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RESEARCH ARTICLE

EFFECTIVENESS OF GLASS CARBOMER CEMENT IN CLASS II RESTORATIONS IN PRIMARY MOLARS (A RANDOMIZED CONTROLLED CLINICAL TRIAL)

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ABSTRACT

Introduction: Nanofilled glass ionomer cement emerged as a new generation of dental materials, which mineralizes gradually into fluorapatite to improve the compressive strength and wear resistance of class II restorations in primary molars. The purpose of this study was to evaluate clinically the effectiveness of glass carbomer cement with surface coat as class II restorations in primary molars in comparison to both of Ketac N 100 glass ionomer cement with surface coat and conventional glass ionomer cement with surface coat (Equia Fill). **Materials and methods:** This randomized controlled clinical trial included a sample of 117 children were selected with an age range of 4-7 years, having class II carious primary molars scoring 3, 4 or 5 (ICDAS II). They were randomly equally allocated into three groups according to the restorative material used. Group I (test): teeth were restored with glass carbomer cement, Group II (test): teeth were restored with Ketac N 100 glass ionomer cement and Group III (control): teeth were restored with (Equia Fill). Clinical evaluation was performed at baseline, 6 and 12 months. **Results:** Nano filled GICs (Ketac N & glass carbomer cement) showed significant higher retention rate and durability than Equiafill GIC at three examination times (baseline, 6 and 12 months) $P < 0.0001$. Regarding the effect of the restorations on periodontal health there was a statistically significant difference between the three study groups at baseline and 6 months $P < 0.0001$. No statistically significant differences were found between three study groups at 12 months $P = 0.02$. **Conclusion:** Nanofilled GICs were more effective in restoring class II cavities in primary molars as well as having a better consequential effect on the periodontal health compared to the conventional GICs.

INTRODUCTION

Dental caries is the most frequent chronic childhood disease worldwide (1). Untreated caries may affect seriously the quality of children's life because of pain and acute or chronic infections which may compromise eating and sleeping leading to learning disorders (2). Furthermore, primary teeth when left untreated, lead to detrimental impact on the permanent dentition due to loss in the space available in the dental arch and consequently leading to crowding and malocclusion (3) or developmental defects of the permanent successor teeth (4). Therefore, maintaining the integrity of dental arch in the primary dentition is considered crucial for establishing normal occlusion and function in the permanent dentition (4-6). Along the way to preserve tooth structure and for the application of minimal intervention concept, micro-conservative dentistry has emerged in which a minimum of tooth structure is removed (7). Following this concept slot preparation advocated by Wilson and Mclean (8), involves the removal of the marginal ridge but do not include all the occlusal pits and fissures. The innovation generated along the way with restorative materials for restoring primary molars led to the development of glass ionomers to replace the traditional silver amalgam for better retention in the conservative cavity preparations (9). Conventional glass

ionomer cement (GIC) has the ability to chemically bond to tooth structure and release fluoride, with additional benefits of biocompatibility, antibacterial effects (10,11). However, its prolonged setting time compromise its physical and mechanical properties especially in restoring class II cavities in primary teeth. Therefore, in an attempt to improve its properties, a variety of modifiers have been added to its matrix (12). A promising new technology (Nanotechnology) is applied in the dental field. Using this technology, glass carbomer cement and Ketac N have been introduced as GIC-based restorative materials, with claims of improved physical and mechanical characteristics (13-18). Considering the few published clinical data, on newly developed nanosized glass ionomer cements (13-18), the present study was initiated to assess the clinical performance of these materials as well as the provision of valuable insights into their enhanced physical and mechanical properties, when used in class II restorations in primary teeth. The null hypothesis of the current research was expecting no differences between the glass carbomer cement, ketac N glass ionomer and the conventional glass ionomer cement in clinical assessment.

MATERIALS AND METHODS

This study was a randomized controlled clinical trial, with equal allocation ratio 1:1:1. It was setup and reported according to the CONSORT guidelines (19). The study was approved from the Research Ethics Committee, Faculty of Dentistry, Alexandria University, Alexandria, Egypt, and registered at the National Institutes of Health.

