Original Article / Özgün Araştırma

Clinical Evaluation of Using Three Different Materials in Primary Molar Class II Restorations

Süt Molar Dişlerinin Sınıf II Restorasyonlarında Üç Farklı Materyalin Klinik Başarısının Değerlendirilmesi

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Abstract

Objective: This study aimed to compare the 12-month clinical performance of a glass carbomer cement (GCP glass fill), a glass hybrid cement (Equia Forte) and a compomer material (Dyract XP) in primary molar class II restorations.

Materials and Methods: The study was carried out on 105 primary molars with class II lesion in 35 children aged 6-9 years. Three different restorative materials were placed in each child. Restorations were evaluated according to the modified United States Public Health Service criteria after the first week and at sixth and 12th months. Data obtained were evaluated statistically.

Results: After 12 months, 32 children were available and 96 restorations were evaluated. The clinical success of the compomer material, glass carbomer cement, and glass hybrid cement were 96.9%, 15.6%, and 9.4%, respectively.

Conclusion: After the 12-month treatment period, the clinical success of the compomer material was significantly higher than those of the glass carbomer cement and glass hybrid cement groups.

Öz

Amaç: Bu çalışmanın amacı süt dişi sınıf II restorasyonlarında bir cam karbomer siman (GCP Glass Fill), bir cam hibrid siman (Equia Forte) ve bir kompomer materyalin (Dyract XP) 12 aylık klinik performansının karşılaştırılmasıdır.

Gereç ve Yöntemler: Çalışma 6-9 yaş arası 35 çocuğun sınıf II çürüğü bulunan 105 adet süt molar dişinde yürütülmüştür. Tüm çocuklarda her 3 materyal de kullanılmıştır. Restorasyonlar 1. hafta, 6. ay ve 12. ay sonunda modifiye Birleşik Devletler Halk Sağlığı Servisi kriterleri ile skorlanarak, sonuçlar istatistiksel olarak değerlendirilmiştir.

Bulgular: On iki ay sonunda 32 çocukta 96 restorasyon değerlendirilebilmiştir. Grupların klinik başarısı sırasıyla; kompomer grubunda %96,9, cam karbomer grubunda %15 ve cam hibrid grubunda ise %9,4 olarak bulunmuştur.

Sonuç: Kompomer materyalinin klinik başarısı 12 aylık takip sonunda hem cam karbomer hem de cam hibrid siman gruplarına göre istatistiksel olarak anlamlı düzeyde yüksek bulunmuştur.

Introduction

In recent years, the studies on restorative materials used for the restoration of primary teeth are continuing intensively. The properties required for these restorative materials are; physical and chemical properties should be compatible with the dental tissue, the aesthetic and mechanical properties should be satisfactory and its technical application to the cavity should be quick and easy.

Polyacid-modified composite resins, also known as compomers, and resin-modified glass ionomer cements are the most commonly used materials for the restoration of primary teeth; however, both materials are controversial due to their resin content (1,2). The use of traditional glass ionomer cements (GICs), which do not contain resin, is limited due to its moisture sensitivity, fracture resistance, low wear resistance, difficulties in processing materials and lack of aesthetics (3). For these reasons, the search for the restorative material of the primary tooth, which does not contain resin material but is sufficient regarding the physical and mechanical properties until the exfoliation of the primary tooth, continues.

In the recent years, glass hybrid restorative systems (Equia Forte Fil) in the high viscosity GIC group, which are developed to eliminate the existing problems such as moisture sensitivity and low physical-mechanical properties of GICs, have been introduced to the market. Glass hybrid cements are easy-to-use restorative systems with smaller and more reactive silicate particles and acrylic acid molecules with higher molecular weight (4).

Glass carbomer cements, which were developed as a result of the biomimetic studies while the search for an ideal restorative continues, are GIC with carbomer filler and nano-sized flourapatite/ hydroxyapatite speacially designed for its compounds. These materials are chemically hardened and do not contain monomer, resin, metal and Bisfenol A. Heat application and coating its surface with a special varnish is necessary for glass carbomer cements to develop (5).

There are many studies showing that compomer materials are successful alternatives to the composite, amalgam and GICs for the primary teeth class II cavities (6-8). However studies on clinical success of glass carbomer and glass hybrid cements are limited. The aim of this study was to compare the clinical succes of a glass carbomer cement (GCP Glass Fill) and a glass hybrid cement (Equia Forte Fil) in comparison with a compomer material (Dyract XP); due to the concerns over the resin content of compomer materials.

