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Original research

Clinical evaluation of a self-adhering flowable composite as occlusal restorative material in primary molars: one-year results

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Purpose

The aim of this study was to evaluate and compare the 1 year clinical performances of a self-adhering flowable composite and a commercially available self-etch adhesive/composite system in occlusal restorations of primary second molars.

Patients and Methods

Thirty-one patients (10 male, 21 female) were recruited into the study. A total of 62 occlusal cavities were restored with either a universal composite or a self-adhering flowable composite according to manufacturers' instructions. The restorations were clinically evaluated 1 month after placement as baseline, and after 3, 6 months and 1 year post-operatively using modified USPHS criteria by two operators.

Results

Lack of retention was not observed in any of the restorations. With respect to color match, marginal adaptation, secondary caries and surface texture, no significant differences were found between two restorative materials tested after 1 year. None of the restorations had marginal discoloration and anatomic form loss on the 1 year follow-up. Restorations did not exhibit post-operative sensitivity at any evaluation period.

Conclusion

The clinical assessment of self-adhering flowable composite exhibited good clinical results with predominating alpha scores after 1 year. Advantage of the application convenience for children is promising for self-adhered flowable composite materials in pediatric use.

Keywords: *Self-adhesive; restorative; primary; children; dentition; caries*

Introduction

Dental caries among children continues to be a major public health problem throughout the world. Preservation of primary teeth is important for the maintenance of arch length, maintenance and improvement of physical appearance, maintenance of healthy oral environment, prevention and relief of pain, functions of chewing and speech (1).

Composite resins are esthetic restorative materials used for anterior and posterior teeth. There are variety of resin products on the market with each having different physical properties and handling characteristics based upon their composition for use in primary dentition. Adhesive systems allow bonding of composite resins to primary and permanent teeth. Practical and time saving restorative materials are convenient for the pediatric practices. Research advancements have mainly aimed on the simplification of the technique while enhancing retention of restorations, minimizing microleakage and reducing sensitivity (2). A further advancement in adhesive dentistry is represented by the recent introduction of a so-called "self-adhering composite resin" (compobond), which combines an all-in-one bonding system and a flowable composite (2). Improving marginal

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adaptation of restorations in relation to their rheological properties is also targeted (2-7). Flowable composites, as compared with conventional hybrid composites, exhibit lower mechanical properties due to their reduced filler content (8,9). However for the restoration of cavities in high load-bearing areas, the use of flowable composites is recommended only for cavity lining (10). Conversely, in the restoration of small-sized cavities, as most of the occlusal forces are resisted by the residual tooth structure, the use of flowable composites as stand-alone materials has been recommended (11). Traditional flowable composite resins require a separate bonding system but this self-adhering flowable composite resin eliminates the need for a separate adhesive application. This presents a practical working condition of treatment for children.

The purpose of this study was to evaluate a self-adhering flowable composite and compare its 12 months clinical performances with a commercially available self-etch adhesive / composite system in occlusal restorations of primary molars. The null hypothesis tested in this study is that no difference could be found between the clinical performances of the composite materials.

Patients and Methods

Study design and ethical approval

This single blind randomized clinical trial was approved by Ethics Committee of the University of Cukurova after written informed consent was obtained from the parents or guardians of all children in the study. The study protocol and informed consent document was approved by the Çukurova University Ethical Committee (April 4, 2014, study approval number 30), a subdivision of Turkish Ministry of Health, works full accordance with the World Medical Association Declaration of Helsinki. Split mouth design was conducted according to the Consolidated Standards of Reporting Trials (CONSORT) (12).

From March 2012 to September 2013, all children scheduled to start the dental treatment in pediatric dental clinic were screened by one instructor and enrolled in this study. The inclusion criteria were; being mentally and physically healthy, having at least two occlusal primary caries lesions on primary molars in a split-mouth design with no clinical or radiographic signs of pulpal or periradicular pathology and pathological wear. All of the primary teeth have their occlusal and proximal contacts.