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Healthy high-carries risk children with active class II cavities in primary molars scored 3, 4 or 5 according to the International Caries Detection & Assessment System (ICDAS II scoring system) without involvement of the buccal and lingual walls. They were between 4 and 7 years old. The participants were recruited from the outpatient clinic, Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Alexandria University.

Sample size estimation: Sample size was estimated based on the following assumptions: alpha error=5%, study power= 80% confidence level= 95%.: a power of 80% and a significance level of P value ≤ 0.05 (20) Sample size was based on Rosner's method (21, 22) calculated by Gpower 3.0.10. After 12 months, the overall success rates were 56% for glass carbomer cement and 86% for conventional GIC (Equia Fill) based on previous study (23), sample size was calculated to be 35 children, and this was increased to 39 to make up of cases lost to follow up. The total sample size = number of groups \times number per group = $3 \times 39 = 117$ child.

Patient's recruitment: Out of 167 screened children who attended the outpatient clinic of Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Alexandria University, 117 children who met the inclusion criteria were enrolled in the clinical trial after informing their parents about the study protocol and signing their informed consent.

Oral hygiene instructions: All participants received oral hygiene instructions and dietary guidance in each visit throughout the entire study period. Parents were instructed to refrain from brushing their children's teeth (24).

Randomization technique and allocation concealment: Random allocation of each participant to Group I glass carbomer cement and Group II Ketac N100 glass ionomer cement (test groups) and Group III conventional glass ionomer cement (positive control) was performed by a trial independent individual using computerized method (www.randomizer.org) and the allocation ratio was intended to be equal. Allocation was in equal blocks to ensure that the study groups had equal number of children. Each child included in this study was given serial number that was used in allocation. A duplicate of this number was kept in an opaque envelope indicating to which group the patient belongs. An independent person who was assigned the role of opening each envelope only at the time of intervention; so that the group to which the child is allocated was concealed from the investigator (25).

Blinding: Blinding of examiners was impossible to be done during intervention and follow up due to different natures of the materials. However, for patients and statistical analysis, the statistician and patients were not known to which group the data belongs (double blinding).

Examiner reliability: The main researcher was trained for assessing the lesion activity by (ICDAS II scoring system) and Ryge Criteria for direct clinical evaluation of restoration (26), The evaluation systems used were Modified Papillary Bleeding Index and modified gingival index (26, 27), and a pilot study was carried out on 20 percent of the sample that was not included in the study, to calibrate the researcher for the aforementioned assessments. Intraexaminer reproducibility was assessed by calculating intraclass correlation coefficients (ICCs) and Cohen's kappa coefficient (K) for the (ICDAS II), Ryge Criteria, (MPBI Scale) and modified gingival index respectively. Intraexaminer reproducibility revealed excellent ICCs (0.92) and K (0.81).

Sample Grouping: All samples were randomly assigned into 3 groups (n=39/each) according to the restorative material tested.

(Test group I): Teeth were restored with glass carbomer cement with surface coat.

(Test group II): Teeth were restored with Ketac N 100.

(Control group): Teeth were restored with conventional glass ionomer cement with surface coat (Equia Fill).

Intervention

Topical anesthesia was applied then infiltration or nerve block anesthesia was given. The selected tooth was isolated with rubber dam and the tooth surface was cleaned with wet cotton pellet to remove debris and plaque. A gingival wedge was placed prior to initiating cavity preparation. Class II slot preparation with occlusal lock was performed where all infected tissue was removed from the surrounding walls and the enamel-dentin junction using #330 bur with water cooling (22). After the cavity preparation, a metallic matrix was cut, burnished, positioned and stabilized by a wooden wedge to define the proximal contour of the restoration. For all the prepared cavities, cavity conditioner was applied to enamel and dentin surfaces and left undisturbed for 10 seconds, then the cavity was rinsed with water for 10 seconds and was gently air-dried for 5 seconds (22). Teeth of all groups were restored according to manufacturer's instructions.