Materials and Methods

Ethics committee approval required for our research was received from the Board of Research Ethics Committee of Aydın Adnan Menderes University Faculty of Dentistry (protocol no: 2017/002, date: 22.03.2017). The patients and their parents who participated in the study, were informed in details and their written consents were received.

The G*Power program (version 3.1.9.2 for Windows) was used to determine the success rate of the power analysis: the total number of samples detected was n=24, for the effect size: 0.576, with a power: 0.80 and α: 0.05. Considering the follow-up aspect of the study, total sample size was determined as 35 due to the possibility of loss in the follow-up.

This study was performed on 35 (20 boys, 15 girls) children aged between six to nine years (average 7,5) who applied Aydın Adnan Menderes University, Faculty of Dentistry Department of Pediatric Dentistry and those participants with a behavior rating three or four scores according to the Frankl behavioral scale (9). Patients having at least three primary molar teeth with class II caries not exceeding ½ of dentin in the radiographic examination, no indication for pulp therapy or other restorative treatment, no undermining of cusps by caries, no caries lesions extending below the gingival margin, not showing pathological internal or external root resorption, and not exceeding 2/3 of the root of physiological root resorption were included to the study. The children were given oral hygiene instructions and additional dental treatments required for other teeth were done during the study period.

Patients with a history of known or suspected allergy and with a history of bruxism, skeletal and dental malocclusion, congenital developmental defect and those who stated that they could not come to their controls regularly were excluded from the study.

The cavity preparation was performed under water cooling with high-speed diamond burs, under local anesthesia if needed, according to minimally invasive preperation rules. Caries was removed with

hand tools and steel burs. Rubber-dam (OptiDam™, Kerr) isolation was used in children who were cooperative and first molar teeth was present in the mouth. Isolation was achieved with cotton roll and suctions in such cases as; the first molar teeth was not present in the mouth; or when parents did not approve the application of rubber dam or in children whose cooperation was affected negatively during the rubber-dam application. In each child three teeth were restored with different materials, by using stratified block randomization and simple randomization methods. The teeth were restored with one of the Compomer material (Dyract XP, Dentsply, Germany), Glass Carbomer Cement (GCP Glass Fill, GCP, Netherlands) or Glass Hybrid Cement (GC Equia Forte Fil, GC Industrial Co, Tokyo, Japan) by using Palodent® Plus matrix system. Restorative materials were applied according to the manufacturers' directions by a single practitioner. Glass carbomer and glass hybrid cements were exposed to heat treatment with a light-curing of GC D-Light Duo LED at 1200-1350 mW/cm^2 light intensity during hardening. For surface protection, both of the glass carbomer and glass hybrid cements were covered with GCP Gloss (GCP, Netherlands) which does not contain resin material. The content of the materials used in the research are provided in details in Table 1.

Restorations were evaluated clinically after one week, six months and 12-months according to the modified United States Public Health Service (USPHS) evaluation criteria (10). Radiographic examination was performed with bite-wing radiographs at sixth and 12th months.

Statistical Analysis

Statistical analysis was performed using the IBM SPSS Statistics 17.0 (IBM Corporation, Armonk, USA) programme. Cochran's Q test was used to determine the significance of the difference in terms of success rates with respect to monitoring time regarding USPHS criteria. The results for $p<0.05$ were considered statistically significant unless indicated otherwise.

Results

Statistical evaluation was carried out from the data of 32 patients and 96 (91.42%) restorations; since three patients did not attend their appointments during the 12-month follow-up. The average age of the patients was 7.5±1.0 (year) and 19 (59.4%) of them were boys and 13 (40.6%) of them were girls. In eight (25.0%) cases restorations were performed under rubber-dam isolation.

When overall results in three restorative material groups were evaluated, no statistically significant differences were observed in the incidence of success between the genders ($p>0.0056$). Also, there was not any significant difference between the restorations performed under rubber dam or cotton rolls isolation ($p>0.0056$).

