12-MONTH CLINICAL PERFORMANCE EVALUATION OF A GLASS CARBOMER RESTORATIVE SYSTEM

Zeynep Kaynar[1] and Nazmiye Dönme[2]

[1]Okan University Faculty of Dentistry
[2]Bezmialem Vakif University

October 21, 2020

Abstract

Rationale,aims and objectives:The aim of this in vivo study was to evaluate the clinical 1 year follow-up of silica and flouroapatite reinforced glass carbomer filling material.Materials and Methods:In this study, total of 100 restorations were performed.All cavities were prepared conventionally.Half of the restorations were restored with nano composite resin (TEP) (Tokuyama Estelite, Tokuyama Dental, Japan) and the other half were restored with glass carbomer material (GC) (GCP Dental, The Netherlands). Each restorative material was applied according to the manufacturer's instructions. Restorations were evaluated with modified USPHS criteria at the end of the first week, 6 months and 12 months.Data were analyzed using Fisher's Exact Chi-Square test, Fisher Freeman Halton Test and Continuity (Yates) Correction.Wilcoxon sign test was used for intra-group comparisons of the parameters.Statistically significance was evaluated at $p < 0.05$.Results:When the filling materials were compared with each other, statistically significant difference was observed at the 12th month on the marginal discoloration. Statistically significant difference was observed between the two materials in the 6th month on the marginal adaptation ($p<0.05$).Conclusions:In view of this results, there is a need to improve the physical properties of the GC filling material and further in vivo study. Clinical Relevance:Due to not provide good marginal sealing for Class II cavities, it is suggested that GC systems are applied to Class I cavities for now. Key Words; Glass-carbomer; Glass-ionomer cement; Resin composite; Clinical trial ClinicalTrials.gov Identifier: NCT04127929 (16.10.2019)

INTRODUCTION

Glass ionomer cements (GIC) have become one of the most widely used materials in dentistry since the 1970s (1). Properties of being able to chemically bond to dental hard tissues, showing anticarcinogenic properties, releasing fluoride, and having an expansion coefficient close to dentin have made the use of GICs widespread. Despite all these advantages, its disadvantages, such as poor compressive, tensile strengths and aesthetic properties, having low fracture and wear resistance, inability to eliminate microleakage, short working time, and long-lasting hardening process, have led to studies to improve the material (2). Glass carbomer cement (GC) (GCP Dental, Netherlands) is one of the materials that have been developed as a result of studies on the improvement of GICs.

Although GC are considered a glass ionomer-based material, the presence of nano-sized powder particles and fluorapatite distinguish GCs from GICs. In the development of this material, it is aimed to create an enamel-like structure using nanoparticle technology(3, 4). There are nano-sized fluorapatite/hydroxyapatite particles in the content of GCs. The addition of nano-hydroxyapatite and nano-fluorapatite is known to increase the mechanical properties of glass ionomers and their bond strength to dentin(5). The reactive glasses inside them are modified with dialkyl siloxanes. The liquid of GC consists of weak polyacrylic acid and does not contain resin, solvent, and monomer (6, 7). With the addition of fluorapatite, the GIC is converted to a material similar to fluorapatite (8). Furthermore, thanks to the fine structure of cement, a smooth and polished surface similar to resin composites has been obtained.

GC is used together an organic, biocompatible surface coating gloss (GCP Gloss, GCP Dental) that is carbon-silicone based. The gloss aids in producing an excellent restorative material by improving the transparency which is necessary for optimum heat-based setting. It also maintains the restorative material from moisture and saliva contamination during the initial setting phase, and from dehydration later on (8). The monomer-free condition and the addition of nano- sized hydroxyapatite and fluorapatite particles in GC ensures it a more biocompatible option than RMGIC (9).

Similar to GICs, GCs are also chemically hardened. Manufacturers have recommended that the wear resistance and compressive strength of the material is increased through the use of a light device with a high light power during the hardening process of GC.

