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ORIGINAL ARTICLE

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Nine-year clinical evaluation of composite resins in Class III restorations

Avaliação de nove anos de restaurações de classe III em resina composta

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ABSTRACT

Objective: The aim of this study was to evaluate the nine-year clinical performance of Class III composite restorations using two microhybrid anterior composite resins [Magic™-Vigodent/(F) and Z100™-3M ESPE/(Z)]. **Material and Methods:** The study was a randomized controlled trial, following the split mouth design. Seventy restorations were placed, thirty-five for each resin composite into 35 patients. The restorations were placed by one operator according to the manufacturers' specifications. Two independent evaluators conducted the clinical evaluation using modified USPHS criteria. After nine-years, 56 restorations (28F-28Z) were evaluated. Data were analyzed using Chi-square, Exact Fisher and McNemar tests ($p < 0.05$). **Results:** No postoperative sensitivity, secondary caries and loss of anatomic form was observed after nine-years for both composites. There were no significant differences between the two composites tested at baseline and after nine-years. Significant differences for Z and F restorations between baseline and nine-year with respect to color matching and for F regarding the marginal integrity were detected. **Conclusion:** The clinical performance of both materials was considered acceptable after the 9-year evaluation.

KEYWORDS

Clinical trial; Composite resins; Anterior teeth; Esthetics; Direct restoration.

RESUMO

Objetivo: O objetivo deste estudo foi avaliar após nove anos a performance clínica de restaurações de classe III em resina composta, utilizando-se duas resinas microhíbridas para dentes anteriores [Magic-Vigodent/(F) e Z100-3M ESPE/(Z)]. **Material e Métodos**: Trata-se de um estudo clínico controlado aleatório, o qual utilizou o desenho de boca dividida. Setenta restaurações foram realizadas em trinta e cinco pacientes, sendo trinta e cinco para cada resina composta. As restaurações foram realizadas por um único operador seguindo as especificações dos fabricantes. Dois avaliadores independentes avaliaram as restaurações utilizando-se o critério USPHS modificado. Após nove anos, 56 restaurações (38F – 28Z) foram avaliadas. Os dados foram analisados por meio dos testes Qui-quadrado, Exato de Fisher e McNemar ($p < 0,05$). **Resultados:** Não foram detectados sensibilidade pós-operatória, cárie secundária e perda de forma anatômica no período analisado para ambas resinas. Não houve diferenças entre o período inicial e de nove anos para as resinas testadas, exceto para Z e F foram em relação à a cor e para a integridade do material para F. **Conclusão:** O comportamento clínico das duas resinas testadas foi considerado adequado após nove anos de avaliação.

PALAVRAS-CHAVE

Pesquisa clínica; Resinas compostas; Dentes anteriores; Estética; Restauração direta.

INTRODUCTION

Esthetic restorative materials have to simulate the natural tooth in color, texture, and translucency and should have adequate strength, wear, and sealing characteristics [1-5]. In anterior teeth, although light-cured resin composites have been extensively used in Class III cavities, most of trials assessed clinical performance for 3 years or shorter periods [6-8] and only few studies reported observation up to 5 years and longer [4,9,10].

In addition, there are controversial findings about the performance of composites in restorations of anterior teeth [11]. Factors related to patient, operator, tooth, cavity size, and materials have been reported in the literature as potentially relevant for restoration failures [2,4,12,13], although their evidence is still limited. This is mainly attributed to the different experimental designs of clinical studies [14].

Considering this reality, randomized controlled trials provide a high level of evidence for hypothesis testing [14]. Therefore, the basis of knowledge regarding restoration survival takes into account the analysis of studies of different designs, such as cross-sectional or longitudinal studies, or clinically controlled experiments. Cross-sectional studies are most frequently found in the literature because they are relatively simple to carry out and provide fast results. Long-term studies and investigations under controlled standardized conditions (ie, split-mouth technique) are considerably more reliable. [15].

The purpose of this prospective clinical trial was to evaluate after nine-year the clinical performance of two microhybrid composite resins. The null hypotheses established are: 1) there is no difference between these two materials after nine years of evaluation; 2) there is no difference between baseline and the nine-year evaluation for each material.

