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Evaluation of Packable and Conventional Hybrid Resin Composites in Class I Restorations: Three-year Results of a Randomized, Double-blind and Controlled Clinical Trial

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Clinical Relevance

Long-term randomized, controlled, clinical trials of treatment outcomes are clearly needed to evaluate the long-term performance of composites in posterior teeth.

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SUMMARY

The clinical performance of packable and conventional hybrid resin composites in Class I restorations for a period of three years was compared using a randomized controlled double-blind clinical trial with self-matching design. A

total of 50 pairs of Class I restorations were placed in 32 adult patients by one dentist in a self-matching prospective clinical trial. The paired teeth were divided into the TPH Spectrum/XenoIII (TS) restoration group and the Synergy Compact/One Coat (SC) restoration group according to a random number table. Application of the materials followed the manufacturer's instructions. The restorations were evaluated by two independent evaluators using US Public Health Service (USPHS)-Ryge modified criteria. Statistical analysis was performed using the McNemar's test with Yates' continuity correction. After three years, 40 pairs of restorations were available for evaluation. Four TS and two SC restorations failed due to fracture. Only one TS-restored tooth showed postoperative sensitivity at baseline and the symptom disappeared one week later. Alpha ratings of TS vs SC restorations were as follows: 95% vs 98% for color match, 85% vs 88% for marginal integrity, 88% vs 90% for anatomical form, 85% vs 83% for marginal discoloration, 88% vs 93% for occlusal contact. For both materials, Alpha ratings were 88% for surface texture. The three-year clinical performances of the two restorative materials were satisfactory and not significantly different for each of the parameters evaluated.

INTRODUCTION

In recent years, resin-based composite restoration has become widely accepted as an alternative to dental amalgam in posterior dentitions due to its superiority in esthetics and its ability to conserve tooth structure. High wear rates, marginal leakage, secondary caries and poor proximal contact were the main shortcomings of resin composite restorations used in posterior teeth in earlier years.[1] Qvist and others reported that approximately 32% of resin composite restorations failed within 10 years and 50% of the failed Class I and Class II restorations were due to secondary caries and bulk fractures.[2] Considerable technical progress has since been made in adhesive systems, resin matrix, filler size and content.[3] Improved conversion rates through light-activated polymerization have led to far more encouraging results in recent studies. For example, the average annual wear of several recent generation posterior resins has been shown in laboratory and clinical studies to be equivalent to that of silver amalgam.[4-5] Despite improvement in the quality of resin composites, their application in the restoration of posterior teeth still presents challenges to clinicians due to technique sensitivity, time consumption and complexity.[6] For a restorative procedure to be successful, the restorative material must have the handling characteristics that allow for easy application in a busy dental practice. Dentists often have a preference for composites with a specific consistency, as this parameter will affect the application and manipulation of the material.[7] The polyglass material Solitaire (Heraeus Kulzer, Wehrheim, Germany) was introduced in 1997 as the first "packable" resin composite to be marketed. Manufacturers claimed that these types of materials are superior to other resin composites, because they possessed the following properties: the ability to be used in the load-bearing area of posterior teeth, superior handling characteristics, less curing shrinkage, similar annual wear and the modulus of elasticity of amalgam, and similar thermal expansion coefficient to teeth.[8] Despite these claims, recent studies have not provided evidence that packable composites are superior to other types of resin composites. It has been shown that the physical and mechanical behaviors of packable composites were, in fact, similar to that of hybrid resin composites.[9-11]

Though laboratory tests can provide useful information on the physical and mechanical properties of different resin composites, the long-term performance of these materials still depends on clinical evaluations.[1] There is a paucity of information on the effectiveness of packable resin composites in posterior restorations. Some clinical studies showed that both packable and hybrid composites provide acceptable performance during one-to-three year observation periods.[3,12-14] Though some studies have taken into consideration restoration distribution, restoration size and occlusion, the rigor of the study design has generally been weak when the CONSORT guideline for clinical trials is used as a yardstick.[15] No randomized, blind and controlled clinical trials have been done to evaluate the long-term performance of packable composites compared to hybrid resin composites commonly used for posterior restorations.

Therefore, the current study evaluated the clinical performance of a packable and a conventional hybrid resin composite using a randomized double-blind and controlled clinical trial design following the CONSORT guidelines.