Exclusion criteria were having one of the following situations; disabilities, pulpitis, non-vital or endodontically treated teeth, profound or chronical periodontitis, deep carious defects(close to pulp, < 1mm distance) or pulp capping, heavy occlusal contacts or history of bruxism, systemic disease or severe medical complications, allergic history concerning methacrylate, rampant caries, xerostomia, lack of compliance and language barriers.

After the clinical and bitewing radiographic examination, convenient sample of 33 healthy children between 4 and 9 years of age were selected. Children were asked for their assent after the parents gave written consents. Split mouth design was applied for the study. The children were randomly assigned either right or left halves of their dentition and were treated with local anesthesia and rubber dam isolation by a pediatric dentist. The side, which restoration method was allocated, was assigned by computer-generated randomisation. The advantage of such a split-mouth design over randomising individual patients was the reduction in interparticipant variability (13). Each child was treated by the same operator to avoid behavioral problems.

Interventions

During the restorative procedure, the operator removed only carious lesions and performed no retention such as undercutting or dovetailing. Occlusal cavities were prepared

Table 1: *Restorative Materials*

Materials	Manufacturer	Composition	Application
Vertise flow	Kerr, Orange, CA, USA	GPDM, Prepolymerized filler, 1-micron barium glass filler, nano-sized colloidal silica, nano-sized Ytterbium fluoride	Apply the first layer of Vertise Flow with moderate pressure for 15-20 seconds, light-cure for 20 seconds. For A3.5 and Universal Opaque, cure for 40 seconds.
			If necessary, build the restoration incrementally with Vertise Flow in 2mm or less thickness, light-cure for 20 seconds. For A3.5 and Universal Opaque, cure for 40 seconds.
Clearfil SE Bond primer	Kuraray Medical Inc, Okayama, Japan	MDP, HEMA, dimethacrylate monomer, water, catalyst	Apply for 20 seconds and dry thoroughly with mild air.
Clearfil SE Bond bond	Kuraray Medical Inc, Okayama, Japan	MDP, HEMA, dimethacrylate monomer, microfiller, catalyst	Apply after application of primer, air-flow gently and light-cure for 10 seconds.
Filtek Z250	3M ESPE, St Paul, MN, ABD	BIS-GMA, UDMA and BIS-EMA. Encore-GMA, UDMA, Encore-EMU, Zirconium/ Silicon 60% (0.01 to 3.5 micrometers)	Place Filtek Z250 Restorative in increments. Light-cure each increment for 40 sec (Reference Light-Cure chart for thickness and cure time.)

Abbreviations: GPDM (glyceroldimethacrylate dihydrogen phosphate), MDP(10-methacryloyloxydecyl dihydrogen phosphate), HEMA (hydroxyethyl methacrylate), BIS-GMA (bisphenol-glycidyl methacrylate), UDMA (urethane dimethacrylate), BIS-EMA (bisphenol-polyethylene glycol dimethacrylate)

2mm to 4mm depth. The dentist prepared the teeth with a 330 bur (KG Sorensen, Sa˜o Paulo, Brazil) in a high speed hand-piece with water coolant. Afterwards a round carbide bur was used at slow speed in dentin. During the dental cavity preparation, if pulp tissue was exposed or the required cavity size was larger than the study design, the teeth were excluded from the study. Eventually 2 patients were excluded.

All 31 patient received two different types of restorative treatment. A total of 62 occlusal cavities were restored with either a self-adhering flowable composite (VF) or a commercially available self-etch adhesive/composite system (CR) according to manufacturers' instructions. Restorative materials were handled and applied in accordance with the manufacturers' instructions (Table 1).

Figure 1 shows primary tooth occlusal restoration with self-adhering flowable composite.