Teeth restoration

For test group I: Glass carbomer cement capsule was mixed by the amalgamator for 10-15 seconds; placed into the cavity, and light cured for 10 seconds (23).

For test group II: Ketac N100 glass ionomer cement was mixed by the amalgamator for 10 seconds; placed into the cavity and light cured for 10 seconds (23).

For control group: Conventional glass ionomer cement was mixed by the amalgamator for 10 seconds; applied into the cavity and light cured for 10 seconds (23). The restorations of all teeth included in the study were finished and polished using rubber cups (23). Teeth in test group I and control group were coated with surface coat and light cured for 10 seconds by using LED light curing system (23). After completion of the restorative procedures, all teeth in the three groups were evaluated at baseline, 6 and 12 months. Debris and plaque on the tooth surfaces were removed before evaluation using a wet cotton pellet.

Evaluation of retention rate: Clinical evaluation was performed through visual inspection at baseline, 6 and 12 months follow up, using Ryge Criteria for direct clinical evaluation of restoration. The restorations were evaluated by taking different scores from Alpha 1 (clinically excellent), Alpha 2 (clinically good), Bravo (clinically sufficient with few defects), Charlie (restoration partially missed), Delta (restoration is totally missed) according to the degree of restoration lost (26).

Effect of the restoration on the periodontal health: Clinical evaluation was performed at baseline, 6 and 12 months follow up, using the criteria of modified papillary bleeding index (MPBI) and modified gingival index (MGI). The restorations were evaluated by taking different scores for (MPBI) evaluation scores from 0 (no bleeding within 30 secs of probing), 1 (bleeding between 3 to 30 secs of probing), 2 (bleeding within 2 secs of probing), 3 (bleeding immediately upon probing) and for (MGI) evaluation scores 0 (absence of inflammation), 1 (mild inflammation or slight change in color or texture), 2 (mild inflammation in all gingival margins or papillary), 3 (moderate inflammation), 4 (severe inflammation) (26, 27).

Statistical analysis: Data were analyzed using IBM SPSS (Statistical Package for Social Science) statistical software (version 25). The collective quantitative data was tested for normality, which was confirmed using Shapiro Wilk test. Descriptive statistics were summarized using mean and standard deviation (SD). Independent t test was used for intergroup comparisons. Repeated measures ANOVA with post hoc Bonferroni test for intragroup was used to compare retention rate and effect of the restoration on the periodontal health among the groups, with a P value ≤ 0.05 .

RESULTS

At baseline, 167 children (mean age equals 5.6 ± 0.80 SD) with a total of 167 class II cavities in primary molars were assessed for eligibility, 57 were excluded, and 117 children (65 males, 52 females) with 117 class II cavities were included in the study. All participants received the allocated intervention and no one has been lost during the different follow-up periods (Figure 1). Regarding the retention of the restorations, at baseline comparing the three study groups, teeth restored with glass carbomer and ketac N GICs showed 100% alpha 1 scores while teeth restored with conventional GIC Equia Fill showed 100% alpha 2 scores with a statistically significant difference between the three study groups $P < 0.0001$. At 6 months follow up, teeth restored with glass carbomer cement showed 82.1% alpha 1 scores, those with Ketac N GIC showed 100% alpha 1 scores while teeth restored with conventional GIC Equia Fill showed 100% Bravo scores with statistically significant difference between the three study groups $P < 0.0001$. After 12 months follow up, teeth restored with glass carbomer cement showed 66.7% alpha 2 scores, teeth restored with Ketac N GIC showed 92.3% alpha 1 scores while teeth restored with conventional Equia Fill showed 100% Charlie scores with statistically significant differences between the three study groups $P < 0.0001$ (Table 1). For within group comparisons, teeth restored with glass carbomer cement at baseline, all teeth showed 100% alpha 1 scores, at 6 months follow up teeth showed 82.1% alpha 1 scores and 12.8% Bravo scores while at 12 months follow up 66.7% showed alpha 2 scores and 33.3% Bravo scores with statistically significant differences $P < 0.0001$. While, teeth restored with ketac N GIC at baseline, showed 100% alpha 1 scores, at 6 months showed 100% alpha 1 scores and at 12 months showed 92.3% alpha 1 scores with no statistically significant differences $P = 0.050$. Regarding the conventional GIC Equia Fill, at baseline all teeth restored showed 100% alpha 1 scores, at 6 months 100% showed Bravo scores and at 12 months 100% showed Charlie scores with statistically significant differences $P < 0.0001$ (Table 1). By studying the effect of the restoration on the periodontal health, results of the present study revealed that the modified papillary bleeding index (MPBI) and modified gingival index (MGI) data showed statistically significant differences between the three study groups at baseline and 6 months follow up ($P < 0.0001$, $P < 0.0001$ respectively). Whereas, no statistically significant differences between the three study groups at 12 months follow up, regarding MPBI $P = 0.020$ and MGIP $P = 0.049$. Within group comparisons, regarding MPBI and MGI for teeth restored with glass carbomer GIC, Ketac N GIC and Equia Fill GIC results showed statistically significant differences at baseline, 6 and 12 months follow up ($P < 0.0001$, $P < 0.0001$, $P < 0.0001$ respectively). Repeated measures ANOVA analysis with post hoc Bonferroni test for intragroup revealed statistically significant differences for nanofilled GICs with $P \leq 0.05$, regarding the retention rate and effect of the restoration on the periodontal health among the study groups.