Although the mechanical and physical properties of the GC restorative system have been studied laboratory studies in the literature, there is a limited number of studies investigating the clinical performance of this material. Therefore, the aim of this randomized controlled clinical trial was to compare the clinical performance of GC with a nanohybrid posterior composite resin (TEP) (Tokuyama Estelite Posterior,Tokyo,Japan) in the restoration of Class II and Class I cavities and to evaluate the clinical performance for 12-months.The hypothesis of the study was that both restorative systems would have similar clinical performance.

METHOD

Study design

This study was a randomized, controlled, double-blinded clinical trial where teeth were randomly assigned to one of the two restorative material groups with an allocation ratio 1:1.

This clinical study was approved by Clinical Research Ethics Committee. Patients were informed about the purpose of the study, treatment strategies, dental materials to be used, risks of treatment and written consents were taken before beginning the study. The study was registered at Clinical Trials.gov Protocol Registration and Results System with the ID: NCT04127929 (16.10.2019). PASS Sample Size Software (NCSS, LLC, Kaysville, Utah) was used to calculate the sample size. In order to get the f= 0.25 effect difference between the groups with 80% power and an alpha error of 5%, at least 50 restorations per group were needed.

The study sample consisted of 100 premolar/molar teeth in healthy, cooperative patient with the following eligibility criteria: patient (26 female, 10 male) between the ages of 20 and 25 years (mean age: 23 years) with a proximal and occlusal lesion on at least one premolar or molar who were available for follow-up after 1 week, 6 months and 12 months of restoration placement. All patient were recruited from the Restorative Dentistry Clinic at Faculty of Dentistry, during the period from October 2017 until April 2019.

Inclusion and exclusion criteria

The inclusion criteria were; (a) no systemic disorders, (b) older than 18 years of age (20-25 years of age), (c) presence of molar/premolar teeth with occlusal or proximal caries, (d) no parafunctional habits such as grinding or clenching of the teeth, (e) having good cooperation, (f) having agreed to attend regular follow-up controls. The exclusion criteria were; (a) presence of any indication for endodontic treatment or extraction (abscess, swelling, and fistula, pain in palpation and percussion, spontaneous pain or night pain), (b) teeth with congenital developmental defect, (c) teeth with pathological mobility, (d) patients under the age of 18, (e) teeth which do not have normal occlusion due to skeletal or pathological reasons, (f) loss of contact or opposite teeth. Tooth Selection criteria were (a) being vital, (b) no sensitivity to percussion, (c) no spontaneous pain, (d) no luxation, (e) having agreed to come to regular follow-up controls

Lesion Selection

A total of 100 Class I (54), and Class II(46) (MO or OD) carious lesion at levels of D1 or D2 (according to clinical and radiographic evaluations) with minimum two and maximum four permanent premolars or molars according to International Caries Detection and Assessment System (ICDAS) (10) were included to the study.

Randomization and Allocation

The included teeth were assigned randomly by the second author blindly, using the "bowl technique," to one of the two restorative material groups.

According to type of restorative material to be applied, patients included in the study were randomly divided into two groups. (1.group) Nano-hybrid composite restoration group (ClassI; 28, Class II; 22) and (2.group) Glass Carbomer restoration group (Class I; 26, Class II;24). Two different restorative materials were used in this study (Table 1).

Restorative procedure

The same experienced dentist performed all restorative procedures. Routine professional oral care, including dental surface cleaning and oral hygiene motivation, were performed. The initial photos of the teeth were taken using a digital camera (Nikon D7200, Tokyo, Japan) with the help of an intraoral photo mirror.

Local anaesthesia (Ultracain DS Fort, Sanofi Health Products, Istanbul, Turkey) was performed depending on the patient's needs. The removal of caries on the occlusal and proximal surfaces of the teeth was started using aerator (W&H, Austria) and diamond burs (G&Z Instruments, Austria). A steel bur was used to remove caries in dentin tissue. Cavities were prepared in accordance with the minimally invasive approach.