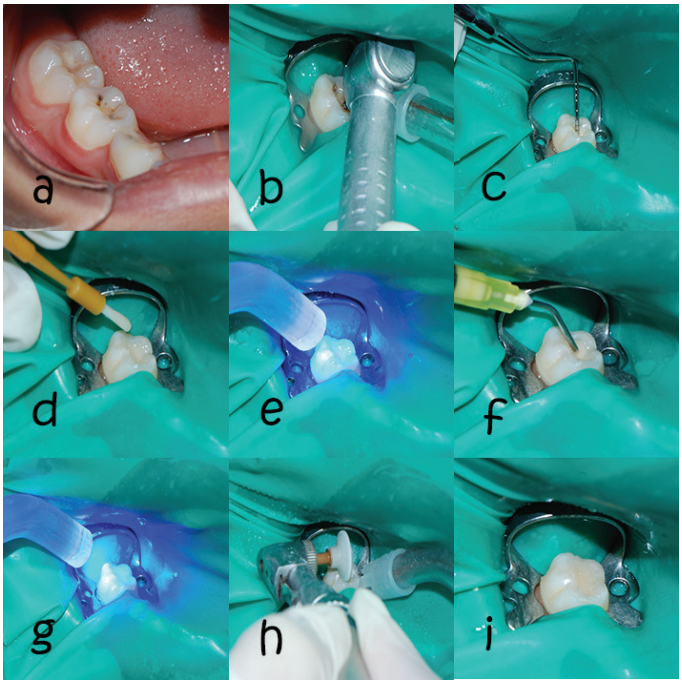

Figure 1. *Cavity preparation and the application of the flowable composite resin. a: preoperative, b: cavity preparation, c: prepared cavity, d: first layer replacement and brushing for 20 seconds, e: 20s polymerization, f: second layer placement, g: 20s polymerization h: finishing and polishing, i: final restoration.*

The occlusal relationship was checked with carbon paper (Accufilm II, Parkell, USA) and adjusted with fine granulation burs. Final finishing and polishing procedures were carried out with fine and ultrafine granulation diamond burs (KG Sorensen, Sa˜o Paulo, Brazil) and finishing was made with a diamond polishing paste (Dentsply, Rio de Janeiro, RJ, Brazil).

Outcomes

The restorations were clinically evaluated 1 month after restorations, and after 3, 6 months and 1 year post-operatively using modified United States Public Health Service (USPHS) criteria by two previously calibrated operators who were different from the treatment applied operator (14). The restorations were re-evaluated by two blind examiners (total weighted kappa (k) between 0.85 and 0.92 for intraexaminer and interexaminer agreements). Each restoration was assessed at baseline placement and at the 1st, 3rd, 6th months and first year with modified USPHS criteria for retention (R), color match (CM), marginal discoloration (MD), secondary caries (SC), wear (W), marginal adaptation (MA) and postoperative sensitivity (PS). The Alfa and Bravo scores were considered clinically acceptable/ successful of the restorative treatment, while, Charlie scores were clinically unacceptable/ unsuccessful restorative treatment and had to be replaced and excluded from the study. All evaluations were carried out with a dental operating light, mouth mirror, dental explorer and dental floss. Figure 2 shows one year follow up pictures of the self-adhesive restorations.

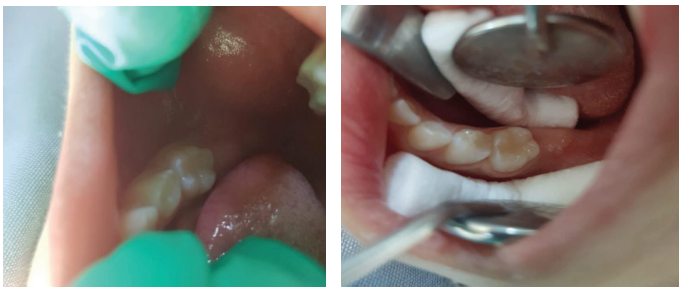

Figure 2. *1 year follow up pictures of the self-adhesive restorations.*

In addition, each patient received professional cleaning of the teeth and neutral topical fluoride application during the dental appointments. All of the procedures were done by the operators involved in the study.