DISCUSSION

Results of the present study showed that both nanofilled GICs were more effective in restoring class II cavities in primary molars than conventional GIC. The differences between the three study groups necessitate rejection of the null hypothesis as the retention, sealing properties and effect on the periodontal health of nanofilled glass ionomer cements showed better results than conventional glass ionomer cement (28, 29). This study compared the clinical effectiveness of nanofilled GICs (glass carbomer, ketac N) to conventional GIC (Equia fill) in restoring class II cavities in primary molars. The inter group comparisons of the three study groups, showed a significantly higher retention rate of both ketac N and glass carbomer cement over the conventional glass ionomer with surface coat due to incorporations of nanoparticles which increases physical and mechanical properties of the restoration materials. However, this finding disagrees with the in-vitro study of Cehreli *et al.*, (30) who found that there was no significant difference between coated glass carbomer and coated conventional GIC when restoring primary molars, so, the difference in the results may be attributed to the different nature of the study as evaluation the clinical performance of the restorations were affected by many factors such as forces of mastication, brushing and dietary habits and type of food intake. Moreover, the results of the present study is in accordance with the data of Hassan *et al.*, (17) who evaluated the micro leakage and marginal integrity of the newly developed glass carbomer cement with and without protective surface coating (SC) in primary molars. They found that, the surface coat when added to the glass carbomer cement yields less micro leakage than the uncoated glass carbomer and conventional GIC and consequently might improve the longevity of the restoration which is one of the aims of the present study (17). In the coated restorations, the surface gloss used with the glass carbomer cement was more effective in its sealing ability as compared to the resin-based surface coating applied to the conventional GIC. Although, both restorative materials have common ingredients (e.g., glass), the manufacture does not provide detailed information regarding how the surface gloss acts, it is evident that its proprietary formulation provides better chemical interaction with the glass carbomer cement that enhances sealing properties (31-36). In the present study, ketac N showed significantly higher retention rate than conventional glass ionomer at baseline, 6 and 12 months follow up and when compared to glass carbomer cement at 12 months follow up only. This finding could be attributed to the composition of the ketac N glass ionomer cement and the manufacturer's instructions which included using ketac N primer before application of the restoration to increase bond between tooth structure and restoration (37-39). In the current study, within group comparison, teeth restored with glass carbomer cement and conventional GIC evaluated at baseline, 6 and 12 months follow up,

Table (1): Retention of the restorations among the study groups at different examination times