Before restoration of the teeth, cavity isolation was provided with rubber-dam, cotton rolls and saliva suction for both materials. The sectional matrix system (Palodent V3, Dentsply, USA) was used to create a contact in Class II cavities. For composite resin restoration group, in both cavity types (Class I and Class II), enamel edges were roughened by 35% orthophosphoric acid for 30 seconds according to selective etch method. After rinsing and drying procedures, two-step self-etch adhesive system (Clearfil SE Bond, Kuraray, Japan) was applied in both cavity types (Class I and Class II), where composite material would be applied. The cavities were restored using both restorative materials according to the manufacturer's instructions. In nano-hybrid composite restoration group, composite material was applied in the cavities with incrementally and light cured with LED light curing unit (VALO Cordless, Ultradent,U.S.A.) set at a standard power of 1000 mW/cm^2 was used for polymerization. For Glass carbomer restoration group, etching and bonding procedures were not applied. In Glass carbomer restoration group, glass carbomer material was placed in the cavity in a single stage. After the cavity was completely filled, the surface cover with silicone content was applied to the cavity and condensed with finger pressure. After that, the restoration was cured for 60 seconds using the GCP CarboLED (GCP Dental), which is a thermo-cure, high-energy lamp that operates on wavelengths higher than those produced by regular light-cure devices (1400 mW/cm^2)

After removing the rubber dam, occlusion control, finishing, and polishing was done with fine grain, yellow band, end flame-shaped diamond burs. (G&Z Instruments, Austria). The restorations were polished under water cooling using polishing pastes containing diamond particles (Kuraray Twist Dia, Japan). The all restorative procedures steps are showed in Fig. 1.

Clinical evaluation

The restorations were evaluated clinically one week, and subsequently 6-month and 12 month follow-ups. The clinical evaluation was performed by two calibrated observers other than the clinician who performed clinical applications using modified United States Public Health Service (USPHS) criteria (Table 2) (11). Restorations were scored using the terms Alpha, Bravo and Charlie. Alpha was used for restorations that were considered clinically successful; Bravo was used for the restorations with several deficiencies but requiring no replacement; and Charlie was used for the clinically unacceptable restorations where the restoration had to be replaced (12). In case of a disagreement, a consensus between examiners was achieved after discussion. Prior to the study, calibration was performed on e-calib between the two observers.

Statistical Analysis

Statistical analysis was performed with SPSS Statistics software, Version 22. Fisher's Exact Chi-Square test, Fisher Freeman Halton Test and Continuity (Yates) Correction were used to compare qualitative data.

Wilcoxon sign test was used for intragroup comparisons of parameters. Level of significance was set at $p < 0.05$.

RESULTS

A flow diagram is presented in Fig. 2. After 12-months, 100 restorations in 36 patients were evaluated and scored according to the USPHS criteria. The overall clinical recall rate of restorations at the 12-months recall was 100%. The clinical properties of the restorations were evaluated according to CONSORT flow diagram. The clinical properties of the restorations were evaluated according to the modified USHPS criteria and scored (Table 3).

Retention: No significant difference was found between the one-week, six-months and 12-months performance results of the both of restorative material groups in terms of retention. In the TEP group, there was no statistically significant change in terms of alpha score in the 6 and 12-months compared to the one-week ($p>0.05$).In GC, there was a statistically significant increase in Charlie score in the 12\sout-months (8%) compared to the 1 week (0%) (Fig. 3).

Surface Texture Change: There was no significant difference between the two restorative materials in terms of surface texture changes in the one-week, six-months and 12-months.In the TEP group, Bravo scores for surface texture change in the sixth month (10%) and 12-months (16%) were found to be statistically significantly higher compared to the one-week (0%) *($p=0.05$).* In GC, Bravo scores for surface texture change in the sixth month (14%) and 12-months (14%) were found to be statistically significantly higher compared to the one-week (0%) *($p<0.05$).*

Colour Match: There was no significant difference between the two restorative materials in terms of colour match in the one-week, six-months and 12-months.In the TEP group, there was no statistically significant change in terms of colour match in the six-months and 12-months compared to the one-week. Also in the TEP group, there was no statistically significant change in terms of colour match in the 12-months compared to the sixth month ($p>0.05$).In GC, Bravo scores for colour match in the six-months (10%) and 12-months (10%) were found to be statistically significantly higher compared to the one-week (0%) ($p<0.05$).There was no statistically significant change in terms of colour match results in the 12-months compared to the sixth-months results (*$p>0.05$).*

Marginal Discoloration: There was no significant difference between the two restorative materials in terms of marginal discoloration in the one-week and 12-months.A statistically significant difference was observed between the two restorative material groups in terms of discoloration at the 12-months *($p<0.05$)* . In GC group, Bravo and Charlie scores for marginal discoloration in the 12-months (12% and 14%, respectively) were found to be statistically significantly higher compared to the one-week (0% and 0%, respectively) (*$p<0.05$*).Bravo and Charlie scores for marginal discoloration in the 12-months (12% and 14%, respectively) were found to be statistically significantly higher compared to the six-months (4% and 0%, respectively) (*$p<0.05$*) (Fig. 4).