Statistical Analysis

The data were processed by SPSS software (12.0, SPSS Inc., Chicago IL, USA). 'Sample size' was calculated 28 at 80% power, while carrying out a two tailed test at 5% significance level. 'Sample size' was calculated by G*Power 3.0.10 (15). The kappa statistic was used to measure interrater reliability. The descriptive statistics; the frequency, the mean, the standard deviation and median were calculated for each group. Normality was analyzed using Shapiro–Wilks test. Modified USPHS results were assessed by Mann–Whitney U-test at significance level of $p<.05$.

Results

Baseline characteristics (patients and teeth)

31 patients attended the 1st, 3rd and 6th months recall and 29 patients attended 1 year recall. Lack of retention was not observed in any of the restorations. Split mouth design avoids residual confounding. The age, gender and bio-characteristic of the two groups were identical. Baseline characteristics of the groups; are also included the modified USPHS criteria's of the treatment day results; are given at the Table 2. The children were between the ages of 4 to 9, mean 6.67.

Baseline data and final outcome

With respect to color match, marginal adaptation, marginal discoloration, secondary caries, postoperative sensitivity no significant differences were found between a self-adhering flowable composite (VF) and a commercially available self-

Table 2: *Baseline characteristics of the groups*

	N	Frequency	Mean/median	
gender				
male	15	%48.4		
female	16	%51.6		
Age				
4	2	%6.5	6.67/7	
5	4	%12.9		
6	7	%22.6		
7	9	%29.0		
8	7	%22.6		
9	2	%6.5		
group				
CR	31	%50		
VF	31	%50		
Modified USPHS criteria				
Retention*/alpha/bravo/charlie*	62	%100	1	Alpha
Color Match*/alpha/bravo/charlie*	62	%100	1	Alpha
Marginal Discoloration*/alpha/bravo/charlie*	62	%100	1	Alpha
Secondary Caries*/alpha/charlie*	62	%100	1	Alpha
Wear*/alpha/charlie*	62	%100	1	Alpha
Retention*/alpha/charlie*	62	%100	1	Alpha
Color Match*/alpha/charlie*	62	%100	1	Alpha

Table 3: *Modified USPHS scores of 1st and 3th month*

	1.month		3. month	
	VF Mean±SD (Median)	**CR Mean±SD (Median)**	**VF Mean±SD (Median)**	**CR Mean±SD (Median)**
Retention	1.00±0.00(1.00)	1.03±0.18(1.00)	1.03±0.18(1.00)	1.03±0.18(1.00)
Color Match	1.03±0.18(1.00)	1.00±0.00(1.00)	1.03±0.18(1.00)	1.00±0.00(1.00)
Marginal Discoloration	1.00±0.00(1.00)	1.00±0.00(1.00)	1.00±0.00(1.00)	1.03±0.18(1.00)
Secondary Caries	1.00±0.00(1.00)	1.00±0.00(1.00)	1.03±0.18(1.00)	1.00±0.00(1.00)
Wear	1.00±0.00(1.00)	1.00±0.00(1.00)	1.00±0.00(1.00)	1.03±0.18(1.00)
Marginal Adaptation	1.00±0.00(1.00)	1.03/ 1.00/ .189	1.00±0.00(1.00)	1.03±0.18(1.00)
Postoperative Sentisivity	1.03±0.18(1.00)	1.03±0.18(1.00)	1.03±0.18(1.00)	1.03±0.18(1.00)
Total	7.06±0.25(7)	7.10±0.31(7)	7.16±0.37(7)	7.6±0.45(7)

Mann whitney U test for grouping materials VF (self adhering flowable composite) and CR (commercially available self-etch adhesive/ composite system) for the 1. and 3. months; $p<0.05$ is statistically significant

etch adhesive/composite system (CR) after 1 month, 3 months, 6 months and 1 year (Figure 2). Table 3 showed the difference between the groups according to results of first and third month USPHS control. A score called 'total' which was the sum of the modified USPHS scores; were added to the tables. At the end of the 3th month 'Total' scores were also not statistically significant between the groups (p=0.765).

