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ORIGINAL ARTICLE

Clinical evaluation of two packable posterior composites: 2-year follow-up

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Abstract The clinical performance of two packable posterior composites, Alert (A)—Jeneric/Pentron and SureFil™ (S)—Dentsply, was evaluated in 33 patients. Each patient received one A and one S restoration, resulting in a total of 66 restorations. The restorations were placed by one operator according to the manufacturer's specifications and were finished and polished after 1 week. Photographs were taken at baseline and after 2 years. Two independent evaluators conducted the clinical evaluation by using modified United States Public Health Service criteria. After 2 years, 60 restorations (30 A and 30 S), 27 class I (16 A and 11 S) and 33 class II (14 A and 19 S) were evaluated in 30 patients. Criterion A for recurrent caries, vitality, and retention was applicable to all 60 restorations. Criterion B was distributed among 40 restorations as follows: surface texture (15 A; 2 S), color (5 A; 6 S), postoperative sensitivity (1 S), marginal discoloration (8 A), marginal adaptation (3 A), and wear resistance (2 A). Data were analyzed using the Exact Fisher and McNemar tests. After 2 years, S showed a significantly better performance than A with respect to surface texture and marginal discoloration. The clinical performance of both materials was considered acceptable over the 2-year period. Further evaluations are necessary for a more in-depth analysis.

Keywords Clinical trial · Composite · Posterior teeth · Esthetics · Direct restoration

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Introduction

In recent years, the placement of resin-based direct composite restorations has become a routine and well-established dental procedure. Despite the excellent long-term results obtained with amalgam restorations, speculation about the possible health risks associated with mercury [41] and the demand for esthetic restorative materials have contributed to the increased use of composite resins in posterior applications [6, 13–15, 36, 50]. In addition, bonded restorations provide a more conservative cavity preparation by preserving valuable tooth structure [22].

Packable composite resins have been introduced into the market with high expectations as better alternatives than amalgam. These resins present new filler designs, a change at the organic resin, improved rheological properties, increased viscosity, and a reduced adherence to hand instruments [2, 21]. Improvements in some handling properties such as manipulation and insertion have also been reported [2, 21].

Alert (A) (Jeneric/Pentron, Wallingford, CT, USA) contains dimethacrylate of ethoxylated bisphenol-A polycarbonate resin mixed with barium boroaluminosilicate glass and silica [16]. SureFil™ (S) (Dentsply/Caulk, Milford, DE, USA) contains a urethane modified Bis-GMA resin mixed with a barium borofluoraluminosilicate glass and silica [16]. The manufacturers argued that these

composites should have better handling properties, which would facilitate clinical manipulation. However, there are also worse handling properties, for example, regarding the adaptation of the material to the margins [39] and stress development during polymerization [10].

Due to the increasing use of composites and the number of new resin brands, it is important for dentists to be aware of the probable longevity and likely modes of failure in posterior composite restorations. This information is best obtained from randomized controlled trials conducted clinically and in the laboratory. This study presents 2-year clinical performance of two packable posterior composite resins, A and S.

Materials and methods

Fifteen male and 18 female (n=33) patients, aging from 8 to 52 years with a mean age of 33.4 years, were selected to participate in this study. All teeth included in the study were in normal functional occlusion with at least one cusp in occlusal contact, and the indications for placement of the restorations were primary caries or replacement of failed amalgam restorations. The exclusion criteria were clinical symptoms of pulpitis, such as spontaneous pain or sensitivity to pressure. A total of 66 restorations, 33 A and 33 S, were placed. The compositions of bonding agents and restorative materials used in this study are shown in Table 1. A pair (one A and one S) of restorations was performed in each patient. Thirty-six restorations were inserted into class II (15 A and 21 S) and 30 into class I (18 A and 12 S) cavity preparations. Restorative materials were randomly allocated to the respective teeth in each patient using lottery numbers. The restorative material and the selected tooth were tabulated to control their respective distributions. The ratio of premolars to molars was 35:31 (Table 2).

All patients completed an informed consent form describing the risks and benefits associated with the treatment. All aspects of the proposed study were reviewed and approved by the Ethics Committee of our institution.

Clinical procedure

Cavity preparation

Conventional amalgam preparations were used to benchmark the prepared cavities, which corresponded mostly to replacements of previous restorations. A conventional class I or II cavity (without beveling) was prepared using a #245 carbide bur at high speed with water spray.