Anatomic Form: There was no significant difference between the two restorative materials in terms of anatomic form in the one-week, six-months and 12-months.In the TEP group, Bravo scores for anatomic form in the six-months (10%) and 12-months (8%) were found to be statistically significantly higher compared to the one-week (0%)

($p<0.05$).

In GC group, Bravo and Charlie scores for anatomic form in the six-months (16% and 4%, respectively) and 12-months (18% and 8%, respectively) were found to be statistically significantly higher compared to the one-week (0% and 0%, respectively)

($p<0.05$).

Marginal Adaptation: When both restorative material groups were evaluated in terms of marginal adaptation, the percentages of Alpha scores for marginal adaptation were 100% in the TEP group and 90% in the

glass carbomer group at the one-week.Although the difference between them was close to the significance level, no statistically significant difference was observed between them (p>0.05).Percentages of Bravo scores for marginal adaptation was 16% and 0% in the glass carbomer group and TEP group in the six-months, respectively. There was a statistically significant difference between the groups in terms of Bravo scores for marginal adaptation (p=0.006; p<0.05).In the TEP group, the Bravo scores at the 12-months (10%) was found to be statistically significantly higher compared to the one-week (0%) (p=0.025; p<0.05).A statistically significant increase was observed between the six-months and 12-months Bravo scores (0% and 10%, respectively) *(p<0.05).* In GC group, there was a statistically significant increase in Bravo score at the 12th month (16%) compared to the first week (10%) (*p<0.05).*Bravo and Charlie scores at the 12-months (20% and 10%, respectively) were found to be statistically significantly higher compared to the six-months (16% and 0%, respectively) *(p<0.05)* (Fig. 5).

Secondary Caries: No secondary caries was observed in any groups at the one-week, six-months and 12-months.

Postoperative Sensitivity: No statistically significant was observed between the materials in terms of postoperative sensitivity at the one-week, six-months and 12\sout-months.

DISCUSSION

Although a large number of laboratory studies have been conducted on this new material (GC) in recent years, the results of studies evaluating the clinical success of this material have not been clear yet when used as a permanent restorative material in adult individuals. The present clinical study evaluated the clinical performance of the glass carbomer filling material used in adults as a permanent restorative material. At the end of the study, differences were observed between the materials in terms of marginal discoloration, marginal adaptation, anatomic form and retention. Therefore our hypothesis was partially rejected.

Today, composite resin materials are the most preferred restorative materials in the restoration of the posterior and anterior teeth. Composite resins show shrinkage during polymerization, leading to several disadvantages including microleakage, deterioration of marginal adaptation, marginal fractures, postoperative sensitivity and development of secondary caries. Glass carbomer filling material, one of the glass-ionomer based restorative materials developed in recent years, has been introduced as an alternative restorative material to composite resins.

The literature review showed that there were no clinical studies in which GC was used as a restorative material for the restorations for adults, however, there were studies where it was used as a fissure sealant. In a study by Gorseta et al.(13), glass carbomer and resin-based fissure sealant material were used as fissure sealants and 100% clinical success was achieved in both materials in terms of retention at the 6-months, however, this rate decreased to 75% at the 12\sout-months but it was not statistically significant. In a four-year clinical follow-up study by Zhang W et al. where high viscosity GIC, GC, and resin-based fissure sealant were used as fissure sealants, GC group was found to be less successful in clinical practice compared to other materials (14).

Azza A. El-Housseiny et al. concluded in their study that Glass carbomer restorations were showed significantly worse clinical performance than resin-modified glass ionomer and composite restoration in at first primary molars in terms anatomical form and marginal adaptation (15). These results are similar to our study.