Table 4 shows the 6th month and 1 year results of the VF and CR groups, there were no significant differences between the groups for retention, color match, marginal discoloration, secondary caries, wear, marginal adaptation, postoperative sensitivity and total USPHS criteria.

Discussion

This study aimed to evaluate the clinical performance of a new self-adhering flowable composite for 1 year using modified USPHS criteria. Based on the findings of

Table 4: *Modified USPHS scores of 6th month and 1 year results*

	6. month		1. year	
	VF Mean±SD (Median)	CR Mean±SD (Median)	VF Mean±SD (Median)	CR Mean±SD (Median)
Retention	1.03±0.18(1.00)	1.00±0.39(1.00)	1.00±0.00(1.00)	1.10±0.49(1.00)
Color Match	1.03±0.18(1.00)	1.00±0.00(1.00)	1.03±0.18(1.00)	1.00±0.00(1.00)
Marginal Discoloration	1.06±0.35(1.00)	1.03±0.18(1.00)	1.07±0.37(1.00)	1.10±0.41(1.00)
Secondary Caries	1.03±0.18(1.00)	1.03±0.18(1.00)	1.07±0.25(1.00)	1.03±0.18(1.00)
Wear	1.00±0.00(1.00)	1.03±0.18(1.00)	1.00±0.00(1.00)	1.07±0.25(1.00)
Marginal Adaptation	1.03±0.18(1.00)	1.06±0.18(1.00)	1.03±0.18(1.00)	1.07±0.25(1.00)
Postoperative Sensitivity	1.06±0.25(1.00)	1.03±0.18(1.00)	1.07±0.25(1.00)	1.07±0.25(1.00)
Total	7.26±0.77(7)	7.29±0.58(7)	7.28±0.79(7)	7.31±0.60(7)

Mann Whitney U test for grouping materials VF (self adhering flowable composite) and CR (commercially available self-etch adhesive/ composite system) for the 6. month and 1st year; $p<0.05$ is statistically significant.

the present study; clinical assessment of self-adhering flowable composite exhibited acceptable clinical results with predominating alpha scores after 1 year. Incorporation of the bonding agent into a flowable composite holds great potential such as; saving chair time and minimizing handling errors. In this study, a commercially self-etch adhesive and a composite resin was used as control group because of its announced gold standard for in vitro studies and its good clinical performance.

The self-adhering flowable composite holds great potential with respect to saving chair time and minimizing handling errors. The advantages for pediatric dentistry are reducing operative procedures, minimizing the technical sensitivity, simultaneous demineralization and resin infiltration as well as in reducing postoperative complaints like pain (16).

The use of flowable restorative systems in dentistry has increased because of their beneficial properties, such as low viscosity, low modulus elasticity and ease of handling (13). For the restoration of cavities in high load bearing areas, the use of flowable composite resins are recommended only for cavity lining but flowable composites has been proposed for the restoration of small-sized cavities, while the occlusal forces are resisted by the residual tooth structure (2).

Various methods were designed for clinical evaluation of restorations (17,18). Among them, modified United States Public Health Service (USPHS) criteria has been used the most widely with various modified forms to determine the clinical performance of dental restorations (14,19-21). In this study modified USPHS criteria was used which is a long-established method used in clinical trials. In between the two materials there were no difference for the criteria's 'retention', 'color match', 'marginal discoloration', 'secondary caries', 'wear', 'marginal adaptation' and 'postoperative sensitivity' in the first, third, sixth months and the first year.

There were limited studies about self-adhering flowable composite resin. Pacifici et al. (22) had concluded that occlusal cavities, restored with self-adhering flowable composite resin, provided satisfactory sealing ability despite the relatively low bond strength recorded on enamel and dentin. The results of the study by Tuloğlu et al. (23) showed that, the self-adhering flowable composite resin has lower bond strength values than conventional flowable resin composite for both primary and permanent dentin. They suggested that the use of a bonding agent significantly increased the shear bond strength values of self-adhering flowable composite resin to both permanent and primary tooth dentin. Self-adhering flowable composite resin established similar bond strength values as glass ionomer cements on primary dentin (24). Although VF resulted in lower bond strengths values on either dental substrate, better marginal sealing ability was visualized in comparison with all-in-one adhesive systems (2,25). Recent studies showed similar successful results of clinical usage of self-adhesive flowable restorative materials in primary dentition (26,27).

