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One-year clinical evaluation of direct nanofilled and indirect composite restorations in posterior teeth

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The aim of this study was to assess the clinical performance of three direct composite resins and two indirect inlay systems in posterior teeth using the modified USPHS criteria. A total of 100 restorations were placed in the molars of 54 patients by one operator. All restorations were directly evaluated by two examiners at baseline, 6 months, and 12 months. Statistical analysis was conducted using McNemar chi-square test at a significance level of 5% ($p<0.05$). Recall rate was 100% at 6 and 12 months, and all the restorations evaluated (*i.e.*, 100%) received Alpha rating for the criteria of retention and gingival adaptation. At 12 months for the surface texture criterion, 80% of Filtek Supreme XT received Alpha rating while it was 95% for Tetric EvoCeram and AELITE Aesthetic. For marginal discoloration, 85% of Tescera ATL and Filtek Supreme XT received Alpha rating while it was 95% for Tetric EvoCeram and AELITE Aesthetic. Further, none of the restorative systems received a Charlie rating for any of the criteria at all evaluation periods. In summary, all the restorations demonstrated clinically satisfactory performance with no significant differences detected among them.

Keywords: Nanocomposite resin, Posterior composite resin, Clinical evaluation

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INTRODUCTION

Esthetic considerations are playing a greater role in the treatment planning of dental care, even in the restoration of posterior teeth[1]. For this reason and also largely because of improved biomechanical properties, direct composite resin restorations are now routinely used as a metal-free alternative for posterior restorations[2]. Besides, another laudable advantage presented by this procedure is that it allows maximum preservation of tooth structure, which concurs with the modern concept of a conservative approach to restorative dentistry[3].

However, early experiences with the direct restorative treatment method indicated that there were more clinical challenges and higher failure rates than amalgam restorations[4]. In the current restorative dentistry landscape, many improvements in materials, techniques, and instruments for placing these posterior composite restorations have occurred since their early days[5]. Esthetic alternatives to cast gold inlays and amalgam restorations include glass ionomers, compomers, direct composites, composite inlays, and ceramic inlays. Nevertheless, the clinical and biological longevity of adhesive restorations is dependent on the performance of the adhesive systems[6]. Bonded restorations require an accurate use of the adhesive technique and knowledge about complex bonding mechanisms[7].

Amongst the currently available composite materials indicated for posterior restorations, hybrid and microhybrid composite resins have high filler loading (more than 60% in volume) with reduced mean particle size (ranging between 0.4 and 1.0 μm). These features provide optimal wear resistance combined with adequate mechanical properties. However, these resins are difficult to polish and surface gloss is lost quickly[8]. As for microfilled resins, they have filler particles of 0.04 μm diameter. These resins have high surface polish and satisfactory color stability. However, microfilled composite resins with low filler loading are not as mechanically resistant as the hybrid resins[9]. For direct composite resins to be considered as an alternative for small- to medium-sized cavities in posterior teeth[10], it is important that various aspects of the patient's occlusion be examined before surgery, such as occlusal contacts, type of restoration of the opposing dentition, presence of wear facets, and position of the tooth within the arch. Having performed such due diligence, favorable or hoped-for esthetic results can be predictably achieved with posterior composite restorations.

Recently, due to an increasing demand for a universal restorative material indicated for all types of direct restorations including posterior teeth, a new category of resin composite was developed and named as nanofilled composites[3]. Nanofilled composites are distinguished from microfilled composites by the loading percentage and the characteristics of the filler particles. On the amount of inorganic filler, microfilled composites are limited in filler loading compared to nanofilled composites. Microfilled composites present nearly 37% to 40% volume filler loading, while nanofilled composites have approximately 60% volume filler loading[9]. On esthetics, strength and durability, dental nanocomposites show high translucency, high polish and polish retention similar to those of microfilled composites while maintaining physical properties and wear resistance equivalent to those of several hybrid composites. Hence, by virtue of the strength and esthetic properties of resin-based nanocomposites, clinicians and dental practitioners can use them for both anterior and posterior restorations[11].