METHODS AND MATERIALS

Subjects

Subjects were selected among volunteers from the freshmen classes of two colleges in Wuhan University. Each volunteer subject signed an informed consent form before participating in the study. Approval for the clinical trial was obtained from the Ethics Committee of Wuhan University School of Stomatology.

Potential subjects had to satisfy the following inclusion criteria: 1) have at least one pair of periodontally-sound and vital premolars or molars with failed restorations or primary caries that required Class I restorations; 2) the cavity had to be medium in size,

extending between one-quarter and one-third of the way up one or more of the cuspal slopes; 3) the selected teeth had to have proximal contact with adjacent teeth; 4) have molar-supported permanent dentitions free of any edentulous spaces and occlusal interferences; 5) had to be able to provide written informed consent and comply with all study procedures.

Patients were excluded from participation if they: 1) were included in other dental studies or clinical trials; 2) had a history of adverse reactions to the components of dental materials to be used in the evaluations; 3) demonstrated evidence of occlusal parafunctions and/or atypical tooth wear; 4) had intrinsic staining of the teeth and any existing tooth-colored restorations; 5) had medical or dental histories that might complicate provision of the proposed restoration and/or influence the behavior and performance of the restorations in clinical service; 6) could not maintain an acceptable standard of oral hygiene (OHI-S>3). Oral hygiene was based on the OHI-S (oral hygiene index simplified) score, which was categorized as good (score of 0-1.2), satisfactory (score of 1.3-3) or poor (score >3)[16]; 7) had an opposing tooth to the selected tooth that needed restoration or replacement of the restoration.

A packable resin composite, Synergy Compact (Coltène/Whaledent, Mahwah, NJ, USA), was used for the study group, and a hybrid resin composite, TPH Spectrum (Dentsply Caulk, Milford, DE, USA), was used for the control group. One Coat (Coltène/Whaledent) and Xeno III (Dentsply Caulk) self-etching adhesives recommended by the manufacturers for each resin composite were used for Synergy Compact (SC) and TPH Spectrum (TS), respectively. The paired teeth were assigned to the SC restoration group and the TS restoration group using a computer-generated random number table. Table 1 shows the components of the restorative materials used.

Operative Procedures

One dentist on the research team performed the cavity preparation and placement of the restorations. In terms of cusp involvement, pre-operative clinical photographs were taken to assess the width of the lesions. Radiographs were taken to confirm the extent of the depth of the lesions and the health status of the periodontal tissue. After complete removal of the existing restorations and caries, an adhesive cavity design—no additional extension for prevention, no preparation of undercuts, round-shaped cavity walls—was prepared with a #245 carbide bur (Diatech, Coltène/Whaledent) under constant cooling. Bevels were cut in enamel margins using an ISO #234 504 012 extra fine diamond bur (Diatech, Coltène/Whaledent). A rubber dam was used in clinical situations where contamination of the cavity with saliva, blood or sulcus fluid could not be prevented by means of cotton rolls and suction, mainly in lower molars. A thin layer of calcium hydroxide cement (Dycal, Dentsply Caulk) was applied as a liner when the remaining distance to the pulp was estimated to be less than 0.5 mm. A glass-ionomer cement (Fuji Lining LC, GC Corporation, Tokyo, Japan) was placed over the calcium hydroxide as a base when deemed necessary by the operator. Application of the resin composites and adhesives was done following the manufacturer's instructions. The composite materials were applied using the oblique layering technique, with each layer not exceeding 2 mm. Each layer was cured separately using the 3M Freelight LED curing light unit (3M Dental Products, St Paul, MN, USA).

