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ORIGINAL ARTICLE

Clinical Evaluation of Composite Restorations with and without Polyethylene Fiber in First Permanent Molars: A 24-Month Randomized Clinical Trial

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ABSTRACT

Objective: To evaluate the 24-month clinical performance of composite resin restorations with and without polyethylene fiber in the first permanent molars of pediatric patients with extensive caries. **Material and Methods:** In total, 75 Class II restorations were placed in the permanent molar teeth of 75 children (mean age 11.3 years) with (FC; n=38) or without (C; n=37) fiber. One operator placed all the restorations. The restorations were evaluated using the modified USPHS criteria in terms of retention, color match, marginal discoloration, anatomic form, marginal adaptation, secondary caries, and postoperative sensitivity. Statistical data were analyzed using chi-square and Cochran tests ($p<0.05$). **Results:** At the end of two years, 65 restorations (FC:31; C:34) were followed up. No changes were observed during the first six months. After 24 months of follow-up, there were minor changes in marginal adaptation and marginal color in both groups; however, no statistically significant difference was observed between the clinical performances for all criteria ($p>0.05$). **Conclusion:** Extensive composite restorations with or without fibers displayed good clinical performance in high load-bearing areas after 24 months.

Keywords: Composite Resins; Polyethylene; Dentition, Permanent; Molar; Dental Caries.

Introduction

The first permanent molars are the earliest erupting teeth in the permanent dentition. Therefore, they are accepted as the key to permanent dentition and as a guide for alignment [1]. In addition, the first permanent molars exposed to caries attacks early are the teeth most vulnerable to caries, owing to their morphology. The longevity of the restorations of these teeth plays a prominent role in good oral health [2].

Resin composites have been used in dental applications since the 1960s and are now widely used as restorative materials in teeth, with a routine treatment approach in pediatric dental clinics [3]. However, the limitations of resin composites, such as polymerization shrinkage, lack of toughness, and low fracture resistance, have become significant issues in restorative dentistry [4]. These disadvantages result in postoperative sensitivity, secondary caries, and bulk fractures. This adversely affects the longevity of resin composite restorations, particularly in structurally compromised teeth in high-stress-bearing areas [5,6].

Recently, studies on composite materials have focused on developing mechanical-physical properties, reducing polymerization shrinkage, and increasing bond strength [7].

The clinical success of composite resin materials has improved with changes in filling characteristics, the use of low-elastic modulus liners as an intermediate layer [8], the application of incremental techniques [9], and the development of adhesive materials [10].

In general, an ideal restorative material should mimic the intact tooth's optical and functional properties and preserve the weakened residual tooth structure due to extensive caries or trauma. Therefore, further improvements are needed, especially for treating extensively carious permanent molars [11,12].

Fiber-reinforced composite restorations developed in recent years have been presented to improve the negative properties of composite resin systems applied by the traditional method. The fibers act as a crack stopper and reduce polymerization shrinkage by decreasing the mass of composite resin material between the remaining dentin structure and the fiber [13]. Many authors have conducted tremendous research in this field and have reported that polyethylene fiber is an innovative approach [14]. This is because it increases flexural strength and fracture toughness. Its woven fiber orientation provides the stresses to be dispersed throughout the restoration, reinforcing the restoration and the remaining tooth structure in multiple directions [15,16].

In vitro studies on fiber applications with composite resins in restorative dentistry have obtained favorable results [17-20]. However, there are limited follow-up clinical trials [21-23] and a few case reports [24-26] on this subject. Although much is known about its optimal mechanical properties regarding *in vitro* studies, there needs to be more information on the clinical performance of polyethylene fiber in the direct restorations of young permanent teeth severely structurally damaged by excessive caries.

The study aimed to evaluate the clinical performance of composite resin restorations with or without polyethylene fiber in children's excessively carious first permanent molars. The null hypothesis for this study was that using polyethylene fibers with extensive direct composite resin restoration would not improve the clinical performance of areas under high stress.

Material and Methods

Before conducting the study, the research protocol was approved by the Faculty of Medicine Ethics Committee (Ethics No:2018/09) at Selcuk University. This clinical trial was registered at ClinicalTrials.gov (NCT04612543).