Apart from direct composite resin restorations, indirect laboratory-processed composite resin systems are also an esthetic alternative for intracoronal posterior restorations. Laboratory-processed inlays/onlays fabricated with composite resins provide excellent esthetic results that may also reinforce tooth structure[12]. This is because a more conservative preparation design can be used since the bonding procedures strengthen the cusps and provide additional support for the dentition. Additional clinical benefits include precise marginal integrity, wear resistance similar to enamel, wear compatibility with opposing natural dentition, ideal proximal contacts, and excellent anatomic morphology[13].

Before a restorative material can be applied clinically, its performance must be screened and evaluated using *in vitro* studies. However, a direct correlation between the *in vitro* and *in vivo* performances of an adhesive restorative system can hardly be made. This is because the three-dimensional configuration of a prepared tooth is inherently different from the flat surfaces usually used to test adhesive materials in the laboratory. Additionally, the bonded interface is subjected to a variety of different stresses and more challenging situations over time *in vivo*[14]. For these reasons, clinical evaluations of direct and indirect resin-based composite restorations, which are placed using the currently available range of commercial restorative materials, are needed to substantiate and corroborate the data obtained from the *in vitro* studies of these materials. To the end that relevant criteria can be applied consistently during clinical trials to assess the performance of restorations[15], the United States Public Health Service (USPHS) evaluation system is the most commonly used direct method for quality control of restorations[16]. This scoring system was designed to provide comprehensive evidence for clinical acceptance rather than in degrees of clinical success.

The aim of this study was to compare the clinical performance of three conventionally placed nanofilled composite restorations and two indirect composite inlays at 12 months, using the modified USPHS criteria — also known as Ryge criteria — as the main evaluation tool.

MATERIALS AND METHODS

Patient selection

With approval from the Ethics Committee of the School of Dentistry, Selcuk University (Konya/Turkey), young adult patients were selected from this pool of candidates: routine polyclinic patients of the dental school clinic, as well as volunteers from staff and students and their families. Written informed consent forms were obtained from all patients at the start of this research study.

Each patient required two Class I or II cavities to be restored with a dental composite. The clinical procedures of cavity preparation and restoration placement were performed by one calibrated dentist of the Department of Operative Dentistry. Data presented in this report were derived from the Class I and II resin-based composite restorations placed over a period of 1 year (2005–2006). Operating sites were isolated with cotton rolls and a salivary suction device. Extremely large restorations (*i.e.*, faciolingual occlusal isthmus which was more than two-third of the distance between facial and lingual cusp tips) were avoided. All restorations included for evaluation in this study had all-enamel margins, were in occlusion at baseline, and had no pulp exposure at placement.

In 54 patients, 22 men and 32 women with a mean age of 23 years (range: 20–28 years), a total of 100 Class I and Class II direct composite resin restorations and indirect composite resin inlays were placed. The restorations which were evaluated were distributed as follows: 45 first molars and 21 second molars in the lower arch; 31 first molars and three second molars in

Table 1 Distribution of restorations by location

	FS	TEC	AE	E	TATL	Total
Upper first molar	8	4	10	1	8	31
Upper second molar	1	–	2	–	–	3
Lower first molar	7	11	4	12	11	45
Lower first molar	4	5	4	7	1	21
Total	20	20	20	20	20	100

Table 2 Distribution of restorations by cavity type

	FS	TEC	AE	E	TATL	Total
Class I	11	12	14	11	1	49
Class II	9	8	6	9	19	51
Total	20	20	20	20	20	100

the upper arch. Their distributions in terms of location and cavity type are summarized in Tables 1 and 2 respectively. All teeth were in occlusion and had at least one proximal contact with an adjacent tooth.

