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Six-year Clinical Evaluation of Packable Composite Restorations

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Clinical Relevance

As a posterior composite, Filtek P60 exhibited very good clinical performance in Class II cavities for six years.

SUMMARY

Objective: For decades, resin composites have been used with increasing frequency as posterior restorative materials, because of the demand for aesthetic restoration. This study evaluated the six-year clinical performance of Filtek P60 (3M ESPE) packable composite restorations in combination with a one-bottle etch and rinse adhesive, Single Bond (3M ESPE), in Class II restorations.

Methods: A total of 47 restorations were placed in the Class II cavity preparations (27 premolars and 20 molars) of 33 patients (22 female/11 male; mean age 34) by the same operator. The restorations were evaluated by two examiners at baseline and 1, 2, 3 and 6 years according to the method developed by Ryge, which also is known as the United States Public Health Service (USPHS) criteria. The following characteristics were observed: marginal adaptation, anatomical form, surface texture, marginal discoloration, surface staining, post-operative sensitivity and secondary caries. The Chi-square and Wilcoxon signed rank test with Bonferroni adjustment were used for statistical analysis (p=0.05).

Results: All the restorations received Alpha scores at baseline assessment, except for one restoration, which showed post-operative sensitivity. At the three-year recall examination, two patients, with a total of three restorations, were not included. From baseline to three years, only two of the 44 restorations changed from Alpha to

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DOI: 10.2341/08-48

Bravo, for numerous reasons. At the six-year recall, 44 restorations were available for examination. The majority of restorations exhibited Alpha or Bravo scores for the evaluated criteria. No significant differences were found for any of the clinical criteria ($p>0.05$). Only two restorations needed to be repaired due to caries that began independently from the restorations. Three or four restorations showed slight surface staining and marginal discoloration.

Conclusions: The clinical performance of the posterior composite restorations that were evaluated was acceptable after six years of service.

INTRODUCTION

Amalgam is still a widely used restorative material for posterior teeth, because of handling procedures, beneficial material properties, fast application and affordability, and clinical success.[1] Recent advances in adhesive dentistry and increased patient demand for tooth-colored restorations have increased the use of resin-based composites.[2] In recent years, composite restorations have become a routine procedure for Class I and Class II lesions, because many patients reject amalgams either for aesthetic reasons or for their supposed toxic effects.[3]

Posterior resin composites have become more popular with advances in adhesive dentistry. Initially, the performance of resin composites was poor, due to inadequate wear resistance, various types of fractures, postoperative sensitivity, marginal leakage, secondary caries, insufficient occlusal morphology and lack of appropriate proximal contact.[4] There have been several important investigations and publications about composites in recent dental history.[1-8] Continuous research in this field has contributed to improvements and developments. Considerable technical progress concerning adhesive systems, resin matrix, filler size and content has led to excellent results.

Packable resin composites with viscosities higher than that of previous materials were introduced in the late 1990s to dentists who wanted to use a tooth-colored posterior restorative material that handled more like dental amalgam. These packable resin composites were stiffer and less sticky than traditional composites and allowed for easier placement.[5] Manufacturers have eliminated the stickiness by altering the filler morphology (Solitare and ALERT) or the matrix monomers (Filtek P60 and Prodigy).[1]

Packable or high-density posterior resin-based composites are marketed extensively as amalgam substitutes. Their handling properties are similar to those of dental amalgam in that they permit faster placement and tighter interproximal contact with Class II restorations than conventional posterior resin-based composites.[6]

Because of the increasing use of composites and the number of new resin brands, dentists must be aware of the estimated longevity and likely modes of failure of posterior composite restorations. This information is best obtained through randomized, controlled clinical trials.[7] Since packable resin-based composites were only introduced to the market in 1998, clinical studies on these substances have not been extensive.[8]

This study evaluated the six-year clinical performance of Filtek P60 (3M ESPE, St Paul, MN, USA) packable composite restorations in combination with the one-bottle etch and rinse adhesive Single Bond (3M ESPE) in Class II restorations.

METHODS AND MATERIALS

Subjects

Thirty-three healthy adult subjects, 11 male and 22 female, with a mean age of 34 years, were recruited from among patients receiving care at Hacettepe University's Department of Conservative Dentistry. When the study began, Hacettepe University did not have an ethics committee. However, informed consent was obtained from each patient prior to treatment. Forty-seven restorations (approximately one-to-three restorations per subject) were placed in 20 molars and 27 premolars. All the restored teeth were in occlusion with natural dentition and had proximal contact with adjacent teeth.