Study Design and Patient Selection

This randomized, controlled clinical study compared composite resin restorations with and without polyethylene fibers in the first permanent molar teeth. The materials, compositions, and batch numbers are listed in Table 1.

Table 1. The materials used and their composition.

Materials	Manufacturer	Composition	Batch Lot Number
G-ænial Posterior	GC Europe	Methacrylate monomers (UDMA and dimethacrylate co-monomers), Pre-polymerized fillers (16-17µ): Silica containing Strontium and Lanthanoid, Fluoride containing inorganic fillers with fluorine content> 100 nm: Fluoroaluminosilicate Inorganic fillers <100 nm: silica Traces of pigments, catalysts (Bis-GMA-free) 81 wt%	1409222
Tetric N-Flow	İvoclar Vivadent AG, FL, Schaan	Ba glass, Ba-Al Fluorosilicate glass , Al_2O_3, YbF_3, 79 wt% Bis GMA, UDMA, TEGDMA	1135203
Clearfil SE Bond	Kuraray Med Inc.,Okayama, Japan	Primer: MDP, HEMA, hydrophilic dimethacrylate, N,N-diethanol p-toluidine, water. Adhesive resin: MDP, Bis-GMA, HEMA, hydrophobic methacrylate, CQ, N,N diethanol p-toluidine, silanated colloidal silica	041755
Ribbond –THM	Ribbond Inc, Seattle, WA, USA	Ultra-high molecular weight polyethylene	9532

Patients attending the Department of Pediatric Dentistry, Faculty of Dentistry, Selcuk University, for routine dental care were examined clinically and radiographically using periapical radiography. The study was conducted in 75 patients. The mean age of the patients was 11.3 years (range: 9-14 years).

To be included in the study, all teeth needed to have normal functional occlusion with at least one cusp in occlusal contact. They were all further evaluated radiographically to determine the lesion depth and acceptability. In this analysis, by visual inspection and using an explorer and mirror, the restorations were evaluated according to the following modified USPHS criteria: color matching, marginal discoloration, secondary caries, marginal adaptation, anatomical form, retention loss, and postoperative sensitivity. Satisfactory restorations were scored as either A (ideal) or B (clinically acceptable). Score C was attributed to unsatisfactory restorations. The inclusion and exclusion criteria for selecting patients for the study are shown in the Consolidated Standards of Reporting Trials (CONSORT) statement form [27]. Volunteers participating in the study were informed about the research protocol and possible complications. Finally, two written informed consents (one for parents and the other for children) were obtained from them.

Patients with parafunctional habits, such as bruxism and periodontal problems, and those unable to attend follow-up visits were excluded. Permanent first molar teeth with deep dentin caries, no evidence of pulp complications, and occlusion were included in this study. Permanent first molars with hypoplasia, tissue anomalies, or endodontically treated were excluded from this study.

Randomization and Blinding

Individuals who met the eligibility criteria were selected and allocated into two groups: (C) resin composite and (FC) resin composite with polyethylene fiber groups. Subject randomization was conducted using a computer-generated random list [28]. The number corresponding to each treatment procedure was recorded on cards placed in sequentially numbered, opaque, sealed envelopes. The main researcher (unblinded to the study) opened the envelope immediately prior to the clinical procedure. An unblinded pediatric dentist with more than two years of experience performed all clinical procedures. A randomized controlled study was designed with a sample of 75 first permanent molars randomly divided into two treatment groups. Of the total restorations, 37 were performed with resin composite (group C) and 38 with resin composite with polyethylene fiber (group FC). Each patient received a single application (with or without fibers). Before treatment, patients were provided with the necessary information and instructions regarding good dietary habits and oral hygiene. Two experienced, double-blinded dentists evaluated the restorations according to the modified USPHS criteria. Before starting the assessments, two experienced evaluators, apart from the operator, were trained for intra- and inter-examiner reliability. For this purpose, they observed ten photos representing each score for each criterion. Cohen's Kappa scores calculated for intra and inter-examiner reliability were 0.93 and 0.98, respectively. When any disagreement occurred during the evaluation, the final decision was made by consensus between the evaluators.