MATERIAL AND METHODS

Study Design

This study was approved by the Local Ethics Committee of Bauru School of Dentistry, University of Sao Paulo, SP, Brazil, according to the guidelines of the Declaration of Helsinki (Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects). Patients were informed of the study and were free to decide whether they would participate or not. Before entering the trial, each patient gave written informed consent.

The inclusion criteria were presence of two Class III carious lesions or unsatisfactory restorations; teeth with pulp vitality; a good general state of health; age between 18 and 60 years; absence of periodontal disease; appropriate oral hygiene; nonsmoker; and absence of parafunctional habits. All patients received oral hygiene instructions before operative treatment was performed.

Randomization

The study was a clinical randomized controlled trial with split-mouth design, where the two composite resins were compared in each individual, one immediately after the other, in 35 pairs of permanent teeth. The composite resin Fill Magic™ (Vigodent, Rio de Janeiro, Brazil) was used as a test group and the Z100™ (3M ESPE, St. Paul, USA) as the control group (Table I). An independent supervisor was responsible for the randomization procedures and the overall logistics of the clinical procedures. After pre-treatment information was retrieved and the patients were found to fulfill the eligibility criteria, including agreement to participate, the composite resins for each tooth were randomized using the following procedure: 1) Sequence of the methods: randomization was carried out by the sealed envelope technique. Each envelope contained a paper slip allocating the sequence of the methods to be tested. For example: 35 envelopes contained the sequence: first Fill Magic™ and second Z100™, while

other 35 envelopes indicated the sequence: first Z100™ and second Fill Magic™. 2) Sequence of the cavity preparations: the supervisor randomly assigned the first tooth to either Fill Magic™ or Z100™ using the flip of a coin.

Clinical Procedure

Operative procedures were performed by one instructed and experienced dentist and one chair-side assistant using the following protocol:

Color selection

The dental surfaces were carefully polished with water/pumice slurry (SS White, Rio de Janeiro, Brazil) to remove the biofilm and stains. The shade was selected under natural illumination.

Cavity preparations

Cavity preparations were performed under local anesthesia and rubber dam isolation. They were limited to the removal of previous restorations or carious tissue using stainless steel burs (#1011, 1012 and/or 1013; KG Sorensen, São Paulo, Brazil) at low-speed. No retention grooves were placed, but all buccal enamel cavosurface margins were beveled using diamond point (#3118; KG Sorensen, São Paulo, Brazil).

Restorations

Deep cavities were lined with calcium hydroxide (Hydro C; Dentsply, Rio de Janeiro, Brasil) and resin-modified glass-ionomer cement (Vitrebond; 3M ESPE, St Paul, USA). Shallow and medium cavities were not lined.

Enamel surfaces were etched with a 37% phosphoric acid gel (3M ESPE, St Paul, USA) for 30 s and dentin surfaces for 15 s, then they were thoroughly rinsed for 30 s. Water excess was removed with absorbing paper to keep the dentin surface moist.

Two different bonding protocols were performed according to the resin composite system used. In the test group, Magic Adhesive™ system (Vigodent, Rio de Janeiro, Brazil) was applied to enamel and dentin before placing Fill Magic™ composite resin. In the control group, Scotchbond Multi-Purpose Plus™ (3M ESPE, St Paul, USA) was applied before placing Z100™ composite resin. Both adhesive systems were slightly thinned with a mild oil-free air stream and light-cured for 20 s with a visible light curing unit with a 520 mW/cm2 out put (Optilux 150, Demetron Research Corp., CT, USA).

The composite resins were inserted into cavities with appropriate instruments according to an incremental placement technique and each increment was polymerized for 40 s with the same light curing unit.

Restorations were finished at the placement visit by removing the roughest excesses with a sharp scalpel blade (Becton Dickinson, São Paulo, Brazil).

In a subsequent appointment, after 1 week, wet polishing was carried out using 12-bladed finishing burs (Jet Burs, Sybron Beavers Dental, Morrisburg, Canada) and aluminum oxide disks (Sof-LexTM; 3M ESPE, St Paul, USA) of decreasing abrasive order.