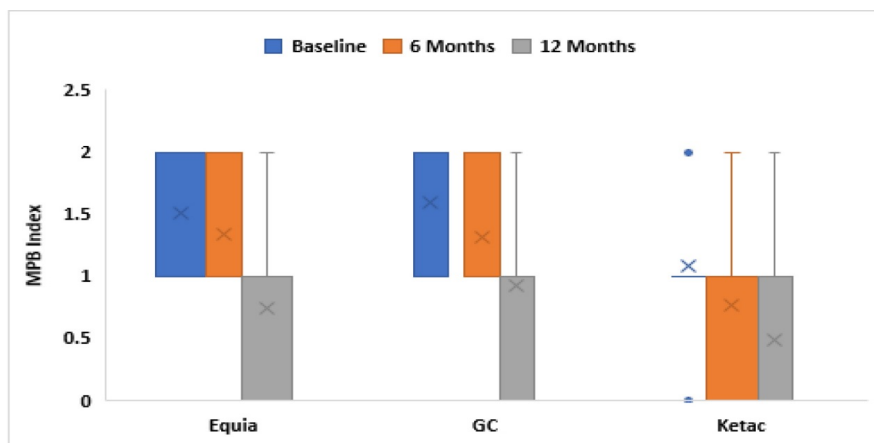
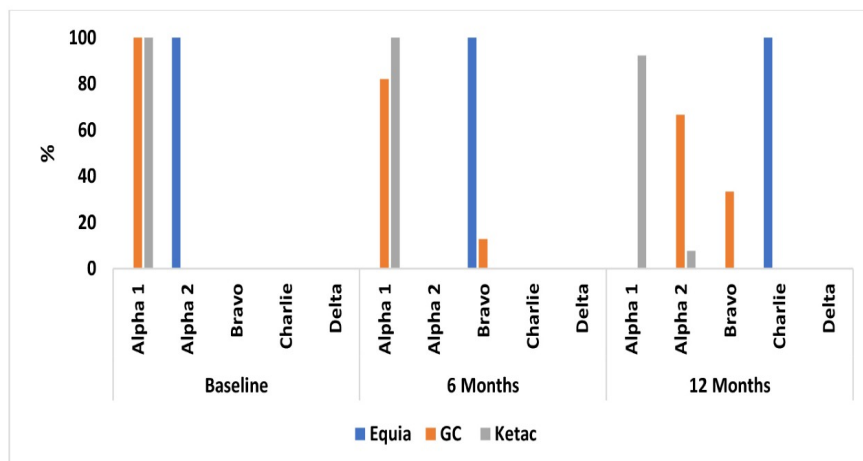
		Equia (n=39)	GC (n=39)	Ketac (n=39)	Test (p value)
		n (%)			
Baseline	Alpha 1	0 (0%)	39 (100%)	39 (100%)	116.00 ($< 0.0001^*$)
	Alpha 2	39 (100%)	0 (0%)	0 (0%)	
	Bravo	0 (0%)	0 (0%)	0 (0%)	
	Charlie	0 (0%)	0 (0%)	0 (0%)	
	Delta	0 (0%)	0 (0%)	0 (0%)	
6 Months	Alpha 1	0 (0%)	32 (82.1%)	39 (100%)	101.583 ($< 0.0001^*$)
	Alpha 2	0 (0%)	0 (0%)	0 (0%)	
	Bravo	39 (100%)	5 (12.8%)	0 (0%)	
	Charlie	0 (0%)	0 (0%)	0 (0%)	
	Delta	0 (0%)	0 (0%)	0 (0%)	
12 Months	Alpha 1	0 (0%)	0 (0%)	36 (92.3%)	109.607 ($< 0.0001^*$)
	Alpha 2	0 (0%)	26 (66.7%)	3 (7.7%)	
	Bravo	0 (0%)	13 (33.3%)	0 (0%)	
	Charlie	39 (100%)	0 (0%)	0 (0%)	
	Delta	0 (0%)	0 (0%)	0 (0%)	
Test (p value)	78.00 ($< 0.0001^*$)	72.066 ($< 0.0001^*$)	6.00 (0.050*)		
Post hoc test	$P_1 < 0.0001^*$, $P_2 < 0.0001^*$, $P_3 < 0.0001^*$	$P_1 = 1.00$, $P_2 < 0.0001^*$, $P_3 < 0.0001^*$	$P_1 = 1.00$, $P_2 = 1.00$, $P_3 = 1.00$		