Restorative Procedures

Procedures in clinical practice for the restoration of all teeth were standardized and performed by one operator (O.S.). Local and topical anesthesia were applied to all patients before starting the procedure. Deep carious lesions were cleaned with a step-by-step caries removal method until hard dentin (similar to solid dentin) was reached. Extensive cavities were prepared based on a minimally invasive treatment philosophy under the adhesive protocol. Isolation was provided with the help of cotton rolls and saliva ejectors. After the isolation of cavities, the same practitioner performed restoration protocol and material application according to the manufacturer's instructions. The materials used in this study and their contents are listed in Table 1.

Both groups achieved optimal proximal contacts with a metal matrix system (Tofflemire, Kerr Hawe, Bioggio, Switzerland) after cavity preparation. Then, a bonding agent, a two-step self-etch primer and bond (Clearfil SE bond, Kuraray, Tokyo, Japan), was applied to all cavity surfaces according to the manufacturer's instructions. After the bonding procedure, the remaining tooth composite resin walls were created and cured for 20 seconds in the FC group. All light curing was done with a VALO LED light curing unit (Ultradent Products Inc, South Jordan, UT, USA). For circumferential fiber design preparation, the cavity was converted to a class I cavity after the missing walls were restored with composite resin. The optimal length and width of the fiber were then targeted to fit the pre-converted class I cavity properly. The fiber length was measured using a thin matrix band. Prepared ribbond fiber pieces, 2 mm wide approximately 12 mm long (Ribbond THM, Ribbond Inc, Seattle, WA, USA), were wetted with an unfilled resin (Ribbond Wetting resin, Ribbond Inc.) for 2 min in a non-light environment. The inner surfaces of the prepared class I cavities were lined with a flowable resin. After removing the excess resin, the pre-wetted polyethylene fiber was condensed circumferentially, embedded with a hand instrument into the bed of the unpolymerized flowable composite, and then polymerized for 20 seconds. After curing for 20 s, the composite resin was incrementally applied to the rest of the cavity, and each increment was cured for 20 s. Afterward, the excesses determined using the articulation paper in occlusion were removed, and the restorations were completed with the help of microfine finishing diamonds (859.016, 863.016, 379.016 MDT Dental; Afula, Israel). Sof-Lex abrasive discs (Optidisc, Kerrhawe) were used to polish the restorations. In the C group, the clinical procedure was performed as in the FC group, but no fibers were used.

Evaluation and Statistical Procedures

Modified USPHS criteria scores were used to assess the clinical performance of direct composite restorations [26]. Two experienced examiners (T.G. and K.F.) evaluated the restorations. The recall period for baseline evaluation was two weeks after placement of the restoration, while clinical check-ups for the evaluation of restorations were performed at 6, 12, and 24 months.

Statistical analysis was performed using SPSS software. The Wilcoxon-Mann-Whitney test and the chi-square test (5% significance level) were used to compare the data and differences between groups. In this study, in addition to the statistical evaluation of the materials with each other, each material was also examined in terms of the temporal variation of its achievements using Cochran's Q test. Therefore, we evaluated whether the increase in the failure rate of the material over time was statistically significant. Clinical and radiological data were evaluated using Cochran's Q test regarding success and failure rates for each group at all control times. Thus, each group was examined in terms of the change in success rates over time.

Results

The CONSORT diagram of the study (i.e., enrolment, intervention allocation, follow-up, and data analysis) is presented in Figure 1. The study was conducted in 75 patients. The mean age of the patients was 11.3 years (range: 9-14 years).

With an 86% recall rate after 24 months, only 65 of the 75 restorations (31 FC) and (34 C) could be assessed due to several factors, such as unavailable phone numbers or giving up participation. Six and four patients were lost to follow-up in the FC and C groups, respectively, and they were not included in the study. The distribution of restored teeth according to the applications with or without polyethylene fiber and the locations of the restored teeth are presented in Table 2.

The distribution of restorations by teeth was not statistically different regarding the type and jaw ($p>0.05$). The clinical evaluation scores observed at baseline and after the 24-month investigation are presented in Table 3.