In a three-year clinical follow-up study by Xuan Hu et al. when glass carbomer fissure sealant, resin-based fissure sealant, and glass ionomer fissure sealant were used, no significant differences were observed between the materials in terms of pit and fissure retention rate (16).

Chen et al. conducted a study in which they followed the anti-caries effects of glass ionomer, GC and resin-based fissure sealants for six months, one year and two years and found that the lowest retention rate was in the GC group at the end of two years (17).

In a study by Olegario et al., GC, high viscosity glass ionomer, and compomer material were clinically monitored for three years using atraumatic restoration technique and the clinical success of GCP material was found to be significantly lower than that of compomer and high viscosity GIC material (18).

In the present study, there was no difference between the one-week and the 6-months in the glass carbomer group, however, there was a statistically significant increase in the 12th-month Charlie score compared to the one-week ($p=0.046$; $p<0.05$). This finding was similar to the findings reported by Olegario et al.(18).

As with GIC materials, it is recommended to use a silicone-based fissure sealant to protect the surface from moisture and saliva for GC applications (8). In a laboratory study by Zoergiebl J et al. (19), fissur sealant application was reported to have no effect on the mechanical properties of GCs. On the other hand, Menne-Happ U et al. (8) reported in their laboratory study that the fissure sealant applied to the glass carbomer protected the surface of the material from dehydration and made finishing and polishing processes easier. Menne-Happ U et al. (8) compared the groups which applied sealant and which did not applied and reported that surface cracks were formed in the group in which no fissure sealant was used when glass carbomer samples were examined visually and attributed this to the dehydration due to not using any fissure sealant. In the present *clinical*study, silicone-based sealant was applied both to facilitate condensation of the material and to protect it from dehydration. Following the fissure sealant application, light was applied for 60 seconds. There was no significant difference between the materials in the first week, sixth month, and 12-months when the cavities restored with both materials in terms of surface texture. This may be due to the use of a silicone-based fissure sealant on the surface of the glass carbomer material.

No statistically significant difference was found between the TEP and GC groups in terms of marginal adaptation at the one-week. However, there was a statistically significant difference between TEP and GC group only in terms of six-months Bravo scores ($p=0.006$; $p<0.05$). However, percentages of Alpha, Bravo and Charlie scores of GC group were 70%, 20% and 10% at the end of the 12-months, respectively. Therefore, a statistically significant difference was observed between the two groups in this regard ($p=0.014$; $p<0.05$).Although there was no polymerization shrinkage in the glass carbomer material unlike the composite resins, significantly lower values were obtained in terms of marginal adaptation. This may be due to the fact that GC was less resistant to occlusal forces than posterior composite resin (84% filler by weight and 70% filler by volume).This result was compatible with the findings reported in the six-months clinical follow-up study by Glavino et al. (20) whom used GC as a fissure sealant.

Secondary caries formation, incidence of which is directly proportional to follow-up period, is one of the criteria considering for the clinical success of restorations (21). Some clinicians suggest that a four to six-year follow-up is needed to determine the clinical success of any restorations (22). In this study, no significant difference was found between the restorative materials in terms of secondary caries formation. This may be due to the fact that the clinical follow-up period was limited to 12 months. Also the presence of silicate and fluoride in the content of GC may be one of the factors preventing secondary caries formation.

In clinical practice, nanohybrid composites is preferred because these materials have strong mechanical properties like hybrid composites and also have good polishing properties like microfill composites (23). When the teeth restored with TEP were evaluated for color matching, bravo score was obtained in only two restorations at the end of the 12-months.The high success rate (96% alpha, 4% bravo) may be due to the high polishing feature of nanohybrid composites.

Considering the marginal discoloration results in the GC group at the end of 12 months, the TEP group was observed to have 100% Alpha score whereas GC group had 14% Charlie score and restoration was required to be replaced. This may be attributed to the fact that GC materials are less resistant to masticatory forces than TEP. Although these results were obtained after a one-year clinical follow-up, longer-term clinical follow-up is needed for the reliability of the marginal discoloration results of both materials.