*Statistically significant difference at p value < 0.05 ; P_1 : comparison between baseline and 6 months, P_2 : comparison between baseline and 12 months, P_3 : comparison between 6 months and 12 months

Table 2. Comparison of modified papillary bleeding index&modified gingival index among the study groups at different examination times

		Equia (n=39)	GC (n=39)	Ketac (n=39)	Test (p value)
FDI Criteria (Modified papillary bleeding index)					
Baseline	Mean (SD)	1.51 (0.51)	1.59 (0.50)	1.08 (0.58)	16.659 (<0.0001*)
	Median (IQR)	2.00 (1.0)	2.00 (1.0)	1.00 (0.0)	
	Min - Max	1.0 – 2.0	1.0 – 2.0	0.0 – 2.0	
6 Months	Mean (SD)	1.33 (0.48)	1.31 (0.47)	0.77 (0.54)	24.237 (<0.0001*)
	Median (IQR)	1.00 (1.0)	1.00 (1.0)	1.00 (1.0)	
	Min - Max	1.0 – 2.0	1.0 – 2.0	0.0 – 2.0	
12 Months	Mean (SD)	0.74 (0.78)	0.92 (0.66)	0.49 (0.60)	7.811 (0.020*)
	Median (IQR)	1.00 (1.0)	1.00 (1.0)	0.00 (1.0)	
	Min - Max	0.0 – 2.0	0.0 – 2.0	0.0 – 2.0	
Test (p value)		30.868 (<0.0001*)	25.310 (<0.0001*)	17.083 (<0.0001*)	
Post hoc test		$P_1=1.00$, $P_2<0.0001^*$, $P_3=0.001^*$	$P_1=0.379$, $P_2=0.001^*$, $P_3=0.082$	$P_1=0.210$, $P_2=0.002^*$, $P_3=0.302$	
FDI Criteria (Modified gingival index)					
Baseline	Mean (SD)	1.51 (0.51)	1.59 (0.49)	1.08 (0.58)	16.659 (<0.0001*)
	Median (IQR)	2.00 (1.0)	2.00 (1.0)	1.00 (0.0)	
	Min - Max	1.0 – 2.0	1.0 – 2.0	0.0 – 2.0	
6 Months	Mean (SD)	1.33 (0.48)	1.31 (0.47)	0.77 (0.54)	24.237 (<0.0001*)
	Median (IQR)	1.00 (1.0)	1.00 (1.0)	1.00 (1.0)	
	Min - Max	1.0 – 2.0	1.0 – 2.0	0.0 – 2.0	
12 Months	Mean (SD)	0.74 (0.78)	0.92 (0.66)	0.54 (0.60)	6.014 (0.049*)
	Median (IQR)	1.00 (1.0)	1.00 (1.0)	0.00 (1.0)	
	Min - Max	0.0 – 2.0	0.0 – 2.0	0.0 – 2.0	
Test (p value)		30.868 (<0.0001*)	25.310 (<0.0001*)	17.083 (<0.0001*)	
Post hoc test		$P_1=1.00$, $P_2<0.0001^*$, $P_3=0.001^*$	$P_1=0.379$, $P_2=0.001^*$, $P_3=0.082$	$P_1=0.210$, $P_2=0.002^*$, $P_3=0.302$	

*Statistically significant difference at p value <0.05

**Figure 1. Flow chart follow consort guidelines****Figure 2. Retention of the restorations among the study groups at different time intervals**