The same operator placed all restorations by using rubber dam isolation. Deep cavities were lined with calcium hydroxide (Dycal—Dentsply/Caulk) and/or glass ionomer cement (Vitrebond—3M ESPE Dental Products, St Paul, MN, USA). Shallow and medium cavities were not lined. The entire cavity was etched with 37.5% phosphoric acid gel (3M ESPE Dental Products) for 20 s and washed for 20 s. Prior to application of the adhesive systems, absorbent paper was applied to the dentin and the enamel was thoroughly dried with compressed air. The absorbent paper was used to remove the excess of water in dentin, thereby allowing penetration of the adhesive systems.

After the cavity preparation and etching, separate protocols were adopted for S and A restorations. For S, the adhesive system Prime & Bond NT (Dentsply/Caulk) was applied to the entire surface of the prepared cavity for 20 s and thereafter photocured for 10 s. A curing unit,

Table 1 Composition of bonding agents and restorative materials used in this study

Material	Composition			Manufacturer
Bond 1	PMGDM, HEMA, light-cured initiator, and acetone[a,c]			Jeneric/Pentron, Wallingford, CT, USA
Prime & Bond NT	PENTA, UDMA, Resin R5-62-1, T-resin, D-resin, nanofiller, cetylaminehydro-fluoride, and acetone[a,c]			Dentsply/Caulk, Milford, DE, USA
	Filler type and average particle size	Filler volume and weight (%)	Matrix type	
Alert	Ba-Al-Si glass, SiO_2 and filler 0.7 μm (fibers: 60–80 μm)[b,d]	62–70 vol.%[b,c,d] 80–84 wt.%[b,c,d]	Bis-GMA ethoxylated[b,c]	Jeneric/Pentron, Wallingford, CT, USA
SureFil™	Ba-B-F-glass, SiO_2 plus filler 0.8 μm[b,c,d]	58–66 vol.%[b,c,d] 77–82 wt.%[b,c,d]	UDMA[b,c]	Dentsply/Caulk, Milford, DE, USA

PMGDM pyromellitic glycerol dimethacrylate, *HEMA* 2-hydroxyethyl methacrylate, *PENTA* phosphoric acid dipenthaerytrytole penthcrylate, *UDMA* urethane dimethacrylate

[a]Perdigão & Lopes (1999) [34]

[b]Manufacturer's technical information

[c]Loguercio et al. (2001) [23]

[d]Manhart et al. (2001) [29]

Table 2 Distribution of restorations by tooth and cavity type

Resins	Number of restorations		Tooth				Class			
			Premolars		Molars		I		II	
	Baseline	2-year	Baseline	2-year	Baseline	2-year	Baseline	2-year	Baseline	2-year
Alert	33	30	17	15	16	15	18	16	15	14
SureFil™	33	30	18	16	15	14	12	11	21	19

Curing Light XL 1500 (3M Dental Products), with a power density of 550 mW/cm^2 was used. As far as A, the adhesive system Bond 1 (Jeneric/Pentron) was applied to enamel and dentin with a microbrush and left undisturbed for 20 s; then, the surfaces were photocured for 20 s according to the manufacturers' instructions with the same curing unit used for S.

For both materials a Tofflemire retainer with a steel matrix band and wooden wedge was used to reestablish the anatomical shape and the proximal contacts of the teeth. Before the insertion of A, a thin layer (0.5–1.0 mm) of flow resin (Flow-it, Jeneric/Pentron) was applied across the entire pulpal floor and in the proximal box at the gingival margin and photocured for 40 s. Finally, both composites were applied incrementally to the cavity in oblique layers not exceeding 2 mm. Each layer was cured separately for 10 s and then the restoration was cured for 40 s on the buccal, occlusal, and lingual surfaces. This curing mode was selected to reduce the polymerization contraction stress [3, 32, 48, 49]. Occlusal adjustments were made at the placement visit using carbide finishing burs (Jet-Sybron, Morrisburg, ON, Canada). The quality of interproximal contacts was checked with dental floss. After 1 week, the restorations were finished with Enhance polishing points (Dentsply, Petrópolis, RJ, Brazil) and paste (Kota Ltda, São Paulo, SP, Brazil).

Clinical photographs of A and S restorations were taken with a Nikon (Tokyo, Japan; N60/Medical lens) at the baseline and 2-year recall visit. These photographs were not used for indirect evaluation, though.

Evaluation

Two independent clinicians directly evaluated each restoration at baseline and after 2 years using a modified United States Public Health Service (USPHS) system [4] (Table 3). The examiners were not involved in the placement of the fillings and were unaware of the materials used in this double-blind study. The kappa score for interexaminer agreement for all the evaluation criteria was 0.89. In cases where the two examiners disagreed on a rating, both reexamined the restoration and arrived at a joint final decision.

The data for A and S at baseline and after 2 years were analyzed using the Exact Fisher test. The McNemar test was used to analyze differences in longevity of each restorative material. Logistic regression analysis was calculated to identify if there was dependence of class and tooth type in relation to the observed results.