The preservation of primary teeth is important for the management of the developing dentition until normal exfoliation takes place. Restorations of primary teeth are usually performed using composite resin, compomer or glass ionomer and needs to be durable. For the clinical success of composite resin restoration an effective bond between dental materials and tooth substrates is critical (28). Pediatric restorative dentistry is a dynamic area with rapid development of technology and new materials. Among the materials used in the pediatric dental restorations, self-adhering flowable composite resin, with its clinical handling properties and the ability of reducing the time on dental unit, has different advantages during dental treatment.

Conclusion

Clinical assessment of self-adhering flowable composite exhibited good clinical results with predominating alpha scores after 1 year in this study. The findings of this clinical study suggest that self-adhering flowable composite resin can be used successfully in occlusal cavities of primary teeth. The advantage of the application convenience for children is promising for self-adhered flowable composite materials in pediatric use.

Türkçe Öz: *Kendinden adezyonlu akışkan bir kompozitin süt dişlerinde okluzal kavite materyali olarak klinik değerlendirmesi: 1 yıllık sonuçlar. Amaç: Kendinden adezyonlu akışkan kompozitler ayrı bir adeziv olmadan*

diş dokusuna bağlanır ve bond maddesini doğrudan akışkan rezinin içine yerleştirerek restoratif prosedürü kolaylaştırır. Bu çalışmanın amacı, kendinden adezyonlu akıcı bir kompozitin ve konvansiyonel bir kompozit sisteminin klinik performanslarını 12 ay süresince değerlendirmek ve karşılaştırmaktır. Gereç ve Yöntem: Otuz bir hasta (10 erkek, 21 kadın) çalışmaya alındı. Üreticinin talimatlarına göre konvansiyonel bir kompozit veya kendinden adezyonlu bir akışkan kompozit ile toplam 62 okluzal kavite restore edildi. Restorasyonlar işlem sonrası 1 ay ve sonrasında 3, 6 ve 12. aylarda modifiye USPHS kriterleri ile klinik olarak değerlendirildi. Bulgular: Restorasyonların hiçbirinde retansiyon problemi gözlenmedi. Renk uyumu, marjinal adaptasyon, ikincil çürükler ve yüzey dokusu açısından 12 ay sonra test edilen iki restoratif materyal arasında anlamlı bir fark bulunmadı. Restorasyonların hiçbirinde 12 aylık takipte marjinal renk değişikliği ve anatomik form kaybı olmadı. Restorasyonlar, herhangi bir değerlendirme sırasında işlem sonrası hassasiyet göstermedi. Sonuç: Kendinden adezyonlu akıcı kompozitin klinik değerlendirmesi, 12 ay sonra baskın alfa skorları ile iyi sonuçlar vermiştir. Çocuklar için uygulama rahatlığının avantajı, pediatrik kullanımda kendinden adezyonlu akıcı kompozit malzemeler için umut vericidir. Anahtar Kelimeler: Kendinden adezyonlu; restoratif; süt; dişlenme; çocuk; çürük

Ethics Committee Approval: The study protocol and informed consent document was approved by the Çukurova University Ethical Committee (April 4, 2014, study approval number 30).

Informed Consent: Informed consents was provided by the participants' parents.

Peer-review: Externally peer-reviewed.

Author contributions: BAS, IY and MCD designed the study. IY and CD participated in generating the data for the study. BAS and IY participated in gathering the data for the study. IY participated in the analysis of the data. BAS and IY wrote the majority of the original draft of the paper. BAS and IY participated in writing the paper. All authors approved the final version of this paper.

Conflict of Interest: The author had no conflict of interest to declare.

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