Table 1: *Restorative Materials Used in This Study*

Brand Name (Batch #)	Composition	Manufacturer
TPH Spectrum (0402000705)	Matrix: Bis-GMA, Bis-EMA, TEGDMA Filler (57vol.%; 77wt.%): Bariumaluminiumborosilicate (mean particle size <1.5 µm), Highly dispersed silicon dioxide (particle size 0.04 µm) photo initiators, stabilizers	Dentsply Caulk, Milford, DE, USA
Xeno III self-etching adhesive system (0411001721)	Liquid A: HEMA, Water, Ethanol, BHT, Highly dispersed silicon dioxide Liquid B: Phosphoric acid modified methacrylate resin, Mono fluoro phosphazene modified methacrylate resin, UDMA, BHT, Camphorquinone, Ethyl-4-dimethylaminobenzoate	Dentsply DeTrey GmbH, Konstanz, Germany
Synergy Compact (IF674)	Matrix: Bis-GMA, Bis-EMA, TEGDMA Filler (59vol.%; 74wt.%): strontium glass, silanized barium glass, silanized amorphous silica, hydrophobed. Particle size: 0.04–2.5 µm, average 0.6 µm photo initiators, stabilizers	Coltène/Whaledent, Mahwah, NJ, USA
One Coat self-etching adhesive system (0073451)	Primer 1: Water, Acrylamidosulfonic acid, Methacrylates Bond 2: Methacrylates, Polyalkenoate methacrylized Polyalkenoate methacrylized	Coltène/Whaledent Mahwah, NJ, USA

Note: Bis-GMA=bisphenyl glycidyl methacrylate; Bis-EMA=Bisphenol A ethoxylate dimethacrylates; TEGDMA=triethylene glycol-dimethacr; HEMA=2-hydroxyethyl methacrylate; BHT=Butylated hydroxy toluene; UDMA=urethane dimethacrylate.

The dentist contoured the restorations using a superfine diamond bur (Diatech, Coltène/Whaledent) immediately after curing and polished them using finishing and polishing systems recommended by the manufacturers: PoGo diamond micro-polishers (Dentsply Caulk) for the TS restorations and Brilliant Gloss polishers (Coltène/Whaledent) for the SC restorations. Clinical photographs were taken after polishing the restorations and at each recall visit.

Outcome Evaluations

The primary outcome measure was failure of the restoration, which was defined as the need for replacement of the restoration due to fracture, secondary caries or loss of restoration. Other outcome measures were ratings of the restorations using the modified USPHS/Ryge criteria (Table 2).[17-18]

Two independent clinicians not involved in the original placement evaluated the restorations after their placement at baseline and after one, two and three years, using dental mirrors and probes. When disagreement occurred during evaluation, the case was jointly reviewed and a consensus was obtained between examiners. The examiners were calibrated before the baseline evaluation. Inter-examiner reliability was assessed using Cohen's kappa tests. The training was conducted on 100 posterior-resin restorations in patients not enrolled in the current clinical study. A kappa score of 0.88 was achieved following the calibration exercise.

Statistical Analysis

The sample size estimate was based on paired comparisons of binary data using failure rate as the primary outcome measure.[19] Data from a non-randomized clinical study showed an odds ratio (OR) of 3.0 in the failure of packable composites as compared to that of hybrid composites in Class I and II restorations.[14] The authors of the current study expected that OR was lower in the current study. Assuming an OR of 2.5, a minimum of 38 pairs of restorations were needed to allow the study to have 80% power for a two-sided test at an alpha level of 0.05. Considering that this was a long-term study with an estimated dropout rate of about 10%, the required sample size was adjusted accordingly. A minimum of 47 pairs needed to be enrolled to achieve the required statistical power. The authors of the current study aimed to enroll 50 pairs of restorations for the study.

Table 2: *Modified USPHS/Ryge Criteria Used for Clinical Evaluation*[16]

Category	Rating	Characteristic
Color-match	Alpha	The restoration matches the adjacent tooth in color and translucency.
	Bravo	There is a mismatch in color, shade or translucency, but not outside the normal range of tooth color, shade and/or translucency.
	Charlie	The mismatch is outside the normal range of tooth color, shade and/or translucency.
Marginal Integrity	Alpha	No visible evidence of a crevice along the margin into which an explorer will catch.
	Bravo	The explorer catches a crevice along the margin, but there is no exposure of dentin or base.
	Charlie	Visible evidence of a crevice with exposure of dentin or base.
Anatomic Form	Alpha	The restoration is not undercontoured.
	Bravo	The restoration is undercontoured, but there is no dentin or base exposed.
	Charlie	Sufficient restorative material is missing so that dentin or base is exposed.
Marginal Discoloration	Alpha	No existing marginal discoloration.
	Bravo	Presence of discoloration at the margins between the restoration and the tooth structure; discoloration does not penetrate along the margins of the restoration toward the pulp.
	Charlie	The discoloration penetrated along the margins of the restoration in a pulpal direction.
Surface Texture	Alpha	The surface is smooth and the adjacent tissues showed no irritation.
	Bravo	The surface of the restoration is slightly rough or pitted but can be refinished.
	Charlie	The surface is deeply pitted or shows irregular grooves, which were not related to the natural anatomy and could not be refinished.
	Delta	The surface is fractured or flaking.
Secondary Caries	Alpha	No evidence of secondary caries along the margin of the restoration.
	Bravo	Presence of softness, opacity at the margins as evidence of undermining or demineralization, or etching or white spots as evidence of demineralization in areas where an explorer catches or resists removal after insertion.
Occlusal Contact	Alpha	Normal.
	Bravo	Slight.
	Charlie	No occlusal contact.
Vitality of Pulp	Alpha	Normal to the stimulus.
	Bravo	A little sensitive or dull to the stimulus.
	Charlie	Activated pain or delayed pain to the stimulus.
Sensitivity	Alpha	Not present.
	Bravo	Sensitive but diminishing in intensity.
	Charlie	Constant sensitivity, not diminishing in intensity.

