pre-existing amalgam restorations may also have influenced the observed results.

Considering that 14 restorations changed from score A to B in the final evaluation period and that of these, six restorations were P60 composite resin (condensable), we believe that the physicochemical characteristics of the material may have justified this higher incidence, since other studies that evaluated the clinical performance of composite resins that are compatible with micro-hybrid resins and nanotechnology, have shown that resins with larger particle size would be subject to a more limited performance in relation to texture and polishing quality [8,17,18].

This fact is directly related to the discoloration of the composite resins overtime since one of the probable causes of the discoloration of these materials is the rough surface and the increased porosity that is associated with poor oral health and food dyes, which allow the adsorption and absorption of dyes by the material [19].

The cavosurface marginal discoloration observed in 18 restorations, that presented a score A in the baseline assessment and decreased to Score B in the final evaluation, may also be related to these factors, mainly the type of diet of the patients and hygiene, since as observed in tables 6 and 7, the decrease was distributed symmetrically among the evaluated materials and in 11 of the 18 patients, the presence of poor hygiene or diet was detected, according to the information collected.

The contour or loss of material observed in composite resin restorations on posterior teeth is a complex and multifactorial problem. Some factors may interfere directly or indirectly such as the chemical properties of the material itself, the occlusion, the size of the cavities, the characteristics related to the patient (diet, tooth brushing frequency, parafunctional habits), resin insertion technique, degree of conversion and technical skill of the operator [5].

In the present study, 27 previously categorized restorations with respect to the contour changed to Score B during the final evaluation. It is possible to infer that the chemical characteristics of the material may have influenced the observed result given that: all restorations were performed according to the manufacturers' recommendations; adequate LED equipment (Radii/SDI) was used; and these factors contribute to a lower incidence of bubbles and better monomer conversion rates. It was also observed that the restorations that presented the highest wear rate, although not statistically significant, were the resins of the G2 (Hybrid) and G3 (Micro Hybrid) groups and those with the least wear were the G4 (nano -hybrid).

Although hybrid and micro-hybrid composite resins are indicated for posterior teeth due its adequate mechanical properties [2], the smaller particle composites present less general wear due to the reduction of the friction between the masticatory surfaces. The nanotechnology resin using nanometric particles and nanoglomerates with high filler content showed lower incidence of wear in areas of high masticatory stress when compared to the resins of the other groups.

It is known that the type of teeth influences significantly the analysis of the data of a clinical research. Studies have shown that wear is less when restorations with composite resin are placed in premolars, and higher following distally to molars [20]. In the present study, of

the 27 restorations that changed the B score in the final wear assessment, 21 were molar teeth. This data may also have contributed to the observed result.

Despite all the observations, in general, the results showed a stable and acceptable performance of the composite resins. It makes evident the indication of composite resins in posterior teeth, when aesthetics, preservation of tooth structure and marginal sealing are prioritized, especially when we compare these materials with metal restorative materials.

However, we corroborate another study [4], who evaluated the clinical performance of composites for 17 years and emphasizes that long-term studies be necessary to identify the types and reasons for failures, as well as the expected life of the materials. The 6-month assessment does not allow potential differences in longevity to be observed since the mean failure rate of these restorations is around 2% per year [21].

## CONCLUSION

The materials used in this study presented satisfactory and similar clinical performance after six months clinical evaluation. None of the evaluated composite resins showed superior or statistically significant results.

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Date submitted: 2018 May 03

Accept submission: 2018 Jun 12