Results

There were no significant differences between the two restorative materials used in this study at baseline (Table 4). After 2 years, 60 restorations (30 A and 30 S) were evaluated in 30 patients. S showed significantly better surface texture (p=0.0004) and marginal discoloration (p=0.0046) than A. There were statistically significant differences between baseline and 2-year results as follows: for S with respect to color (χ^2=4.17, p=0.041) and for A regarding the marginal discoloration (χ^2=6.13, p=0.013) and surface texture (χ^2=13.07, p=0.000).

Logistic regression analysis revealed that class type and tooth localization was not significantly associated with the results of surface texture and marginal discoloration. However, the two groups of composites were significantly associated with the results concerning the surface texture and marginal discoloration.

Discussion

The tested packable resin composites (S and A) were marketed in 1998. Consequently, some studies have already analyzed their clinical performance [23, 24, 35, 36, 44, 46, 47, 51].

This study showed that S had significantly better clinical performance than A in terms of surface texture and marginal discoloration, while they both performed similarly according to the other criteria. This finding could be attributed to the fact that both resins have similar filler concentrations and average filler sizes. Regarding filler volume, weight, and average size, S has 66%, 82%, and 0.8 μm while A has 70%, 84%, and 0.7 μm, respectively [29]. Both materials also demonstrated comparable diame-

Table 3 Evaluation criteria

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
Vitality	Alfa (A): present
	Charlie (C): absent
Color matching	Alfa (A): no mismatch of color, shade and translucency between restoration and adjacent tooth
	Bravo (B): slight mismatch of color shade and translucency, but within normal clinical limits
	Charlie (C): mismatch of color and nonesthetic appearance
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
Retention	Alfa (A): restoration continuous with tooth
	Bravo (B): restoration discontinuous with tooth, but without exposure of the dentin or base
	Charlie (C): material missing to expose dentin or base
Surface texture	Alfa (A): surface is as smooth as the surrounding enamel
	Bravo (B): surface is rougher than surrounding enamel
	Charlie (C): surface is very rough
Marginal adaptation	Alfa (A): no visible evidence of crevice along margin can be detected by explorer
	Bravo (B): crevice detected, but without exposure of the dentin or base
	Charlie (C): dentin or base exposed
	Delta (D): the restoration is mobile or fractured
Wear resistance	Alfa (A): completely intact without perceptible loss of contour
	Bravo (B): slight loss of contour not requiring replacement
	Charlie (C): extensive loss of contour requiring replacement

tral tensile strength, fracture toughness, and compressive strength in vitro [11, 19]. Other studies concluded that S and A exhibited promising mechanical and physical properties for posterior restorations [28, 29].

All restorations evaluated in this study demonstrated acceptable clinical performance within the evaluation period based on the Alfa and Bravo ratings for clinically satisfactory restorations [4, 43]. An important finding was that all restorations received score A for recurrent caries, vitality, and retention, whereas few restorations received score B for the other criteria. Two possible explanations for the good clinical performance are (1) the relatively short evaluation period consistent with findings of many authors who did not observe significant differences in short-time periods [1, 9, 20, 23–26, 35, 36] and (2) improved partially physical and mechanical properties of the new composite resins [13].

The findings of this study are in agreement with results of clinical trials evaluating class II restorations in molars

Table 4 Number of restorations evaluated in each score for each material, period, and criterion

Evaluation criteria	Alert				SureFil™			
	Baseline		2-year		Baseline		2-year	
	A	B	A	B	A	B	A	B
Secondary caries	33	0	30	0	33	0	30	0
Postoperative sensitivity	33	0	30	0	33	0	29	1
Vitality	33	0	30	0	33	0	30	0
Color matching	33	0	25	5	33	0	24	6
Marginal discoloration	33	0	22	8	33	0	30	0
Retention	33	0	30	0	33	0	30	0
Surface texture	33	0	15	15	33	0	28	2
Marginal adaptation	33	0	27	3	33	0	30	0
Wear resistance	33	0	28	2	33	0	30	0