Table 1. Materials and their contents used in the study

Material	Type	Content	Producing company
Dyract XP	Compomer	UDMA, TCB Resin, TEGDMA, trimethacrylate and dimethacrylate resin, camphoquinone, ethyl-4benzoate, BHT, UV stabilizator, strontium-alumino-sodium-floro-fhosphor-silicate glass, silicon dioxide, stronsium flour, iron oxide and titanium oxide pigments	Dentsply, Germany
Prime & Bond NT	Dentin bonding agent	PENTA, UDMA, Tresin, D-resin, nanofiller, photoinitiator, stabilizators, acetone, cetylamine hidroflorid	Dentsply, U.S.A
GCP Glass Fill	Glass carbomer cement	Floro-aluminosilicate, glass apatite, polyacid	GCP, Netherlands
GC Equia Forte Fil	Glass hybrid cement	Floroaluminosilicate glass, polyacrylic acid dust, processed glass particule	GC Industrial Co (Tokyo, Japan)
GCP Gloss	-	Modified polysiloxane	GCP, Netherlands

UDMA: 4-trimethylhexane, TCB: Tungsten-carbide burs, TEGDMA: Triethylene glycol-dimethacrylate, BHT: Butylhydroxytoluene, UV: Ultraviolet

The results of the restorations regarding modified USPHS criteria during the 12-months follow-up period are shown in Table 2. In terms of overall success, success rates at first week are statistically similar between the three groups of restorative materials (p=0.174), however; there is a statistically

Table 2. The results of the restorations regarding modified United States Public Health Service criteria during the 12-months follow-up period

			Compomer	Glass carbomer cement	Glass hybrid cement
Anatomical form	1st week	Alpha	32 (100%)	28 (87.5%)	30 (93.8%)
		Bravo	-	2 (6.3%)	1 (3.1%)
		Charlie	-	2 (6.3%)	1 (3.1%)
	6th month	Alpha	31 (96.9%)	10 (31.3%)	9 (28.1%)
		Bravo	-	2 (6.3%)	-
		Charlie	1 (3.1%)	20 (62.5%)	23 (71.9%)
	12th month	Alpha	31 (96.9%)	5 (15.6%)	2 (6.3%)
		Bravo	-	1 (3.1%)	2 (6.3%)
		Charlie	1 (3.1%)	26 (81.3%)	28 (87.5%)
Marginal integrity	1st week	Alpha	32 (100%)	30 (93.8%)	29 (90.6%)
		Bravo	-	-	2 (6.3%)
		Charlie	-	2 (6.3%)	1 (3.1%)
	6th month	Alpha	31 (96.9%)	6 (18.8%)	8 (25%)
		Bravo	-	6 (18.8%)	1 (3.1%)
		Charlie	1 (3.1%)	20 (62.5%)	23 (71.9%)
	12th month	Alpha	30 (93.8%)	2 (6.3%)	3 (9.4%)
		Bravo	1 (3.1%)	4 (12.5%)	1 (3.1%)
		Charlie	1 (3.1%)	26 (81.3%)	28 (87.5%)
Marginal discoloration	1st week	Alpha	32 (100%)	32 (100%)	31 (96.9%)
		Bravo	-	-	-
		Charlie	-	-	1 (3.1%)
	6th month	Alpha	32 (100%)	21 (65.6%)	20 (62.5%)
		Bravo	-	-	-
		Charlie	-	11 (34.4%)	12 (37.5%)
	12th month	Alpha	31 (96.9%)	10 (31.3%)	9 (28.1%)
		Bravo	-	1 (3.1%)	-
		Charlie	1 (3.1%)	21 (65.6%)	23 (71.9%)
Color match	1st week	Alpha	32 (100%)	16 (50%)	23 (71.9%)
		Bravo	-	16 (50%)	8 (25%)
		Charlie	-	-	1 (3.1%)
	6th month	Alpha	32 (100%)	6 (18.8%)	11 (34.4%)
		Bravo	-	14 (43.8%)	8 (25%)
		Charlie	-	12 (37.5%)	13 (40.6%)
	12th month	Alpha	31 (96.9%)	2 (6.3%)	2 (6.3%)
		Bravo	-	8 (25%)	6 (18.8%)
		Charlie	1 (3.1%)	22 (68.8%)	24 (75%)

Table 2 continued

Retention loss	1st week	Alpha	32 (100%)	29 (90.6%)	31 (96.9%)
		Bravo	-	3 (9.4%)	-
		Charlie	-	-	1 (31%)
	6th month	Alpha	31 (96.9%)	11 (34.4%)	9 (28.1%)
		Bravo	-	9 (28.1%)	11 (34.4%)
		Charlie	1 (3.1%)	12 (37.5%)	12 (37.5%)
	12th month	Alpha	31 (96.9%)	6 (18.8%)	3 (9.4%)
		Bravo	-	4 (12.5%)	6 (18.8%)
		Charlie	1 (3.1%)	22 (68.8%)	23 (71.9%)
Secondary caries	1st week	Alpha	32 (100%)	32 (100%)	32 (100%)
		Bravo	-	-	-
	6th month	Alpha	32 (100%)	27 (84.4%)	29 (90.6%)
		Bravo	-	5 (15.6%)	3 (9.4%)
	12th month	Alpha	31 (96.9%)	12 (37.5%)	9 (28.1%)
		Bravo	1 (3.1%)	20 (62.5%)	23 (71.9%)