Operative Procedure

Both a preoperative radiograph and clinical photograph were taken of the site. Shade selection was made prior to the restorative procedure, while the teeth were moist, using a Filtek P60 3 shade guide (A_3, B_2, C_2), which was produced by 3M ESPE. The cavity was prepared using a conservative cavity design and a flat end cylinder bur (836 R Diatech, Heerbrugg, Switzerland) in a high-speed handpiece. All carious tooth structure was removed using a steel round bur (Dentsply/Maillefer, Tulsa, OK, USA) in a low-speed handpiece. The cavity preparation was limited to the removal of caries. Adhesive cavity design was performed without beveling the cavosurface margins. Isolation was achieved with cotton rolls and salivary evacuation.

After preparation, a thin layer of calcium hydroxide liner (Dycal, Dentsply/Caulk, Milford, DE, USA) was placed in the deepest part of the cavity to protect the pulpal tissue. No liner was used in moderate and superficial cavities. Metal band matrices (ivory and flat bands, E Hahnenkratt, Ltd, Königsbach Stein, Germany) with wooden wedges (Barman's anatomical wedges, Swedish Dental Supplies, AB, Akarp, Sweden) were used to establish the anatomical shape and proximal contacts of the teeth. The enamel was etched for 30 seconds, then the dentin was etched for 15 seconds with

37.5% phosphoric acid gel (3M ESPE) and washed for 20 seconds. After thoroughly rinsing with water, the cavity was carefully dried for no more than three seconds in order to prevent dessication. The one bottle adhesive Single Bond (3M ESPE) was then applied to the etched surfaces according to the manufacturer's instructions (Table 1). The operator checked the surfaces to confirm that they were uniformly glossy before light curing (Hilux Expert, Benlioglu Dental, Ankara, Turkey) for 10 seconds. The composite Filtek P60 (3M ESPE) was packed into the cavity with a non-serrated amalgam plugger in 2 mm increments. All increments were cured for 40 seconds. The restoration was finished with diamond finishing burs. Final polishing was performed with rubber points (Edenta Composite Polishing Kit, AU, St Gallen, Switzerland).

Clinical Evaluation

The restorations were rated by two independent examiners at baseline and 1, 2, 3 and 6 years with mirrors and probes using the method developed by Ryge, which also is known as the United States Public Health Service (USPHS) criteria.[9] Evaluation parameters included marginal adaptation, anatomical form, surface texture, marginal discoloration, surface staining, post-operative sensitivity and secondary caries. For each of the criteria, a score of Alpha (A) was used to indicate the highest degree of clinical acceptability. The scores of Bravo (B), Charlie (C) and Delta (D) were used to indicate progressively lower degrees of clinical acceptability (Table 2).

Statistical Analysis

Changes in the parameters during the six-year period and the relationship between the baseline scores and those at the recall periods were assessed using a statistical software program. Chi-square tests (2 x 2) were used to examine the differences for the evaluated criteria[10] (p=0.05). The baseline scores were compared with those at the recall periods using the Wilcoxon signed rank test with Bonferroni adjustment.[11]

RESULTS

The results are summarized in Table 3. All the restorations received Alpha (A) scores at the baseline assessment, except for one restoration, which showed postoperative sensitivity. At the one-year recall, all 47 restorations (100%) exhibited Alpha (A) scores. At the two-year recall, two restorations had a Bravo (B) score: one (2.13%) for marginal discoloration and the other (2.13%) for surface staining.

At the three-year follow-up examination, 44 of the 47 restorations (93.61%) were examined. Two patients with a total of three restorations (6.38%) were not included in the examination due to patient dropout. From baseline to three years, the same two restorations (4.55%) as the two-year recall showed a Bravo (B) score, because of marginal discoloration and surface staining.

At the six-year recall, 44 restorations were examined by the operators. The vitality of the restored teeth did not change during the six-year period. Anatomical form and post-operative sensitivity were classified as Alpha (A) for all restorations (p>0.05). According to the radiographs taken, there was no secondary caries in any of the restorations. After six years, two restorations (4.55%) showed evidence of a slight crevice along the marginal interface (p>0.05). Three restorations (6.81%) were graded as Bravo (B) for surface texture and surface staining (p>0.05). Four restorations (9.09%) had marginal discoloration at the six-year recall period (p>0.05). No significant differences were found for any of the clinical criteria (p>0.05). Only two restorations needed repair due to caries that developed independently from the restorations.