GC is condensed and shaped by processing the surface with the help of a hand instrument following the application on the cavity with finger pressure. The consistency of GC is more liquid than the composite, making it difficult to give a natural anatomical form. However, no significant difference was observed in this

study when compared with composite resin. In a clinical follow-up study by Subramaniam et al. (24) using GC fissure sealant, nanoparticle content of glass carbomers was reported to increase the compressive stress and wear resistance. In contrast to this study, the GC material had a Charlie score of 8 % according to anatomic form in the present study. This means that GC is not resistant to masticatory forces like composite resins.

Postoperative sensitivity, which is defined as spontaneous or short-term pain sensation developed in response to a stimulus following the completion of restorations, is an important criterion in the evaluation of clinical studies (25, 26). Pain threshold varying by person, physician's sensitivity, and differences in the application procedure make the evaluation of the sensitivity criterion difficult (27). There was no statistically significant difference between the restorative materials used in terms of postoperative sensitivity ($p>0.05$). During the application stages of GC, no acid etching process and no additional bonding agent is required. These may be effective for the have contributed to the prevention of sensitivity problems.

CONCLUSION

Within the limitations of this study, we can conclude that,

1. Although similar results were obtained after one year of clinical follow-up for all restorative materials, statistically significant difference was observed at marginal adaptation and marginal discoloration.
2. When the restorations made using glass carbomer filling materials were evaluated in terms of anatomic form, retention, and marginal adaptation, restorations with Charlie score in the six and 12-months were replaced.
3. Due to these results physical properties of glass carbomer filling materials are needed to be improved more and further *clinical*studies should be carried out.

ACKNOWLEDGEMENTS

This study was supported by Bezmialem Vakif University, Scientific Research Projects Unit (project no: 6.2017/10).

COMPLIANCE WITH ETHICAL STANDARDS

Conflict of interest The authors declare that they have no conflict of interest.

REFERENCES

1. Jackson RD, Morgan M. The new posterior resins and: a simplified placement technique. J Am Dental Assoc 2000,131:375-83.

2. Wilson AD. A new translucent cement for dentistry: the glass-ionomer cement.Br. Dent. J 1972,132: 133-5.

3. Ikemura K, Tay FR, Endo T, Pashley DH. A review of chemical-approach and ultramorphological studies on the development of fluoride-releasing dental adhesives comprising new pre-reacted glass ionomer (PRG) fillers. Dent Mater J 2008,27:315-39.

4. Gordan VV, Mondragon E, Watson RE Garvan C, Mjör IA. A clinical evaluation of a self-etching primer and a giomer restorative material: results at eight years. J Am Dental Assoc 2007,138:621-7.

5. Shafiei F, Abouheydari M. Microleakage of class V methacrylate and silorane-based composites and nano-ionomer restorations in fluorosed teeth. J Dent 2015,16:100-5.

6. Najeeb, Shariq, et al. "Modifications in glass ionomer cements: nano-sized fillers and bioactive nanoceramics." Int J Mol Sci 2016,17: 1134.

7. Van RD, Davidson C, De AG, Feilzer A. In situ transformation of glass-ionomer into an enamel-like material. Am J Dent 2004,17:223-7.

8. Menne-Happ U, Ilie N. Effect of gloss and heat on the mechanical behaviour of a glass carbomer cement. J Dent 2013,41:223-30.

9. Gorseta K, Glavina D, Borzabadi-Farahani A Van Duinen R, Skrinjaric I, Hill R,. One-year clinical evaluation of a Glass Carbomer fissure sealant, a preliminary study. Eur J Prosthodont Restor Dent 2014,22: 67-71.

10. Gugnani N, Pandit IK, Srivastava N, Gupta M, Sharma M. International Caries Detection and Assessment System (ICDAS): A New Concept. Int J Clin Pediatr Dent 2011, 4:93-100.

11. Franco EB, Benetti AR, Ishikiriama SK, Santiago SL, Lauris JRP, Jorge MFF Maria Navarro FL. 5-year clinical performance of resin composite versus resin modified glass ionomer restorative system in non-carious cervical lesions. Oper Dent 2006,31:403-8.

12. Türkün LŞ, Türkün M, Özata F. Two-year clinical evaluation of a packable resin-based composite. J Am Dental Assoc 2003,134:1205-12.