Restorative materials

Three nanofilled composite restorative systems (Filtek Supreme XT (FS), 3M ESPE; Tetric EvoCeram (TEC), Ivoclar Vivadent; AELITE Aesthetic (AA), Bisco) and two indirect inlay restorative systems (Estenia (E), Kuraray; Tescera ATL (TATL), Bisco) were used in this study. Their compositions were summarized in Table 3.

Clinical procedure for indirect composite inlays

All cavities were prepared according to the common principles for adhesive inlays. To achieve convergence angles between opposing walls at an estimated 10 to 12 degrees, cavities were prepared with slightly tapered 80-μm grit diamond bur and finished with 25-μm grit diamond bur (KG Sorensen, Brazil) under water cooling. Care was taken to minimize increase in cavity extension. The cavities were prepared with rounded inner line angles and to a depth allowing at least 2 mm of resin material at the occlusal contact area. All undercuts were eliminated.

Before placement of inlay liner, each tooth was isolated with cotton rolls and a saliva suction device. In most cases, a thin layer of calcium hydroxide liner (Life, KerrHawe, Switzerland) was placed at the pulpal and axial walls. Following which, a light-polymerized glass ionomer cement base (Fuji II LC, GC, USA) was placed to eliminate undercuts in deep areas of the cavities and to replace lost dentin. Location of cervical margins above or below the cementoenamel junction was documented after preparation. Complete arch impressions were taken with a C-silicone impression material (Zetaplus, Zhermack, Italy). Provisional restorations were placed with an eugenol-free, light-curing temporary restorative material (Systemp inlay, Ivoclar Vivadent, Liechtenstein). One laboratory technician of the School of Dentistry prepared all the inlays following the manufacturers' instructions.

The E inlays were built up in layers of 2.5 mm maximally, and each layer was polymerized from the occlusal direction for 120–180 seconds with a curing unit (Hilux Expert, Benlioğlu Dental, Turkey). After the composite inlays were removed from the stone model, they were postcured in a light oven (CS-110 Light and Heat Curing System, Kuraray, Japan) for 180 seconds and then in a heat oven for 10 minutes at 114°C to improve the physical properties. As for the polymerization unit provided for TATL inlays (Tescera ATL™ Processing Unit, Bisco, USA), it comprised two specialized cups (one for pressure/light and one for water/pressure/light/heat). TATL inlays were built up in one increment and polymerized on the stone model in the light polymerization cup for 5 minutes. The

Table 3 Compositions of direct composite and indirect inlay systems

Composite material	Organic matrix	İnorganic filler	Filler content (%) (by weight)	Filler content (%) (by volume)	Type of composite
FS XT	TEGDMA, Bis-GMA, UDMA, Bis-EMA	Zirconia-silica nanoclusters (0.6–1.4 μm), silica nanofillers (5–20 nm)	78.5	59.5	Nanohybrid (Direct)
TEC	Bis GMA, UDMA, DDDMA	Barium glass, ytterbium trifluoride, mixed oxide, prepolymer (40–550 nm)	82	61	Nanohybrid (Direct)
AA	EBis-GMA, Bis-GMA	Glass filler, amorphous silica	73	54	Reinforced nanofill (Direct)
TATL	EBis-GMA, UDMA	Glass filler, amorphous silica	20–60	10–40	Microhybrid (İndirect)
E	UDMA, hydrophobic aromatic dimethacrylate, hydrophobic aliphatic dimethacrylate	Surface-treated alumina microfiller, silanated glass filler, silanated glass ceramics	92	82	Hybrid ceramic (İndirect)

TEGDMA: Tetraethylene glycol dimethacrylate;
Bis-GMA: Bisphenol-A-glycidyl dimethacrylate;
UDMA: Urethane dimethacrylate;
Bis-EMA: Ethoxylated bisphenol A dimethacrylate;
DDDMA: Decandiol dimethacrylate;
EBis-GMA: Ethoxylated Bis-GMA

inlays were then removed from the stone model, and composite inlays were postcured in the heat cup submerged in water at a temperature of 120°C and under a pressure of 6 bar.