A and B means clinically acceptable; C and D means clinically unacceptable; the restoration needs to be replaced.

Table 3: *Distribution of the Restorations*

	TPH Spectrum				Synergy Compact			
Location	**Baseline**	**1-year**	**2-year**	**3-year**	**Baseline**	**1-year**	**2-year**	**3-year**
Maxillary Molar	7	6	6	6	6	5	5	5
Maxillary Premolar	1	1	0	0	1	1	0	0
Mandible Molar	40	35	34	34	41	36	35	35
Mandible Premolar	2	1	0	0	2	1	0	0
Total	50	43	40	40	50	43	40	40

Descriptive statistics were presented on the overall failure rate, color match, marginal integrity, anatomic form, marginal discoloration, surface texture and occlusal contact, as well as pulp vitality and sensitivity. Failure rates and proportions of restorations with alpha ratings were compared between the two study groups using the McNemar's test with Yates' continuity correction at the conclusion of the current study.

RESULTS

A total of 50 pairs of resin composite restorations were placed in 32 patients with a mean age of 20.5 years (10 males and 22 females) at baseline. Five subjects with seven pairs of restorations who were seen at baseline did not return for the 12-month evaluation and three subjects with four pairs of restorations failed to attend the two-year review. The overall recall rate was 80% of the total 50 pairs of restorations. The dropouts were mostly due to patients' relocation. Table 3 shows the number of restorations that were available for evaluation at each stage of the follow-up exams.

Within the evaluation period of three years, a total of six restorations (TS=4, SC=2) failed and had to be replaced due to fracture. Five failed restorations were on molars and the remaining restoration was on a premolar. For TS restorations, one failed at one-year recall, with three accumulating at the two-year recall and four accumulating at the three-year recall. For SC restorations, one failed at the two-year recall and one occurred at the three-year recall. There were no statistically significant differences in failure rates between the TS and SC groups (X^2=0.167, p=0.6831). Two restorations needed a liner or a liner with a base; both were in the SC group. As there was evidence that restorations with liners or bases were prone to fracture,[20] additional analysis was performed, excluding the teeth with liner or bases. No statistically significant difference in failure rate was found between the two groups with teeth having a liner or base excluded from the analysis (X^2=2.250, p=0.1336).

The results of clinical evaluations at one, two and three years after the baseline exam are shown in Figure 1 for color match, marginal integrity, anatomical form, marginal discoloration, surface texture and occlusal contact. At three years after placement, the alpha ratings were 95% for TS and 97.5% for SC for color match, 85% for TS and 87.5% for SC for marginal integrity, 87.5% for TS and 90% for SC for anatomical form, 85% for TS and 82.5% for SC for marginal discoloration, 87.5% for both TS and SC for surface texture and 87.5% for TS and 92.5% for SC for occlusal contact. There were no statistically significant differences between the two groups in all the outcome measures (p>0.05). Typical clinical photographs are represented in Figures 2, 3 and 4.

Postoperative sensitivity was found only in one TS-restored tooth and it lasted for one week. No sensitivity was found at or after the one-year recall. The vitality of the restored teeth had not changed during the three-year period. There was no evidence of secondary caries in any of the restorations.