13. Gorseta K, Glavina D, Borzabadi-Farahani A, Van Duinen R, Skrinjaric I, Hill R, E Lynch. One-year clinical evaluation of a Glass Carbomer fissure sealant, a preliminary study. Eur J Prosthodont Restor Dent 2014,22:67-71.

14. Zhang W, Chen X, Fan M Mulder J, Frencken JE . Retention Rate of Four Different Sealant Materials after four years. Oral Health Prev Dent 2017,15: 307-14.

15. El-Housseiny AA, Alamoudi NM, Nouri S, Felemban O. A randomized controlled clinical trial of glass carbomer restorations in Class II cavities in primary molars: 12-month results. Quintessence Int 2019,50:522-32.

16. Hu X, Zhang W, Fan M Fan M, Mulder J, Frencken JE. Frequency of remnants of sealants left behind in pits and fissures of occlusal surfaces after 2 and 3 years. Clin Oral Investig 2017,21:143-9.

17. Chen X, Du M, Fan M, Mulder J, Huysmans M-C, Frencken JE. Effectiveness of two new types of sealants: retention after 2 years. Clin Oral Investig 2012,16:1443-50.

18. Olegário IC, Hesse D, Mendes FM, Bonifácio CC, Raggio DP. Glass carbomer and compomer for ART restorations: 3-year results of a randomized clinical trial. Clin Oral Investig 2019,23:1-10.

19. Zoergiebel J, Ilie N. Evaluation of a conventional glass ionomer cement with new zinc formulation: effect of coating, aging and storage agents. Clin Oral Investig 2013,17:619-26.

20. Glavina D, Gorseta K, Vranic DN, Skrinjaric I. Retention of GlassCarbomer sealant after 6 months of clinical trial. 88th General Session of the International Association for Dental Research; 2010.

21. Brunthaler A, König F, Lucas T, Lucas T, Sperr W, Schedle A. Longevity of direct resin composite restorations in posterior teeth: a review. Clin Oral Investig 2003,7:63-70.

22. Van Dijken JW, Pallesen U. A randomized 10-year prospective follow-up of Class II nanohybrid and conventional hybrid resin composite restorations. J Adhes Dent 2014,16:585-92.

23. Fontes ST, Fernandez MR, Moura CMd, Meireles SS. Color stability of a nanofill composite: effect of different immersion media. J Appl Oral Sci 2009,17:388-91.

24. Subramaniam P, Babu KG , Jayasurya S,. Evaluation of Solubility and Microleakage of Glass Carbomer Sealant .J Clin Pediatr Dent 2015,39:429-34

25. Liberman R, Ben-Amar A, Gontar G, Hirsh A. The effect of posterior composite restorations on the resistance of cavity walls to vertically applied occlusal loads. Journal of Oral Rehabilit 1990,17:99-105.

26. Opdam N, Feilzer A, Roeters, Smale I J. Class I occlusal composite resin restorations: in vivo post-operative sensitivity, wall adaptation, and microleakage. Am J Dent 1998,11:229-34.

27. Walter M, Wolf B, Schmidt A, Boening K, Koch R. Plaque, gingival health and post-operative sensitivity in titanium inlays and onlays: a randomized controlled clinical trial.J Dent 2001,29:181-6.

Table 1. Description of experimental materials

Restorative Material	**Type**	**Manufacturer**	**Composition**	**Lot No**	**Used color**
Estelite posterior composite resin	Nano-hybrid composite	Tokuyama Dental, Tokyo, Japan	Organic matrix; Bis-GMA TEGDMA Bis-MPEPP İnorganic; Silica-zirconia Particle size:2 um Particle size/ratio: 0.1-10 um Weight;%84 filler Volume;%70 filler	243E67	A 2
Glass Carbomer	Glass-ionomer based	GCP Dental, Netherlands	Nano-floroapatite Nanohydroxyap-atite Polyacids Flouroalumi-nosilicate glass	7609020	A 2
Glass Carbomer Gloss	Silicon based	GCP Dental, Netherlands	Modified polysiloxanes	1607101	

Tablo 2 . Modified USPHS citerias.

