EFFECTIVNESS OF NANO FILLED GLASS IONOMER CEMENT IN CLASS II RESTORATIONS IN PRIMARY MOLARS (RANDOMIZED CONTROLLED CLINICAL TRIAL)

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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 the 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 and conventional glass ionomer cement with surface coat (Equia Fill). The null hypothesis of the current study was expecting no differences between the glass carbomer cement, ketac N glass ionomer cement and the conventional glass ionomer cement in the clinical assessment.

METHODOLOGY

The present study is a randomized controlled double blinded clinical trial, with equal allocation ratio 1:1:1. It was setup and reported according to the CONSORT guidelines. A sample of 117 children was selected with an age range of 4-7 years, having class II active carious primary molars scoring 3, 4 or 5 (ICDAS II). They were randomly allocated into three equal 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 AND DISCUSSION

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, 50 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)
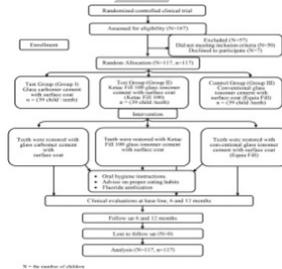

Figure (1): Flow chart follow consort guidelines.

Nano filled GICs (Ketac N & glass carbomer cement) showed significant higher retention rate and durability than Equia fill GIC at three examination times (baseline, 6 and 12 months) P<0.0001.(Table 1, Figure 2) This may be due to incorporations of nano particles which increases physical and mechanical properties of the restoration materials, and also could be attributed to the composition of the ketac N glass ionomer cement and the manufacturer's instructions which recommended using ketac N primer before application of the restoration to increase bond between tooth structure and restoration. Regarding 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) showed statistically significant differences between the three study groups at baseline and 6,12 months follow up (P<0.05). (Table 2, Figure 3). 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. Furthermore, ketac N restorations showed the lowest MPBI and MGI scores that may be attributed to the presence of silane treated nanosized filler particles that permit smooth high polish surface of restorations that limit food accumulations and stagnations in addition to proper tooth brushing throughout the period of follow up, consequently the healing effect of the periodontium. Repeated measures ANOVA analysis with post hoc test for intragroup revealed statistically significant differences for nanofilled GICs with P ≤0.05, regarding the retention rate and effect of the restoration on the periodontal health among the study groups. 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.

Table (1): Comparison of retention rate scores of the restorations among the study groups at the different time intervals

		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*)	6.000 (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	

Table (2): Comparison of MPBI & MGI scores among the study groups at the different time intervals

		Equia (n=39)	GC (n=39)	Ketac (n=39)	Test (p value)
FDI Criteria (MPBI & MGI)					
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 (MPBI)	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	
12 Months (MGI)	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	

CONCLUSION

Based on the study's results, the following conclusions can be made
1. Nano filled GICs were more effective than conventional GIC (Equia fill) in restoring class II cavities in primary molars when followed up for 12 months.
2. Ketac N GIC showed better success rate & durability than glass carbomer cement after 12 months follow up in restoring class II cavities in primary molars.
3. Nano filled GICs showed better consequential effect on periodontal health than conventional GIC at baseline and 6, 12 months follow up in favor of ketac N restoration.

ACKNOWLEDGMENT

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