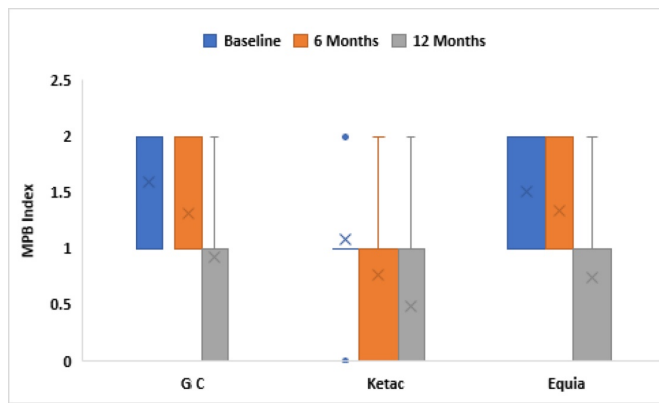


Figure 3. Box plot of modified papillary bleeding index among the study groups at different time intervals

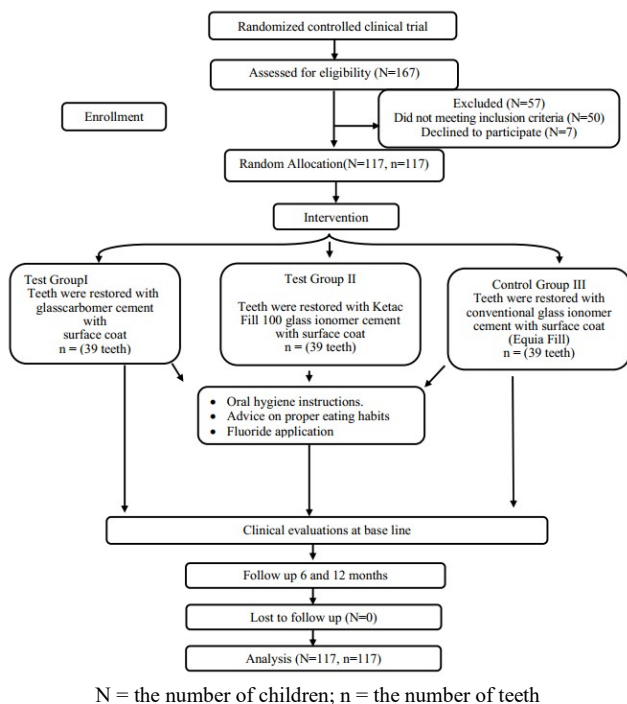


Figure 4. Box plot of modified gingival index among the study groups at different time intervals

Regarding the effect of the restorations on the periodontal health that was assessed by evaluation systems of modified papillary bleeding index (MPBI) and modified gingival index (MGI) (40). There were significant differences between the three study groups at baseline and 6 months follow up only with no significant differences between them at 12 months follow up. This may be due the long term effect of reinforcement of oral hygiene instructions and proper tooth brushing throughout the period of follow up and the consequent healing effect of the periodontium. In the current study, within group comparison, teeth restored with glass carbomer cement, Ketac N GIC and conventional GIC evaluated at baseline, 6 and 12 months follow up, results showed significant differences that may be attributed to the enhanced periodontal health due to improvement in oral hygiene measures (37-39).

The overall results of the present study indicated that then anofilled glass ionomer cement ketac N and glass carbomr cement with surface coat had better retention rate and proper marginal seal than conventional glass ionomer with surface coat. Moreover, the effect of the restorations on the periodontal health assessed by modified papillary index and modified gingival index showed better results. The limitation of this clinical study is related to the short-term of the study (1-year follow-up) for the retention and sealing ability

assessments. However, longer follow up periods would be interrupted by the physiological exfoliation of the teeth unless a younger age group would be used. Nevertheless, further trials with longer observation periods are still necessary to evaluate the esthetic, functional, and biological properties to document whether secondary caries which is regarded as the main reason for failure would develops in these restorations.

CONCLUSION

Based on the study's results, the following conclusions can be made

- Ketac N GIC showed better durability than glass carbomer cement after 12 months follow up in restoring class II cavities in primary molars.
- Nano filled GICs showed better effect on periodontal health than conventional GIC at baseline and 6 months follow up.

Conflict of Interest: The authors declare that they have no conflicts of interest.

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