For any of the criteria in the clinical evaluation, there was no significant difference between the groups (with/without polyethylene fiber) in the 24-month evaluation period ($p=0.4$). Alpha or Bravo scores were observed in each restoration in both groups. After 6, 12, and 24-month evaluation periods, all restorations received alpha scores for color mismatch, anatomical form, retention loss, and postoperative sensitivity. The Bravo score percentages in the 24 months evaluation period for marginal adaptation criteria were 11,8% (n=4) and 6,5% (n=2), and for marginal discoloration, 8,8% (n=3) and 6,5% (n=2) in C and FC groups, respectively. In terms of secondary caries, one restoration of only group C was scored as Bravo, 2.9% (n=1). All restored teeth had preserved vitality during the study. Moreover, the DMFT scores of groups (C and FC) were 6 and 6.5, respectively.

Meanwhile, there was no statistically significant difference between the groups in terms of modified USPHS (color mismatch, marginal discoloration, marginal adaptation, postoperative sensitivity, retention loss, anatomical form, and secondary caries formation) criteria at the end of 24 months of clinical follow-up ($p>0.05$).

When the groups were evaluated in terms of temporal variation, the changes in marginal discoloration and adaptation criteria were found to be statistically significant in Group C ($p=0.007$, $p=0.029$). In contrast, no significant difference was found in the FC group ($p=0.112$, $p=0.112$).