Table 1 - Composition of the materials investigated in this study

Material	specifications	Filler	Manufacturer	Batch #	Shade
Fill Magic™	Microhybrid composite resin Light-curing	particles size: 0.5 µm Filler type: barium glass Vol % of mineral filler: 80%	Vigodent, Rio de Janeiro, RJ, Brazil	34/333	A2, A3
Z 100™		particles size: 3.5 µm Filler type: zirconium silicate Vol % of mineral filler: 66%	3M, St. Paul, MN, USA	9GM	A2, A3

Clinical evaluation and statistical analysis

Two independent and calibrated operators evaluated the restorations. Calibration procedures were carried out using picture slides representing each condition to be assessed in the study. A double-blind design was originally assigned. In cases where the two examiners disagreed on a rating, both re-examined the restoration and arrived at a final joint decision.

All restorations were evaluated at baseline and after 9 years according to modified USPHS criteria (Table II). Data were tabulated twice and statistical analysis was carried out using the Stata 11.0 software package (StataCorp LP; College Station, TX, USA). Cohen's kappa was used to test the inter-examiner agreement. Chi-square test was used for comparisons of frequency distributions. Intra-group comparisons between baseline and other evaluation periods within the same restorative materials were performed by McNemar test. Inter-group comparisons to identify differences between restorative materials at each period were conducted by Fisher exact test. A significance level of 5% was considered for all analyses.

RESULTS

Baseline

Out of 43 patients, 35 participants were selected (34 women and 1 men) with a mean age of 30.7 ± 8.9 years (range 19-53 years; median 29.5). Seventy restorations were placed, thirty-five for each resin composite.

The details of the sample are shown in Table III. There was a statistically significant difference between the test (Fill Magic™) and control (Z-100™) groups regarding the distribution of restorations (X^2 = 23.22; $p < 0.001$). No postoperative sensitivity was reported by the patients at baseline.

Table 2 - Modified USPHS criteria used to evaluate the restorations

Category	Rating and Characteristic
Secondary caries	Alfa (A): No evidence of caries at the margin. Charlie (C): Evidence of caries at the margin.
Postoperative sensitivity	Alfa (A): Not present. Bravo (B): Sensitive but diminishing in intensity. Charlie (C): Constant sensitivity, not diminishing in intensity.
Color matching	Alfa (A): Restoration matches adjacent tooth structure in color and translucency Bravo (B): Mismatch is within an acceptable range of tooth color and translucency Charlie (C): Mismatch is outside the acceptable range
Marginal discoloration	Alfa (A): No penetration of staining at the marginal interface. Bravo (B): Penetration along the margin, but not in a pulpal direction. Charlie (C): Penetration at the margin to the level of dentin or in a pulpal direction.
Anatomic Form	Alfa (A): The restoration is continuous with existing anatomic form. Bravo (B): The restoration is discontinuous with existing anatomic form, but the missing material is not sufficient to expose dentine or lining material. Charlie (C): Sufficient material lost to expose dentine or lining material.
Marginal integrity	Alfa (A): The explorer does not catch when drawn across the surface of the restoration toward the tooth, or, if the explorer does catch, there is no visible crevice along the periphery of the restoration Bravo (B): The explorer catches and there is visible evidence of a crevice, into which the explorer penetrates, indicating that the edge of the restoration does not adapt closely to the tooth structure Charlie (C): The explorer penetrates crevice defect extended to dentino–enamel junction

Table 3 - Description of the sample

Distribution of restoration location by tooth type	Composite resin	
	Fill Magic™ Number (%)	Z100™ Number (%)
mesial central incisor	8 (22.9)	9 (25.7)
distal central incisor	22 (62.9)	4 (11.4)
mesial lateral incisor	5 (14.2)	22 (62.9)
Chi-square test = 23.22, P < 0.001		

Follow-up

Recall rates registered were 100% (n = 70) for baseline and 80% (n = 56) after nine years. Seven patients did not return for their examinations, because they had left the city. Results of the duplicate examinations on restoration status showed very good inter-examiner reproducibility with kappa value of 0.85 and 0.92 in the evaluations after baseline and 9 years, respectively.

There were no significant differences between the two restorative materials tested in this study at baseline and after nine years (Table IV). Percentages indicate the total of restorations classified as clinically acceptable (Alfa and Bravo ratings) in each evaluation period (Table IV).

No postoperative sensitivity, secondary caries, and loss of anatomic form were observed after 9 years for Z100 and Fill Magic restorations.