significant difference between the clinical success of the materials at sixth and 12th months (p<0.001) (Figure 1). The overall success rates are significantly lower in glass carbomer cement and glass hybrid cement groups, when compared to the compomer group (p<0.001). The overall success rates of glass carbomer cement and glass hybrid cement groups are statistically similar at sixth and 12th month (p=0.774 and p=0.687 respectively) (Table 3).

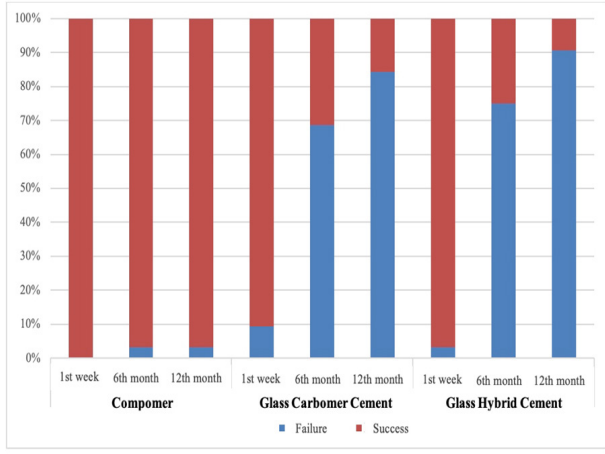

Figure 1. Overall success rates of the three groups

Discussion

As concerns over the biocompatibility of resin-based materials have increased over the last few years, there has been an increasing trend towards resin-free, biocompatible, remineralization-enhancing

Table 3. Overall success rates according to materials and follow-up times

	Compomer (n=32)	Glass carbomer cement (n=32)	Glass hybrid cement (n=32)	p-value †¶
1st week	32 (100%)	29 (90.6%)[a,b]	31 (96.9%)[a,b]	0.174
6th month	31 (96.9%)[A,B]	10 (31.3%)[A,a]	8 (25%)[B,a]	<0.001
12th month	31 (96.9%)[A,B]	5 (15.6%)[A,b]	3 (9.4%)[B,b]	<0.001
p-value ‡¶	0.368	<0.001	<0.001	-

•†Comparisons between materials within each follow-up time, ‡Comparisons between follow-up times in material groups, ¶Cochran's Q test, results for p <0.0167 were considered statistically significant according to the Bonferroni Correction, [A]The difference between the Compomer group and the Glass Carbomer Cement group is statistically significant (p<0,001), [B]The difference between the Compomer group and the Glass Hybrid Cement group is statistically significant (p<0.001), [a]The difference between the 1st week and the 6th month is statistically significant (p<0.001), [b]The difference between the 1st week and the 12th month is statistically significant (p<0.001)

restorative materials (11,12). GICs are one of the most frequently used restorative materials in pedodontics. However; the weak physical and mechanical properties of conventional GIC, its sensitivity to dryness and moisture, lack of aesthetics limits its use (13). Manufacturers have introduced restorative materials such as glass carbomer cement and glass hybrid cement in order to eliminate the negative features of GIC's and provide alternative restorative materials used frequently in the posterior region (3,14). In this clinical study, it was aimed to examine the clinical success of these biocompatible materials compared to a compomer material, which has been widely used in primary teeth.

The negative impact of external effects on the material during the long-lasting hardening reaction of GICs is one of the most important disadvantages and to reduce this critical time as much as possible is desired. It is thought that heat polymerization shortens this period and enables GIC to reach optimum physical properties in a shorter time (15,16). With all this information and according to the recommendation of the manufacturer, in order to obtain the best clinical results; glass carbomer and glass hybrid cement restorative materials were processed with heat through D-Light Duo LED Curing Light light source of 1200-1350 mW/cm^2 light power for 90 seconds, in our study.

Moisture isolation can be provided by the use of rubber dam or cotton rolls together with the suctions. In eight patients who participated our study, isolation was provided with rubber-dam and suctions; and for the rest of the patients cotton rolls and suctions were used. It has been reported that the use of rubber dam or cotton rolls for isolation had the same effect on the clinical success of the restorations (17-19). Similarly, in our study, no significant difference was found between the restorations done with either rubber dam or cotton rolls.