DISCUSSION

The marketing of packable or high-density composites as amalgam substitutes has included the advertising of similar handling properties and occlusal wear, the ability to displace non-sectional matrix bands for achieving tight proximal contacts, fast bulk placement and deep light-curing of the composites.[12] However, several packable composites have exhibited unsatisfactory short-term clinical performances.[3] Some of the materials also performed more poorly than expected in terms of packability, polymerization shrinkage, depth of light curing and displacement of the matrix bands. These materials also displayed greater-than-expected microleakage at the dentin margins.[13-16] In addition, their range of shades was limited. They could not be carved, and their surfaces were rougher than minifilled conventional hybrid composites.[17-18]

Condensable or packable resin-

Table 1: *Properties of the Materials Used in the Study*

Materials	Filtek P60	Single Bond
Type of Materials	Packable resin-based composite	One-bottle etch and rinse adhesive
Ingredients	TEGDMA UDMA (urethane dimethacrylate) Bis-EMA (Bisphenol A polyetheylene glycol diether dimethacrylate).	Water Ethanol HEMA BisGMA Dimethacrylates Photoinitiator system Methacrylate functional copolymer of polyacrylic and polyitaconic acids

Table 2: *Ryge Criteria Used for the Clinical Evaluation*

Criteria	Test Procedure	Ryge Score
Marginal adaptation	Visual inspection with explorer and mirror, if needed	A. No visible evidence of crevice along the margin B. Visible evidence of a crevice along the margin into which the explorer penetrates C. The dentin or base is exposed D. The restoration is fractured, mobile or missing
Anatomical form	Visual inspection with explorer and mirror, if needed	A. The restoration is continuous with the existing anatomical form B. The restoration is discontinuous with existing anatomical form, but the material is not sufficient to expose dentin or base C. Sufficient material lost; exposure of dentin or base
Surface texture	Visual inspection with explorer and mirror, if needed	A. The restoration surface is as smooth as the surrounding enamel B. The restoration surface is rougher than the surrounding enamel C. There is a crevice and fracture on the surface of the restoration
Marginal discoloration	Visual inspection with mirror at 18 inches	A. No discoloration anywhere along the margin between the restoration and the adjacent tooth B. Slight discoloration along the margin between the restoration and the adjacent tooth C. The discoloration penetrated along the margin of the restorative material in a pulpal direction
Surface staining	Visual inspection with mirror at 18 inches	A. The restoration matches the adjacent tooth structure in color and translucency B. Slight mismatch in color, shade or translucency between the restoration and the adjacent tooth C. The mismatch in color and translucency is outside the acceptable range of tooth color and translucency
Post-op sensitivity	Asked patients	A. No postoperative sensitivity at any time during the restorative process and study period B. Experience sensitivity during the restorative process and study period
Secondary caries	Visual inspection with explorer and mirror, if needed, and radiographs	A. No evidence of caries B. Evidence of caries along the margin of the restoration

**A: Highest degree of clinical acceptability; B, C and D: progressively lessening degrees of acceptability.*

based composites do not feel like amalgam; when condensed, they can deform a matrix band when inserted with an instrument and allow for tight proximal contact.[2,19-21] These materials have 60% to 70% filler volume. The range of particle sizes is greater than that of "conventional" hybrid resin-based composites whose filler sizes range between 0.04 and 10 micrometers.[22]

In the current clinical study, the authors observed that Filtek P60 packed well and resisted slumping when carving before curing. The material did not stick to instruments, so that the operator did not have to struggle with pull-back, and they finished well.

The resin matrices of Filtek P60 are comprised of Bis-GMA, UEDMA and Bis-EMA (Table 1). The UEDMA monomer has a high molecular weight but presents considerable flow.[23] On the other hand, Bis-EMA monomer is Bis-GMA derived with the hydroxyl groups removed.[24] Filtek P60's molecules form organic matrices that reduce polymerization shrinkage.[25]

In their *in vitro* study, Ersoy and Civelek[26] evaluated the flexural strength, flexural modulus, depth of cure, polymerization shrinkage and microhardness of two packable composites (Filtek P60 and Solitaire 2), one ion-releasing composite (Ariston AT) and two hybrid composites (Charisma and Filtek Z250). They found that Solitaire 2 exhibited the highest volumetric shrinkage, while Filtek Z250 and Filtek P60 exhibited the lowest. Microhardness results revealed the following tendency: Filtek Z250 = Filtek P60 > Ariston AT = Solitaire 2 = Charisma. Because of the low shrinkage and high microhardness of Filtek P60, in the current study, the majority of restorations exhibited Alpha (A) or Bravo (B) scores for the evaluated criteria at the six-year recall.

Loguercio and others[1] compared the three-year clinical performance of four packable resin-based composite restorative materials with a hybrid resin-based composite. Both Sure-Fil and Filtek P60 displayed excellent clinical performance after three years, as did the