McNemar test only detected significant differences for Z100 and Fill Magic restorations between baseline and 9-year follow-up with respect to color matching (X2 = 7.11, p = 0.007 and X^2 = 9.00, p = 0.029, respectively) and for Fill Magic regarding the marginal integrity (X^2 = 4.16, p = 0.041).

DISCUSSION

In this prospective clinical study, eighty per cent of the patients returned after nine years and 56 out of the 70 restorations were evaluated. This percentage is in accordance with other long-term clinical studies in which the restorations in anterior teeth were evaluated over periods of up to five years [1,4,10,]. Approximately 97% of the participants were women in the present study. This would suggest that women have a

Table 4 - Number of restorations evaluated in each score for each material, period and criterion. Percentages of clinically acceptable ratings (Alfa and Bravo)

Category	Material	Baseline N = 70				9 years N = 56			
		Scores				Scores			
		A	B	C	A+B%	A	B	C	A+B%
Secondary Caries	Fill Magic™	35	0	0	100%	28	0	0	100%
	Z-100™	35	0	0	100%	28	0	0	100%
Postoperative sensitivity	Fill Magic™	35	0	0	100%	28	0	0	100%
	Z-100™	35	0	0	100%	28	0	0	100%
Color Matching	Fill Magic™	35	0	0	100%	19	9	0	100%
	Z-100™	35	0	0	100%	18	9	1	100%
Marginal Discoloration	Fill Magic™	35	0	0	100%	26	2	0	100%
	Z-100™	35	0	0	100%	24	4	0	100%
Anatomic Form	Fill Magic™	35	0	0	100%	28	0	0	100%
	Z-100™	35	0	0	100%	28	0	0	100%
Marginal Integrity	Fill Magic™	35	0	0	100%	22	6	0	100%
	Z-100™	35	0	0	100%	25	3	0	100%

greater perception of oral health in relation to their quality of life than men [16]. Moreover, women were also more likely to be preventive dental visitors [4].

In contrast to general practice studies [1,4], which involve many clinicians, in this study, a single operator placed all the restorations to avoid variability in technique.

The results of the current study indicate that the first null hypothesis was accepted since no differences between resin composites (Z100 and Fill Magic) were observed. It is reasonable to assume that the materials used in all restorations were universal microhybrid composites with no substantial differences, resulting in similar results for each composite. Moreover, a decrease in restoration quality was observed, with most restorations changing from Alpha to Bravo classification in the USPHS criteria after nine years. No scores below Bravo were observed, rendering the restoration acceptable, thus corroborating other long-term clinical evaluations of anterior restorations of resin composites, where majority of restorations received Alpha and Bravo scores [1,4,10]. This result is in line with a recent clinical study indicating that the physical properties of restoratives may have a role on their long-term clinical performance [13].

It is important to emphasize that, in the present study, differences between baseline and 9-year follow-up were observed for color matching and marginal integrity. It was expected that after 9-year follow-up some restorations would be present color matching, since aging in vitro methods have been induced to color change [17]. In relation to marginal integrity, it has been reported that bevelling of the enamel was associated with a significantly reduced deterioration of the anatomical form compared to no bevelling but not with less marginal staining or less detectable margins [18].

One of the other parameters evaluated in the current study was the postoperative sensitivity. At baseline and nine-year recalls, none of the patients reported sensitivity. This is explained by the protective effect of the calcium hydroxide and resin-modified glass-ionomer cement in deep cavities.

Another important aspect to be considered in the present study was that none secondary caries was detected during the nine-year period for each group. This is explained by the fact that the sample is exclusively of patients with appropriate oral hygiene e low caries risk. Caries risk has been previously investigated and has been shown to affect restoration survival [13,15,19]. In the present study, it is likely that the patient population had a low caries risk, as can be concluded from the high-level of oral health and the relatively low percentage of restorations failing due to secondary caries, which has been considered as the main reason for restorations' failures.

There is a lack of systematic reviews about anterior restorations in clinical studies. Maybe the use of different commercial material brands, restorative techniques and methods of evaluation make difficult an overall survival result for anterior resin composites.

CONCLUSION

It can be concluded that the resin composites studied have not yet completely satisfied the need of a durable anterior restorative material. Although, the majority of the criteria evaluated were considered acceptable after nine years of placement.

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