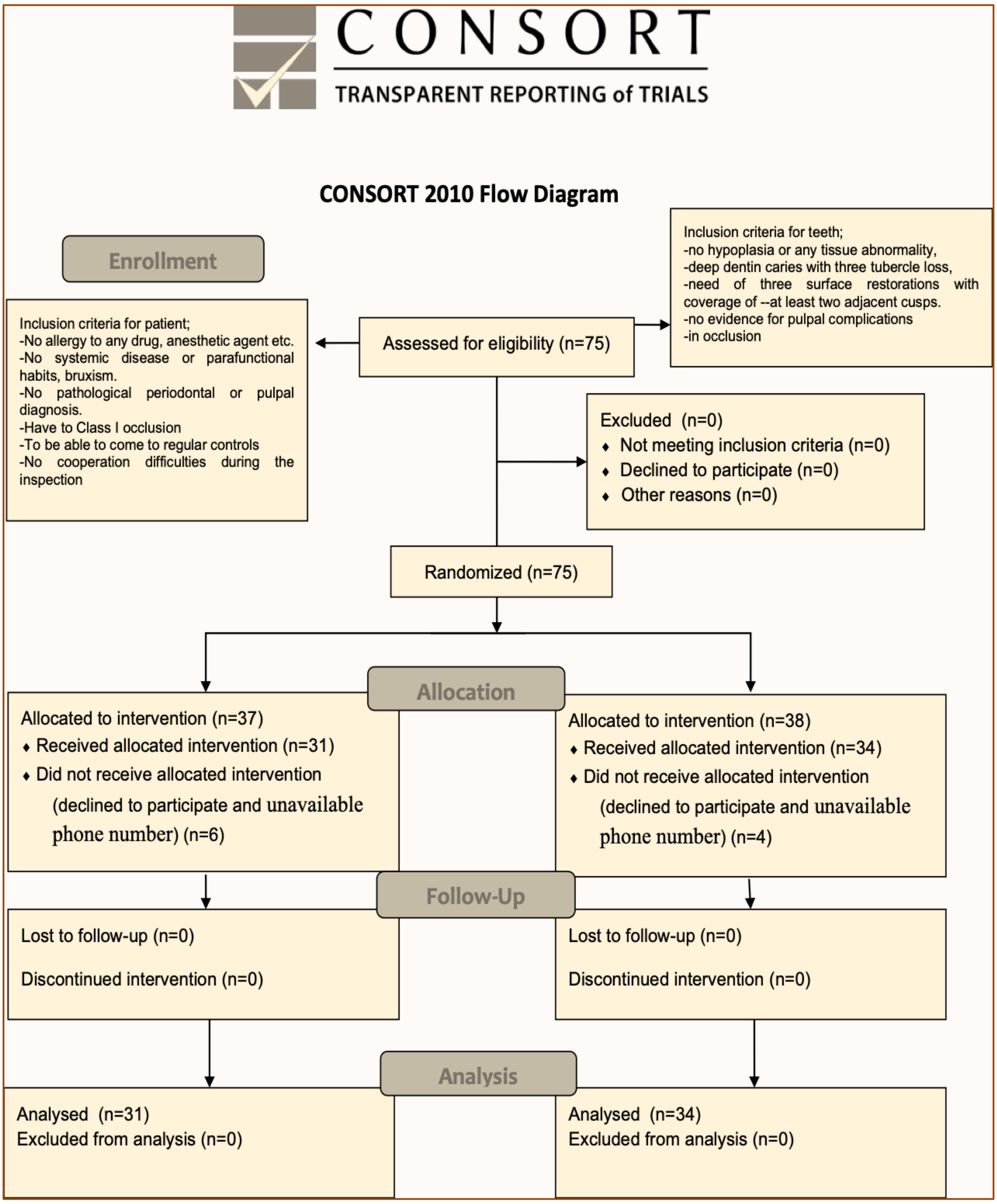

Figure 1. CONSORT flowchart of the study.

Table 2. Distribution of restorations by location.

Location	Groups FC	Groups C	Total	p-value*
	N (%)	N (%)	N (%)	
Upper Right Molar	4 (12.9)	6 (17.6)	10 (15.4)	0.933
Upper Left Molar	6 (19.4)	7 (20.6)	13 (20.0)	
Lower Left Molar	12 (38.7)	11 (32.4)	23 (35.4)	
Lower Right Molar	9 (29.0)	10 (29.4)	19 (29.2)	
Total	31 (100.0)	34 (100.0)	65 (100.0)	

FC: Resin Composite with Polyethylene Fiber; C: Resin Composite; *p<0.05.

Table 3. Results of the clinical evaluation criteria (%) at baseline, 6, 12, and 24-month follow-up.

Criteria	Code	Baseline		6 Months		12 Months		24 Months		Within-group comparison p-value*	
		C	FC	C	FC	C	FC	C	FC	C	FC
Color Match	A	100	100	100	100	100	100	100	100	_	_
	B	0	0	0	0	0	0	0	0		
	C	0	0	0	0	0	0	0	0		
Comparison between groups (p-value*)		-		-		-		-			
Marginal Discoloration	A	100	100	100	100	91.2	93.5	91.2	93.5	0.029*	0.112
	B	0	0	0	0	8.8	6.5	8.8	6.5		
	C	0	0	0	0	0	0	0	0		
Comparison between groups (p-value*)		-		-		0.545		0.545			
Marginal Adaptation	A	100	100	100	100	88.2	93.5	88.2	93.5	0.007*	0.112
	B	0	0	0	0	11.8	6.5	11.8	6.5		
	C	0	0	0	0	0	0	0	0		
Comparison between groups (p-value*)		-		-		0.382		0.382			
Anatomical Form	A	100	100	100	100	100	100	100	100	_	_
	B	0	0	0	0	0	0	0	0		
	C	0	0	0	0	0	0	0	0		
Comparison between groups (p-value*)		-		-		-		-			
Retention Loss	A	100	100	100	100	100	100	100	100	_	_
	B	0	0	0	0	0	0	0	0		
	C	0	0	0	0	0	0	0	0		
Comparison between groups (p-value*)		-		-		-		-			
Secondary Caries	A	100	100	100	100	100	100	97.9	100	0.392	_
	B	0	0	0	0	0	0	2.1	0		
	C	0	0	0	0	0	0	0	0		
Comparison between groups (p-value*)		-		-		-		0.523			
Postoperative Sensitivity	A	100	100	100	100	100	100	100	100	_	_
	B	0	0	0	0	0	0	0	0		
	C	0	0	0	0	0	0	0	0		
Comparison between groups (p-value*)		-		-		-		-			

*p<0.05.