Table 3: *Clinical Rating of Restorations at Baseline,1, 2, 3 and 6 Years*

		Baseline	1 Year	2 Years	3 Years	6 Years
Total Restorations		47 (100%)	47 (100%)	47 (100%)	44 (100%)	44 (100%)
Marginal Adaptation	A	47 (100%	47 (100%)	47 (100%)	44 (100%)	42 (95.45%)
	B	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (4.55%)
	C	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	D	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Anatomical form	A	47 (100%)	47 (100%)	47 (100%)	44 (100%)	44 (100%)
	B	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	C	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Surface texture	A	47 (100%)	47 (100%)	47 (100%)	44 (100%)	41 (93.19%)
	B	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (6.81%)
	C	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Marginal discoloration	A	47 (100%)	47 (100%)	46 (97.97%)	43 (97.73%)	40 (90.91%)
	B	0 (0%)	0 (0%)	1 (2.13%)	1 (2.27%)	4 (9.09%)
	C	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Surface staining	A	47 (100%)	47 (100%)	46 (97.97%)	43 (97.73%)	41 (93.19%)
	B	0 (0%)	0 (0%)	1 (2.13%)	1 (2.27%)	3 (6.81%)
	C	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Post-op sensitivity	A	46 (97.97%)	47 (100%)	47 (100%)	44 (100%)	44 (100%)
	B	1 (2.13%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Secondary caries	A	47 (100%)	47 (100%)	47 (100%)	44 (100%)	44 (100%)
	B	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

hybrid resin (Spectrum TPH) that was tested. The current results at the three-year recall were similar to Loguercio's findings. In the current study, none of the restorations were graded Bravo (B) for surface texture at the three-year recall. However, this criterion changed at the six-year recall, when three restorations were classified as Bravo (B).

de Souza and others[27] evaluated the clinical performance of one microhybrid and two packable resin composites by placing them in the occlusal cavities of posterior permanent teeth. They found that the packable (Filtek P60 and Sure-Fil) and microhybrid (Suprafill) resin composites still exhibited excellent clinical performance after a year. In the current clinical study, all restorations also received Alpha (A) scores at the one-year recall.

In a 3.5-year clinical trial, Poon and others[28] evaluated the performance of a packable (SureFil) and a conventional hybrid resin-based (Spectrum TPH) composite used with a self-etch adhesive system. They reported that both composites were satisfactory for the restoration of Class I and moderately-sized Class II cavities. Two composites in this study had an increased risk of bulk fracture when placed in large intracoronal Class II molar preparations.

Köhler and others[10] evaluated the five-year clinical performance of two resin-based composite restorative materials (Superlux Molar and P-50 APC). Fifty-one restorations were available for examination. A total of 16 restorations (11 P-50 APC and 5 Superlux Molar) had failed over a five-year period. The most common reasons for failure were recurrent caries (n=7) and marginal defects (n=4). The mean wear of Superlux Molar was 167 µm and 158 µm for P-50 APC. Eight of the 11 patients with failed restorations were due to caries, and marginal defects had high counts of mutans streptococci at the baseline. The investigators concluded that the failures were not specifically related to material, tooth type or cavity design. However, they suggested that patient factors, such as caries activity, should be monitored and managed.

da Rosa Rodolpho and others[29] evaluated the clinical performance of the posterior resin-based composite P-50, or Herculite XR, over 17 years. At the end of the study, 98 failures were recorded among the 282 restorations, providing a crude estimate of 34.8% failures. The survival rate was not significant for the material, but it was significant between teeth, cavity type and size. The majority of the restorations exhibited Alpha (A) or Bravo (B) scores for the evaluated criteria. The main cause of failure was fracture of both composites. The clinical performance of the evaluated posterior resin composite restorations was acceptable after 17 years. However, the probability of failure for resin composite restorations in molars for Class II and larger restorations was higher.

Türkün and others[30] investigated the clinical performance of three different resin composite materials: Z100, Clearfil Ray-Posterior and Prisma TPH. At the end of the seven-year study, 70 restorations were available for examination. Four restorations had failed due to secondary caries. No statistically significant differences were found among the materials with respect to

color match, anatomic form and secondary caries. The investigators concluded that after seven years, the three posterior composites tested had acceptable clinical performances.

In another study, Türkün and others[11] evaluated the two-year clinical performance of a packable resin-based composite (SureFil). After two years of clinical service, SureFil packable resin-based composites showed a success rate of 96%. The authors considered it successful in clinical situations with limited sized cavities and in proper application of restorative techniques.

The longevity of restorations is dependent upon many factors, including operator skill, the materials and techniques used, the replacement criteria, patients' compliance with oral hygiene advice, the oral environment and the patients' susceptibility to caries.[31] There are no shortcuts when using posterior resin-based composites, and any compromise in the placement technique could have serious consequences for the clinical performance. Dentists should realize that placing a posterior resin-based composite could take approximately two-and-a-half times longer than placing a similar amalgam restoration.[32]

Clinicians need to assess the advantages and limitations of packable composites' use in clinical restorative situations. Evaluations still need to be conducted to reveal the longer-term clinical performance of packable resin-based composites.

CONCLUSIONS

The results indicate that the clinical performance of the posterior composite restoration Filtek P60 (3M ESPE) was acceptable after six years of service.

(Received 26 March 2008)

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