The processed inlays were adjusted as needed and seated on the master model, and then polished with silicone polisher, brushes, and polishing paste. After a clinical tryout, the inner surfaces of the inlays were etched with 37% phosphoric acid. All inlays were definitively inserted within 1 week after the impressions were made. The bonding of all restorations was performed in a dry working field using cotton rolls and a saliva suction device, but without a rubber dam. The E inlays were cemented with a dual-cure resin cement, Panavia F (Kuraray, Japan); similarly, the TATL inlays were also cemented with a dual-cure resin cement, Duo-Link (Bisco, USA). The inserted restorations were finished with 40-μm grit and 15-μm grit diamond burs (Jota AG, Switzerland), polishing disks and strips (Sof-Lex, 3M ESPE, USA), and a composite polishing kit (Enhance, Dentsply, Milford, USA).

Clinical procedure for direct composite restorations

First, the color of the tooth that needed treatment was determined using a color key. If necessary, local anesthesia was administered to prevent patient discomfort during the restorative procedure. The teeth to be restored were cleaned with a pumice-water slurry in a rubber cup to remove salivary pellicle and any remaining dental plaque. The cavity was opened (or the existing restoration was removed) using a pear-shaped diamond bur (Jota AG, Switzerland) on a high-speed air turbine. Caries was removed by low-speed metal burs (Meisinger, Germany) and hand instruments, leaving discolored but hard dentin at the cavity floor. Cavities were prepared according to the principles of minimally invasive dentistry.

Tooth isolation by means of cotton rolls and a saliva suction device was used for each patient. All cavities were restored using a sectional metal matrix (Contact Matrix, Palodent, USA) which was fixed with a ring and wooden wedges (Kerr, Switzerland), and which was inserted with firm pressure. For all the direct composites, the bonding procedure began with applying freshly mixed self-etch primer (Clearfil SE Primer, Kuraray, Japan) for 20 seconds to the cavity walls, and then dried with gentle air-drying for 5 seconds. Bonding agent (Clearfil SE Bond, Kuraray, Japan) was applied with a microbrush and polymerized for 10 seconds. After application of the self-etching primer and bonding agent, the cavities were filled incrementally with facially and lingually inclined mesiodistal layers of maximally 2 mm. Between each increment (maximally at 2 mm), polymerization was performed with a halogen light-curing unit (Hilux Expert, Benlioğlu Dental, Turkey; tip diameter: 8 mm) for 20 seconds (TEC, AA, FS) or 40 seconds (FS dentin

Table 4 Modified USPHS criteria

Surface texture	Alfa (A)	Surface is not rough
	Bravo (B)	Surface is slightly rough
	Charlie (C)	Surface is highly rough
Marginal integrity	Alfa (A)	Absence of discrepancy at probing
	Bravo (B)	Presence of discrepancy at probing, without dentin exposure
	Charlie (C)	Probe penetrates in the discrepancy at probing, with dentin exposure
Marginal discoloration	Alfa (A)	Absence of marginal discoloration
	Bravo (B)	Presence of marginal discoloration, limited and not extended
	Charlie (C)	Evident marginal discoloration, penetrated toward the pulp chamber
Gingival adaptation	Alfa (A)	Gingival tissues are perfect
	Bravo (B)	Gingival tissues are slightly hyperemic
	Charlie (C)	Gingival tissues are inflammation
Postoperative sensitivity	Alfa (A)	Absence of the dentinal hypersensitivity
	Bravo (B)	Presence of mild and transient hypersensitivity
	Charlie (C)	Presence of strong and intolerable hypersensitivity
Color match	Alfa (A)	Restoration is perfectly matched for color shade
	Bravo (B)	Restoration is not perfectly matched for color shade
	Charlie (C)	Restoration is unacceptable for color shade
Retention	Alfa (A)	Complete retention of the restoration
	Bravo (B)	Mobilization of the restoration, still present
	Charlie (C)	Loss of the restoration

shade). Curing light was directed perpendicular to the occlusal surface. Light output, which did not fall below 600 mW/cm^2, was measured using a handheld curing radiometer (Demetron, Danbury, CT, USA).