USPHS criteria, first published in 1971 and reprinted in 2005, is still the most widely used system to evaluate the important features of dental restorations (10) so; in our study, modified USPHS criteria was used to evaluate restorations.

The results of our clinical study has shown that, the rate of clinically successful restorations at the end of 12 months were 96.9% in the Dyract XP group, 15.6% in the GCP Glass Fill group and 9.4% in the Equia Forte group. In the literature there are many studies showing that compomer materials are successful alternatives to the composite, amalgam and GICs for the primary teeth class II cavities (6-8). Pascon et al. (7) who compared the clinical success of compomer and composite restorations for 24 months; have concluded that the compomer groups showed high clinical success in both class I and class II restorations when compared to composite restorations. Welbury et al. (20) compared the clinical success of a compomer material with a glass ionomer material in primary molar teeth restorations. They reported that after 42 month follow up compomer restorations were significantly more successful than the glass ionomer restorations. Similarly Duggal et al. (8) have reported high retention rates of compomer restorations in class II primary molar teeth when compared with amalgam restorations. In our study the compomer material group showed 96.9% success after 12-months and this result was significantly better than the other two restorative materials.

When the clinical studies examining the GICs were evaluated, it has been reported that the annual failure rates for class I restorations vary between 0% and 17% and for the class II restorations these rates vary between 2.2% and 25.8%. One of the reasons for the varying failure rates in the studies may be the different types of GICs used in the studies (21). The two types of GICs used in our study showed much more higher failure rates than these studies. Although the number of in-vivo studies using GCP Glass Fill is very low, studies evaluating the clinical performance of this material have shown that it has significantly lower clinical success (36%) than a compomer material (56%) in class II restorations (22,23). Similarly in our study GCP Glass Fill restorations were found to be unsuccessful compared to the Dyract XP restorations and have the same clinical success as Equia Forte Fil. The failure of the GCP Glass Fill restorations may be due to the low mechanical properties and the surface covering that cannot protect the material sufficiently.

Success of high viscosity GICs in permanent teeth was evaluated in a few clinical trials and acceptable retention performance was reported (24-26). The studies evaluating the clinical performance of high viscosity glass ionomers in primary teeth are fewer. De França et al. (22) compared the survival rate of atraumatic restorative treatment (ART) class II

restorations in primary teeth, performed with glass carbomer cement and a high-viscosity GIC. After 12 months, the overall success rates of glass carbomer cement and high-viscosity GIC groups were 56% and 86%, respectively and this difference was found to be statistically significant. Olegário et al. (23) have reported a survival rate of 56% after three years of occlusoproximal ART restoration with high-viscosity GIC. The results of these studies do not fully agree with the results of our study. The reason for the low clinical success results in Equia Forte Fil group in our study may be contributed to the covering applied over the material. During the application of restorations, the recommendations of the manufacturers have been followed but as a result of our search for alternative resin-free, biocompatible restorative material for primary teeth, instead of using resin containing surface covering Equia Forte Coat, the surface of the Equia Forte Fil restorations were covered with resin-free silicone-containing surface covering GCP Gloss. This may have negative effects on the mechanical properties of the material (27). Another group with Equia Forte Coat coverage could be added to find out the effect of resin covering on Equia Forte Fil, and this could be the limitation of our study.

Conclusion

Widely used compomer materials in primary teeth restorations have high clinical success rates but they have resin content. In this study we aimed to find an alternative restorative material for primary teeth restorations with no resin content. However; it can be concluded that neither GCP Glass Fill nor Equia Forte Fil applied without resin covering was found to be a good alternative to Dyract XP. Different clinical studies with long-term follow-ups are needed regarding this issue.

Ethics

Ethics Committee Approval: Ethics committee approval required for our research was received from the Board of Research Ethics Committee of Aydın Adnan University Faculty of Dentistry (protocol no: 2017/002, date: 22.03.2017).

Informed Consent: The patients and their parents who participated in the study, were informed in details and their written consents were received.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Concept: I.S., Design: I.S., Ş.E., Supervision: I.S., Ş.E., Fundings: I.S., Ş.E., Materials: Ş.E., Data Collection or Processing: Ş.E., Analysis or Interpretation: I.S., Ş.E., Literature Search: Ş.E., Critical Review: I.S., Ş.E., Writing: I.S., Ş.E.

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