Criterias ***Scores Explanations***

Retention	**Alfa Charlie**	No loss of restorative material Any loss of restorative material
Color match	**Alfa Bravo Charlie**	Matches tooth Acceptable mismatch Unacceptable mismatch
Marginal discoloration	**Alfa Bravo Charlie**	No discoloration Discoloration without axial penetration Discoloration with penetration indirection pulpal
Anatomic form	**Alfa Bravo Charlie**	Continous Slight discontinuity,clinically acceptable Discontinous,failure
Marginal adaptation	**Alfa Bravo Charlie**	Closely adapted,no crevice is visible Crevice is visible,explorer will penetrate Crevice in which dentin is exposed
Secondary caries	**Alfa Charlie**	No caries present Caries present

Retention	**Alfa Charlie**	No loss of restorative material Any loss of restorative material
Postoperative sensitivity	**Alfa Bravo Charlie**	Not present Sensitivity with diminishing intensity Constant sensitivity without diminishing intensity
Surface texture	**Alfa Bravo Charlie**	Enamel-like surface Surface rougher than enamel, clinically acceptable Surface unacceptably rough

Criteria Score *1 week 6-months 12-months*								
GC *n(%)*	TEP *n(%)*	*p*	GC *n(%)*	TEP *n(%)*	*p*	GC *n(%)*	TEP *n(%)*	*p*
Retention Alfa	50 (100)	50 (100)		48(96)	50 (100)	0,45	46 (92)	50 (100)	0,12
Charlie	2(4)	0 (0)		4 (8)	0 (0)				
Color Match Alfa	50 (100)	50 (100)		45 (90)	50 (100)	[1]0,06	43 (86)	48 (96)	[2]0,19
Bravo	5 (10)	0 (0)		5 (10)	2 (4)				
Charlie	2 (4%)	0 (0%)							
Marginal Alfa	45(90)	50(100)[1]	0,06	42(84)	50(100)[1]	0,01*	35(70)	45(90)	[2]0,014*
Adaptation Bravo	5 (0)	0(0)		8(16)	0(0)		10(20)	5(10)	
Charlie	5(10)	0(0)							
AnatomicForm Alfa	50(100)	50(100)		40(80)	45(90)		37(74)	43(86)	
Bravo	8(16)	5(10)		9(74)	4(8)				
Charlie	2(4)	0(0)		4(8)	3(6)				
Marginal Alfa	50(100)	50(100)		48(96)	48(96)[1]	1,000	37(74)	50(100)	[2]0,000*
Discoloration Bravo	2(4)	2(4)		6(12)	0(0)				
Charlie	7(14)	0(0)							
Secondary Alfa	50(100)	50(100)		50(100)	50(100)		50(100)	50(100)	
Caries									
Post-operative Alfa	46(92)	48(96)		48(96)	50(0)		48(96)	50(0)	
Sensitivity Bravo	4(8%)	2(4)		2(4)	0(0)		2(4)	0(0)	
Surface Alfa	50(100)	50(100)		43(86)	45(90)[1]	0,76	40(80)	42(84)[2]	0,311
Texture Bravo	7(14)	5(10)		7(14)	8(16)				
Charlie	3(6)								

Table 3. Baseline, 1-week, 6-months and 12-months clinical evaluation of restorations according to USPHS criteria

Hosted file

`Figure 1.pdf` available at https://authorea.com/users/369108/articles/488042-12-month-clinical-performance-evaluation-of-a-glass-carbomer-restorative-system

Hosted file

`Figure 2.pdf` available at https://authorea.com/users/369108/articles/488042-12-month-clinical-performance-evaluation-of-a-glass-carbomer-restorative-system

Hosted file

Figure 3.pdf available at https://authorea.com/users/369108/articles/488042-12-month-clinical-performance-evaluation-of-a-glass-carbomer-restorative-system

Hosted file

Figure 4.pdf available at https://authorea.com/users/369108/articles/488042-12-month-clinical-performance-evaluation-of-a-glass-carbomer-restorative-system

Hosted file

Figure 5.pdf available at https://authorea.com/users/369108/articles/488042-12-month-clinical-performance-evaluation-of-a-glass-carbomer-restorative-system