After removing the matrix holder and wedges, the gingival areas were cured for 20 seconds from the facial and lingual directions. The occlusion and articulation were checked and adjusted, and then the direct composite restorations were finished with fine-grit diamond instruments (Jota AG, Switzerland), Sof-lex disks (3M ESPE, Seefeld, Germany), rubber polishing instruments, and a composite polishing kit (Enhance, Dentsply, Milford, USA). All finishing procedures were performed under water cooling. In most cases, color photographs of marked occlusal contact points were taken.

Clinical evaluation

Restorations were rated independently with mirror and probe by two experienced dentists (NU, MK) who were not involved with the insertion of indirect composite inlays and direct composite restorations. Restorations were assessed directly after the final finishing (baseline evaluation), at 6 months and 12 months using the modified USPHS criteria (Table 4). This clinical assessment method resulted in ordinally structured data for the outcome variables (alpha=excellent result; bravo=acceptable result; charlie=unacceptable, replacement of the restoration necessary)[5].

Statistical analysis

Ratings for restorations at baseline and follow-up examinations were analyzed using the Fisher's exact test and McNemar chi-square test for each category. The standard value considered to demonstrate statistically significant differences was set at $p \leq 0.05$.

RESULTS

At 1-year recall, all the 54 patients were available for evaluation. The restorations were evaluated for retention and gingival adaptation, whereby 100% Alpha ratings were obtained for both restorative systems. On Alpha rating for the other evaluation criteria, it was as follows: 95% of TATL for color match, 95% of E for postoperative sensitivity, 95% of TEC and AA for marginal discoloration, 95% of TEC and AA for surface texture, and 95% of TATL and TEC for marginal integrity. None of the restorative systems received a Charlie rating for any of the evaluation criteria.

In particular for surface texture (Table 5) and marginal discoloration (Table 6) at 12 months, the lowest ranking results in terms of Alpha rating were as follows: 80% of FS received the Alpha rating for surface texture, and 85% of TATL and FS received the Alpha rating for marginal discoloration.

Using McNemar chi-square test, no statistically significant differences among the restorative materials were shown at baseline, 6 months, and 12 months for all the evaluation criteria. Moreover, all the restorations were rated as clinically acceptable. Nonetheless, for the evaluation criteria of surface texture and marginal discoloration (presented in Tables 5 and 6 respectively), numerical — but not statistically significant — differences were noted.

DISCUSSION

In the present study, new breeds of direct and indirect composites were evaluated using some clinical criteria which had been defined in previous studies[18-20]. In accordance with the American Dental Association guidelines for testing a new material[17], the sample size

Table 5 Results of surface texture evaluation (%)

	Baseline		6 months		12 months	
	A	B	A	B	A	B
FS	100	0	90	10	80	20
TEC	100	0	95	5	95	5
AA	100	0	95	5	95	5
E	100	0	100	0	100	0
TATL	100	0	100	0	100	0

Table 6 Results of marginal discoloration evaluation (%)

	Baseline		6 months		12 months	
	A	B	A	B	A	B
FS	100	0	90	10	85	15
TEC	100	0	100	0	95	5
AA	100	0	95	5	95	5
E	100	0	100	0	100	0
TATL	100	0	90	10	85	15

used in this study was 54 patients, as well as these steps taken to comply with the guidelines: number of restorations (20 per material), distribution of restorations (maximum of two pairs in the same patient), ratio of 1:2 for Class I to Class II restorations.

At all the evaluation periods in this study, the recall rate was 100%. Indeed, availability was still expected to be high at other prolonged evaluation periods because majority of the subjects in this study were young adult patients with a mean age of 23 years (range: 20–28 years), and that they were selected among the volunteers from staff and students and their families. Moreover, such an age range could provide a better performance for clinical evaluations of posterior restorations because of better occlusal harmony.

