EFFECTIVENESS 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 carborner 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 (Equa Fill). The null hypothesis of the current study was expecting no differences between the glass carborner 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 carborner cement, Group II (test2): teeth were restored with Ketac N 100 glass ionomer cement and Group III (control): teeth were restored with (Equa 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)

Nanofilled GICs (Ketac N & glass carborner cement) showed significant higher retention rate and durability than Equa fill GIC in a medium term follow up (6 and 12 months) P<0.0001 (Table 1). Figure 1. This may be due to the incorporation of nanoparticles 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 papilla/bleeding index (MBPI) and modified gingival index (NGI) showed statistically significant differences between the three study groups at baseline and 6,12 months follow up (P<0.05). (Table 2, Figure 2) This may be due to the long term effect of restorations on oral hygiene instructions and proper tooth brushing throughout the period of follow up and the consequent healing effect of the periodontal tissue. Furthermore, ketac N restorations showed the lowest MBPI & NGI scores which could be attributed to the smooth high polish surface of restorations that limit food accumulations and stagnation 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 Bonferroni test for intragroup comparison 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 the current clinical study is related to the short-term of the study (1-year follow-up) for the retention and sealing ability assessment. However, longer follow up periods would be interrupted by the physiological eruption 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 develop in these restorations.

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

<table>
<thead>
<tr>
<th>Time (months)</th>
<th>Baseline</th>
<th>6 Months</th>
<th>12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>MBPI Max (SD)</td>
<td>2.00 (1.0)</td>
<td>1.59 (0.50)</td>
<td>1.50 (0.50)</td>
</tr>
<tr>
<td>MBPI Min (SD)</td>
<td>0.0 (0.0)</td>
<td>0.0 (0.0)</td>
<td>0.0 (0.0)</td>
</tr>
<tr>
<td>MBPI Mean (SD)</td>
<td>1.00 (1.0)</td>
<td>0.92 (0.66)</td>
<td>0.77 (0.54)</td>
</tr>
<tr>
<td>MBPI Median (IQR)</td>
<td>2.00 (1.0)</td>
<td>1.00 (1.0)</td>
<td>1.00 (1.0)</td>
</tr>
<tr>
<td>MBPI Test Value</td>
<td>30.868</td>
<td>25.310</td>
<td>10.614</td>
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</tbody>
</table>

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

<table>
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CONCLUSION
Based on the study’s results, the following conclusions can be made:
1. Nano filled GICs were more effective than conventional GIC (Equa 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 carborner 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, 12 months follow up in favor of ketac N restoration.

ACKNOWLEDGMENT
First of all I am grateful to Allah for everything, I would like to express my sincere gratitude to my supervisors Prof. Dr. Ahmed Abd Elrahman and Prof. Dr. Dalia Talaat, for their continuous support and motivation. Last but not least, would like to thank my family for supporting me spiritually throughout my life.

REFERENCES