DISCUSSION

The results of the current study indicate that the packable composite, Synergy Compact, performed equally well as the hybrid composite, TPH Spectrum, three years after placement in Class I restorations. The cumulative survival rates after three years were 95% for Synergy and 90% for TPH composites, respectively. Alpha ratings on the variables of the modified USPHS/Ryge criteria ranged from 82.5% to 97.5% for both types of composites after three years of service, with no discernable differences between the two groups. These findings indicate that both the packable and hybrid composites are suitable for posterior restorations involving load-bearing surfaces.

The primary cause of failure was fracture of the composite for both groups, which is in agreement with a previous study comparing the long-term effects of packable and hybrid composites.[14] No secondary caries was found in the current study. These findings substantiate the observation that fracture was the most common cause of composite restoration failure for up to five years after placement, while secondary caries most

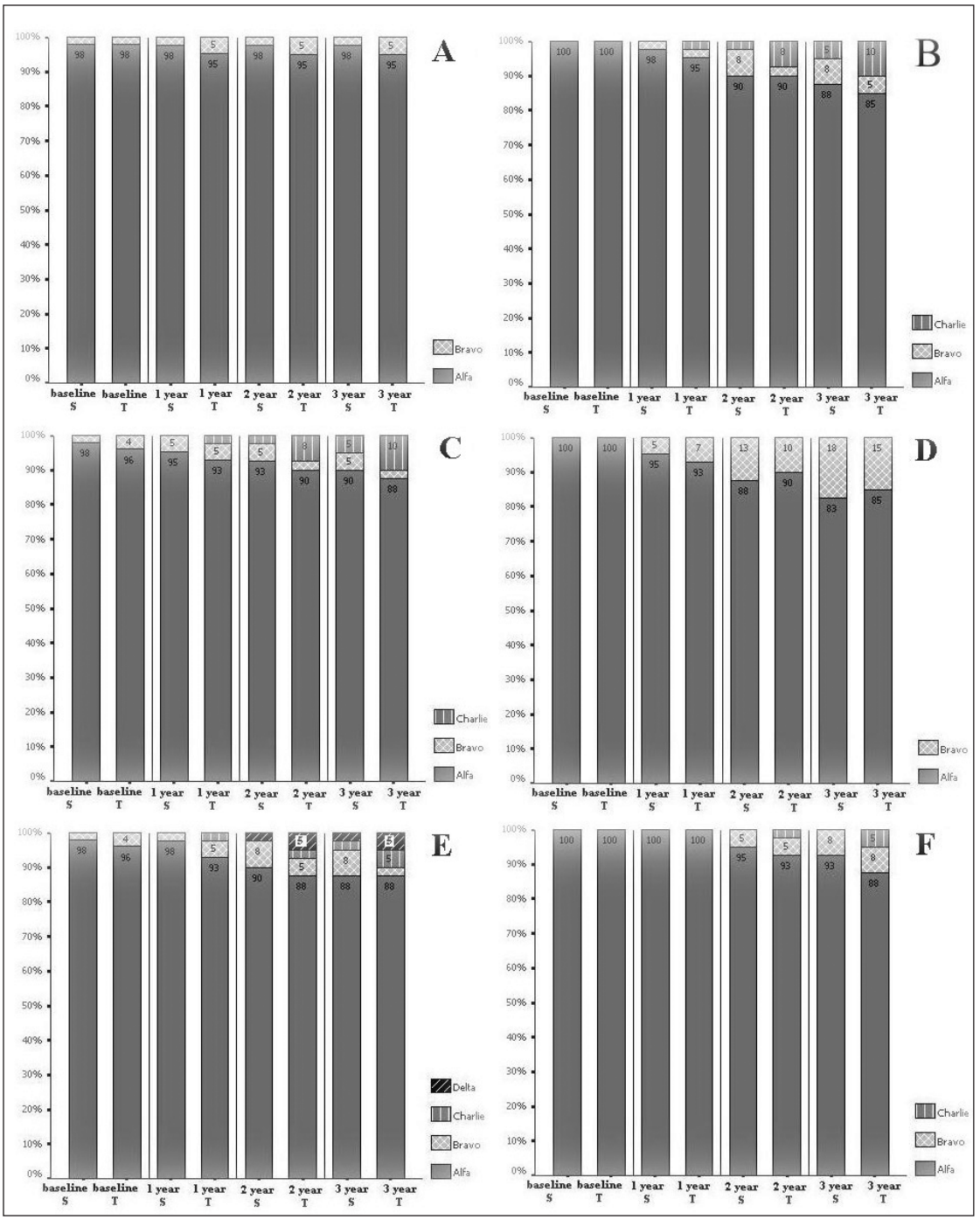

Figure 1: *Results of the clinical evaluation of Synergy Compact and TPH Spectrum restorations. The Ryge scores for Color-match (A), Marginal integrity (B), Anatomic form (C), Marginal discolorations (D), Surface texture (E) and Occlusal contact (F) were shown. S:Synergy Compact restorations; T:TPH Spectrum restorations.*