Discussion

In this study, in the first permanent molar teeth with severe structural damage in children, no significant difference was found in the clinical performance of extensive composite resin restorations with or without polyethylene fiber in stress-bearing situations after 24 months. These results confirmed the null hypothesis. Although all restorations were acceptable according to the modified USPHS criteria, the fiber composite group exhibited better results in terms of marginal adaptation and discoloration.

The first permanent molar teeth are considered to be the most important teeth in permanent dentition for reasons such as the control of the teeth erupting in the back and in front of them, the effect on the maintenance of vertical distance between the jaws and their local position in the occlusal arch and providing support for the main masticatory function [19,21]. In addition, the first permanent molars have a higher risk of severe damage and loss due to their specific morphology, the earliest erupting teeth of the permanent dentition, and the fact that most parents do not have sufficient knowledge and awareness about the first permanent molar teeth. Therefore, the first permanent molars, especially those with extensive caries, require special attention during routine dental examinations in pediatric patients [1,2,27].

Routine treatment protocols for excessively carious permanent molars in high-stress-bearing areas involve cast coverage restorations, extensive amalgam restorations, metal-based restorations, and direct-indirect composite restorations [2,5]. These treatment protocols are seen as inadequate, especially in pediatric patients, because of the need to increase the mechanical connection with pins, retention poles, and boxes, creating areas with high stress that significantly weaken the remaining tooth structure, large pulp chamber, and also require more cooperation during the operation [3-5].

With the advancement in adhesive technology, it has become possible to create conservative and highly aesthetic restoration with direct bonding to the teeth using resin composite restoration [28]. The polymerization shrinkage induces stresses that may cause the composite to pull away from the cavity margins, resulting in adhesive failure and marginal gap formation [29]. Further, although nanohybrid composite has high strength, it has a comparatively low fracture resistance in high-stress-bearing areas such as cusp and marginal ridges [30]. To overcome this problem, various fiber reinforcement systems are used to increase the durability and damage tolerance of resin-bonded composite materials [14].

This study proposed a new restorative protocol with a combination of fiber and direct composite resin restoration to preserve the remaining weakened tooth structure in young permanent first molar teeth. The incremental placement technique was used in conjunction with the flowable composite acting as an "elastic buffer" at the base of the pulp chamber, thereby helping to alleviate contractile stresses and improving marginal integrity [31]. This layer further reduces the thermo-elastic mismatch between the components [32].

Many *in vitro* studies have proven that the direct technique for large composite restorations has some limitations due to the composite resin material's low fracture resistance and toughness. The crack that starts in the cavity walls can cause irreparable damage under high vertical and lateral occlusion forces in structurally weakened teeth that are later restored by direct technique with composite resin [10,22,23]. Various investigators, such as Belli et al. [18], Sáry et al. [20], Tanner et al. [33], and Ellakwa et al. [34], have previously demonstrated in their studies the effect on fiber bending properties and strain energy that fiber restoration and tooth fracture resistance are significantly increased. However, clinical studies in this area are inadequate, and current studies are mostly conducted on vital teeth.

In a study evaluating the clinical performance of polyethylene fiber reinforced composites in endodontically treated anterior teeth with three years follow-up, 1 (1.1%) of 65 restorations failed [35]. Van

Dijken and Sunnegårdh-Grönberg [36] reported that the failure frequency for fiber-reinforced resin composites was 9.8% in Class II cavities after three years. In our study, there was no failed restoration after two years. Tekce et al. [37] found no significant difference in a 3-year follow-up study of restorations made with or without fiber in endodontically treated teeth.

Similar to our study, the 30-month follow-up nanofilled-resin restorations with or without glass fiber layering showed similarly high clinical performance. Only minor changes for marginal adaptation, marginal discoloration, color match, and surface texture were observed, and no differences were detected between the evaluated criteria when comparing the baseline with any of the evaluation periods ($p<0.05$) [23]. Another study showed that no statistically significant difference was observed between fiber-reinforced resin composite and nanohybrid composite restorations tested groups for all USPHS criteria at different follow-up periods except for marginal integrity favoring the fiber restoration at 12 months when the difference became significant ($p<0.001$), and color match favoring the nanohybrid indirect resin composite restorations with substantial difference in scores at all follow-up intervals ($p<0.001$) was found [38]. In contrast to our study, everX Posterior and G-aenial Posterior restorations exhibited significant marginal discolorations after three years, and these changes were clinically acceptable and significantly increased over time [37]. In this study, The Bravo score percentages in the 24-month evaluation period for marginal adaptation criteria were 11,8% (n=4) and 6,5% (n=2), and for marginal discoloration, 8,8% (n=3) and 6,5% (n=2) in C and FC groups, respectively.