[35, 36], as well as studies [23, 24, 38, 44, 46, 47, 51] which report good behavior for S restorations bonded in posterior teeth. Restorations bonded with Prime & Bond 2.1 were evaluated after 3, 6, 9, 12, and 24 months by indirectly measuring wear using the USPHS criteria. At baseline and after 3, 6, and 9 months, all restorations were graded Alfa in all categories. Three out of 22 restorations at 1-year recall and 6 out of 22 restorations at the 2-year recall were graded Bravo for surface staining [35, 36]. Another study evaluating 21 restorations with S and Prime & Bond NT demonstrated excellent clinical performance after 1 year and no restoration received Bravo rating. Turkun et al. observed 96 and 94% success with S after 2 and 3 years, respectively [46, 47]. A 3.5-year clinical evaluation of S showed an increased risk of bulk fracture when placed in large intracoronal class II molar preparations [38]. Changes in surface texture and color match for A restorations increasing after 1 and 3 years have been reported [23, 24], which is in agreement with the findings of this study in which 50% of the A restorations received Bravo score in relation to surface texture. This may be due to the presence of the fibers in A (60–80 μm), which cause some difficulties during the finishing and polishing procedure, mostly affecting the matrix, and partly exposing the fiber particles (Table 1). It was observed that 11 of the 15 A restorations which received an A score were in female patients. The literature documents that bite forces are significantly greater in males than in females [7, 37]. Furthermore, it was observed that 10 of the 15 A restorations which received an A score were in premolars, which wear less readily than molars [45]. These two reasons may explain the A score for surface texture regarding the 50% for A restorations.

Furthermore, Bayne et al. [5] suggested that the presence of large particles may theoretically cause greater wear of the restorative material and the antagonist enamel. When the restoration is subjected to masticatory forces, the stress spreads through the filler particle into the resin matrix. This process results in the easy removal of these particles from the surface, thereby exposing the organic matrix and further accelerating wear.

Other in vitro studies on the surface roughness of various packable composites, including A and S, showed that A presented the roughest surface characteristics [31, 40, 42]. Consequently, Jeneric Pentron released a new version of A aimed at improving handling characteristics and surface texture. According to the manufacturer's information the differences between the old and new A are in the fiber filler process. The new A has nano/microsized silica particles modified on to the plain glass fiber surface when performing the heat treatment for the fiber fillers. Therefore, the finished A should have better wear resistance and polishing ability.

An alternative to overcome the surface roughness of A is the application of a surface sealer. Blalock et al. [8] showed for S a median wear of 25 μm for sealed and unsealed restorations. In contrast, the same authors showed that the sealed A restorations presented a median wear of 25 μm, while the unsealed restorations had a median wear rate of 63 μm. Consequently, large particles may cause long-term clinical problems, including increased wear and surface roughness. If a surface sealer can reduce wear, then it is certainly indicated after the placement of posterior composite restorations. Another potential solution to decrease wear is to periodically reapply a surface sealant on these restorations, but the time for reapplication requires further investigations.

Logistic regression analysis was conducted because the distribution of class type and tooth localization was not homogeneous according to the materials. The statistical analysis showed that class type and tooth localization had no influence on the results of marginal discoloration and surface texture.

The high proportion (90.9%) of respondents who followed through over the 2-year period was due in part to the partnership between the Dental School and the Military Police and to the consistently available captive population of police officers. There is a dilemma regarding the selection of the patients for a clinical trial because a captive population is not representative of the whole population. In this study one quarter of the patients were selected in the Dental School Clinic, but they returned for the 2-year evaluation, making this a reliable population. Furthermore, the randomization was performed using lottery numbers during the selection of patients who needed posterior composite restorations and when inserting the restorative materials tested.

Only one operator placed all the restorations in this study to avoid the influence of the operator on the performance of the restorations. Previous studies with more than one operator showed that some variables evaluated were more dependent on the operator than on the material tested [18, 33].

Because the materials being tested were marketed in 1998, the observation periods cited in the literature [14, 15, 23–26, 30, 35, 36, 38, 40, 44, 46, 47, 51] are not longer than 6 months to 3.5 years. Some systematic reviews showed extensive surveys of the longevity of resin composite in posterior restorations [9, 12, 17, 27]. Observation periods varied from 1 to 17 years, and failure rates ranged between 0 and 45% [9]. Annual failure rates in posterior stress-bearing restorations were from 0 to 9% for direct composites [17, 30]. A linear correlation between failure rate and observation period was found [9]. Although a decreased number of evaluated restorations occur after long periods, these results are consistently worse than short-term evaluation results [9]. The expected median longevity of the resin composite in posterior restorations is 8 years [27]. There remains a need for definitive randomized controlled trials of restoration longevity, of sound design

and adequate power, employing standardized assessments and appropriate methods of analysis [12].

It is recognized that the duration of this study is insufficient to confirm long-term suitability of the tested materials; nevertheless, these findings provide an indication of their initial clinical performance. Clinical evaluation longer than 2 years is necessary to make valid conclusions.

Conclusion

After 2 years, the clinical performance of A and S showed minor changes compared with the baseline. Although the fiber-reinforced A resin composite showed an increased surface roughness, all A and S restorations were in place and showed satisfactory clinical performance.

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