commonly occurred thereafter.[13] Previous non-randomized and non-controlled studies indicated that the clinical performance of both TPH Spectrum and packable composites was acceptable when used for posterior restorations.[3,12-14] The survival rates of posterior composites ranged from 55% and 95% during a five-year observation period.[13] The cumulative survival rates after 3.5 years were 92% for TPH Spectrum and 81.3% for SureFil packable composite in a non-randomized clinical study involving both Class I and Class II restorations.[14] The increased failure rate of the packable composite might not be related to the mechanical properties of the composite itself, because the failure was associated with the size of the restorations. Very large Class II restorations were prone to failure, regardless of the materials used.[14] To control the confounding effects of cavity size and cavity design on the failure of posterior composite restorations, the authors of the current study elected to include only medium-sized Class I restorations. Therefore, failure of the restorations can largely be explained by the mechanical properties of the composite materials used in the current study. The hybrid composite TPH Spectrum has greater diametral tensile strength and flexural strength than packable composite materials, while the latter has higher compressive strength.[21] These properties may have determined that both types of composites could be successfully applied in load-bearing posterior teeth. The packable composite Synergy Compact performed well in the current study. Only two Synergy Compact restorations with a liner and/or base failed after three years. Due to the small number of restorations with a liner or base in the current study, it

Figure 2. *TPH Spectrum (46) and Synergy Compact (47) restoration after three years. Each parameter was scored as Alpha.*

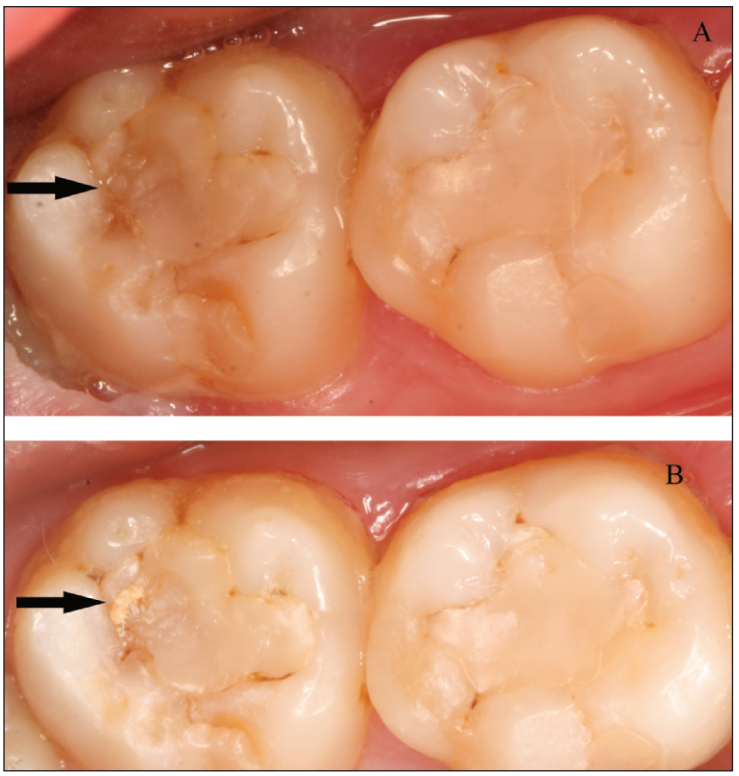

Figure 3. *A: TPH Spectrum (46) and Synergy Compact (47) restoration after two years. Both of them were scored as Bravo for marginal discoloration. Tooth 47 was scored as Bravo for surface texture and marginal integrity (arrow). B: three-year follow-up, Tooth 47 showed restoration fracture (arrow).*

is not known whether placement of a liner or base contributed to failure of the restorations.[20]

A distinctive strength of the current study is the rigor of the study design in accordance with the guidelines for randomized, double-blind and controlled clinical trials. Randomized controlled trials (RCTs) are considered the most reliable form of scientific evidence in health care, because they eliminate spurious causality and biases. In the current study, the random allocation of different treatments to paired teeth was done according to a random number table. This ensured that known and unknown confounding factors were evenly distributed between treatment groups.