Differences in fiber geometry, bond between fibers and matrix, amount and size of fiber, resin matrix, and adhesives can be cited as reasons for the difference in failure between the studies [39]. In addition, it is known that the critical fiber length of 3 mm in fiber-reinforced composites has a beneficial effect on fracture resistance by removing the fracture path from the roots [40,41]. The fiber length is also sufficient in our study.

The synergistic effect of fiber and composite has been said to help create a two-layer restoration that can withstand twice the load of a restoration made from conventional composite alone [34]. No difference was observed in our study. Long-term follow-up studies may be recommended. The success of the fiber assembly can also be attributed to the discontinuous phase formed by the continuous polymer resin matrix due to the individual mixing of the strip fiber with the nanohybrid composite during restoration. There is also a high chance of void formation in this complex, which is known to form huge areas where oxygen is blocked and, therefore, is known to reduce the bending strength of the fibers [38,40]. Therefore, extreme care must be exercised during placement [41].

Furthermore, stiff fibers are difficult to adapt closely to the teeth, which may result in uneven thickness of the composite material, which may result in reduced functionality of the reinforced composite in clinical conditions. It is a time-consuming procedure [39,40].

In a study evaluating Class I and II direct composites in deep, wide cavities, all Class II restorations failed after three years [42]. Akalın et al. [43] reported 4.6% for anatomic form changes after two years. Similar to our findings, it has been reported that 100% of direct Class II posterior composite restorations on endodontically treated teeth were clinically graded Alpha after three years. In addition, contrary to our study, Gönülol et al. [44] found a 10% Bravo score for the silorane restorative system and 6.7% for microhybrid resin composite in endodontically treated teeth. A meta-analysis on the clinical efficacy of Class II restorations revealed that loss of anatomical form is material dependent [40]. It has also been reported that restorations made with macro-filled composites and compomers significantly decrease anatomical form quality compared to those restored with hybrid and micro-filled composites [40]. In line with these results, our study's lower wear rates and anatomical form changes may be due to the use of a microhybrid composite (G-aenial Posterior).

In studies evaluating the overall clinical success of the self-etch adhesive system, selective enamel etching has been investigated in clinical evaluations [45-47]. In long-term follow-up clinical studies of selective etching of enamel cavity margins, the clinical efficacy of the Clearfil SE bonding system had a small positive effect on color and integrity at the marginal margin in restoration by selective etching of enamel cavity margins [45,48].

Studies have also confirmed that the use of self-etch adhesive systems should be limited to enamel for additional etching with phosphoric acid. Etching dentin creates a low-quality hybrid layer prone to nanoleakage [48,49]. In our study, selective etching was not applied due to the small amount of enamel remaining in the cavities and the difficulty of application in pediatric patients.

Conclusion

Significant differences were not detected between the composite restorations with and without fiber based on the clinical evaluation criteria. Both restoration groups with and without fiber showed marginal discoloration and marginal adaptation changes. All restorations showed acceptable clinical performance. However, more clinical studies are needed to compare different fiber-reinforced resin composites with direct composite restorations over extended periods.

Authors' Contributions

SÖ	https://orcid.org/0000-0001-7967-9121	Conceptualization, Methodology, Formal Analysis, Investigation, Data Curation, Writing - Original Draft and Writing - Review and Editing.
GT	https://orcid.org/0000-0003-4844-8157	Methodology, Data Curation and Writing - Review and Editing.

All authors declare that they contributed to a critical review of intellectual content and approval of the final version to be published.

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Conflict of Interest

The authors declare no conflicts of interest.

Data Availability

The data used to support the findings of this study can be made available upon request to the corresponding author.

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