On the isolation of the restoration site, it could be carried out using different methods. In some clinical studies on posterior composites, rubber dam was used to isolate the teeth[21-23], whereas Turkun[24], Kohler *et al.*[25], and Pallesen and Qvist[26] opted for cotton rolls and saliva suction device. Raskin *et al.*[27], in a 10-year evaluation of posterior composites, did not observe significant differences between these two isolation methods.

According to Mitra *et al.*[11], the nanofilled composite was shown to have equivalent — if not higher — mechanical properties than the hybrid composite, since the nanocomposite showed high translucency, high polish and polish retention similar to those of microfilled composite. In other words, these composites might render satisfactory clinical performance in posterior teeth. Moreover, laboratory-processed indirect composite resin systems are an attractive esthetic alternative for intracoronal posterior restorations[12,13]. Then, apart from posterior restorations, nanofilled composites could also double as satisfactory materials for restorations in anterior teeth.

In their four-year clinical study, Geurtsen and Scholer[28] claimed that the most important problem in posterior composite restorations is marginal discoloration. Marginal discoloration is classified based on the penetration of dye into the pulp. In our study, statistical analysis showed that there were no significant differences in marginal discoloration among the restorative materials, despite the presence of numerical differences. Amongst which, indirect E restorations received 100% Alpha rating for marginal discoloration at all the evaluation periods. In a study by Türkün and Çelik[29], a two-year clinical evaluation of the FS restorations yielded similar marginal discoloration outcome as the present study.

After 12 months of clinical service, more indirect composite inlays received Alpha rating for surface texture as compared to the direct composite restorations. However, in a study by Loguercio *et al.*[30], the nanofilled and microfilled composites showed the best surface appearance after 12 months. In the present study, better anatomic form and surface texture results which were obtained for the indirect composite inlays — although not statistically significant — could be attributed to higher wear resistance. The latter improvement was realized because the indirect composite inlays were postcured in a heat oven for 10 minutes. On the other hand, in a two-year clinical evaluation of direct and indirect composite restorations in posterior teeth by Scheibenbogen-Fuchsbrunner *et al.*[7], no significant differences between these two different types of posterior composite systems were observed.

According to the results of this study, both direct and indirect composite resin restorations demonstrated excellent clinical performance whereby no restorations were rated unacceptable in any aspect of the evaluation. Similarly, in a 12-month evaluation of two posterior composite restorative systems by Neto *et al.*[18], 94.1–100% Alpha ratings were obtained for the evaluated criteria according to the modified USPHS system. In another two-year clinical evaluation by Türkün and Aktener[31], all the posterior composite restorations evaluated were also rated as excellent. In a study by Efes *et al.*[32], all the restorative materials showed only minor changes and that no statistically significant differences in their performance were detected between baseline and the follow-up evaluation at 12 months. In particular, the performance exhibited by nanofilled composite resin after 1 year was similar to the packable and microhybrid composite resins.

In the present one-year clinical study; both the direct and indirect composite restorations were rated as clinically acceptable according to the evaluation criteria used and that there were no statistically significant differences in performance among the tested materials. On the lack of statistically significant differences, it could be due to the multiple similarities — in terms of chemical composition and high filler content — underlying the composites used in this study (Table 3). However, differences might emerge over longer periods of use. Nevertheless, better clinical performance might be obtained using E and TATL since they are indirect composite resins specifically designed for restoring posterior teeth. Furthermore, it is claimed that indirect composites, when tempered with heat and light, could have an enhanced degree of cure, thereby leading to improved physical properties.

CONCLUSION

Results of the present study showed comparable clinical performance among the five composites evaluated. After 1 year, the clinical performance of FS, TEC, and AA showed minor changes compared to baseline. Since the clinical performance of the posterior composite restorations was evaluated as acceptable after one-year use, the tested composites could be indicated for restorations in posterior teeth. However, it is cautioned that a longer observation period would be expedient for further confirming the clinical validity of the composite resin systems for posterior restorations.

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