The other strength of the current study is the use of self-control with paired restorations. The most unknown and unquantifiable factor in the performance of posterior composite restorations is the characteristics of the patient receiving the restoration. Mastication forces, occlusal habits, abrasive foods, chemically active foods and liquids, temperature fluctuations, humidity variation, bacterial byproducts and salivary enzymes all contribute as uncontrollable factors that affect the longevity of composite restorations.[1] In order to eliminate the threat of control-selection bias and to increase efficiency, a self-control design was used in the current study, so that both the test and control materials were placed in matched pairs in the same patient with the same oral environment. Furthermore, in order to control the influence of plaque acids and bacterial byproducts on the performance of resin composites,[22-24] patients who could not maintain an acceptable standard of oral hygiene (OHI-S scores>3) were excluded from the study.

In the current study, marginal discoloration was found in 18% Synergy Compact and 15% TPH Spectrum restorations. Marginal discoloration usually results from defects found between the tooth-colored restoration, cavity margins and walls. Such defects may be caused by inadequate restoration placement and finishing procedures, by unsatisfactory bonding and by subsequent stress fatigue. Polymerization shrinkage stress has the potential to initiate failure of the composite tooth interface if the forces of polymerization contraction exceed adhesive bond strength. According to the manufacturer, the volumetric shrinkage for TPH Spectrum is 2.5%. Packable composite, in general, has a higher percentage of filler than hybrid composites. The presence of high filler levels is fundamental to reducing shrinkage of the composite during polymerization, which should, in theory, minimize marginal defects and discoloration.[25] The findings of this study did not show a difference in marginal discoloration between the two study groups, which is in agreement with a previous study that compared SureFil (Dentsply) and TPH Spectrum.[14] Reduced polymerization shrinkage of more highly filled packable composites did not translate into reduced marginal discoloration in this instance.

In summary, the three-year clinical performance of Synergy Compact and TPH Spectrum were satisfactory for Class I restorations in load-bearing areas when used with a self-etching adhesive recommended by the manufacturers. There were no statistically significant

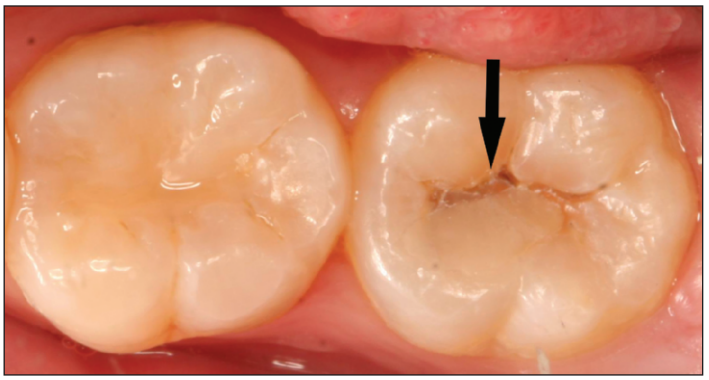

Figure 4. *Synergy Compact (46) and TPH Spectrum (47) restoration after two years. Tooth 46: each parameter was scored as Alpha. Tooth 47: restoration fracture (arrow).*

differences in failure rates and all variables were included in the USPHS/Ryge criteria between the two types of composite materials. To the best knowledge of the authors of the current study, this is the first randomized, double blind and controlled clinical trial comparing the long-term results of a packable composite with that of a conventional hybrid resin composite. In addition, the current study followed strict inclusion and exclusion criteria, used self-control and included only Class I restorations to minimize the effects of potential confounding factors on clinical performance of the materials. The authors acknowledge that such stringent control of confounding factors may limit generalizability of the findings of the clinical trial. In the future, the authors plan to further expand this study to include Class II restorations in a diverse population.

CONCLUSIONS

Within the limitations of this randomized, double blind and controlled clinical trial, it can be concluded that the three-year clinical performance of both Synergy Compact and TPH Spectrum was satisfactory for Class I restorations in load-bearing areas when used with a self-etching adhesive recommended by the manufacturers.

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