Original Article

Clinical and Radiographic Success of Three Adhesive Restorative Materials in Primary Molar Proximal Lesions: A Randomized Clinical Trial

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Abstract

Aim: The aim of this study was to evaluate and compare the clinical and radiographic success of primary molar proximal lesions in 4–8 years children restored with three adhesive restorative materials followed up for 12 months. **Materials and Methods:** This study was carried out on 102 primary molars of 51 children in the age range of 4–8 years. In all the participants, Class II lesions were restored and randomly allocated into three material groups as giomer group, nano-ionomer group, and light-cured glass-ionomer cement (LC-GIC) group based on the restorative material used. All the restorations were evaluated and scored according to federation dentaire internationale (FDI) criteria for clinical and radiographic success rate at 3, 6, and 12 months' interval. Data were formulated in a predesigned format and were subjected to statistical analysis using the Chi-square test and Fisher's exact test. **Results:** There was no statistically significant difference observed among the restorative material groups to all the properties of FDI criteria. The overall success rates of restorative materials at 3, 6, and 12 months' interval were as follows: giomer – 100%, 100%, and 94.1%; nano-ionomer – 97%, 94%, and 85.3%; and LC-GIC – 100%, 94%, and 88.2%. **Conclusion:** The highest clinical success rate was found for the giomer group followed by LC-GIC group and the least for the nano-ionomer group, whereas the highest radiographic success rate was found for giomer as well as LC-GIC group and the least for nano-ionomer group.

Keywords: *FDI criteria, giomer, light-cured glass-ionomer cement, nano-ionomer, primary molars, proximal lesions*

Introduction

Dental caries remains the most common childhood disease despite the evolution in the field of dental and oral health for children.[1,2] Conservative restoration of primary teeth continues to be the most important issue in the scope of pediatric dentistry[3] and is due to the lower biting forces of children and primary teeth having a limited lifespan.[4]

The objective of the restorative materials is to substitute the biological, functional, and esthetic properties of healthy tooth structure.[5] The esthetic restoration of dental caries in primary teeth has always been a challenge for the pediatric dentist due to various reasons. However, the most important challenge is the lack of cooperative ability in children, moisture contamination, and the lack of suitable material for children of this age group.[6]

The glass-ionomer cement (GIC) was introduced with some advantages such as high biocompatibility, ability to form the chemical bond with dentin and enamel, being fluoride-releasing material, making them anticariogenic, and their coefficient of thermal expansion is similar to dentin.[7] However, disadvantages related to glass ionomers, such as lack of strength, prolonged setting time, moisture sensitivity, and poor esthetics reported.[8]

Targeting these disadvantages, resin-modified GIC (RMGIC) was developed that resulted in the higher bond strength, reduced brittleness, lower moisture sensitivity, improved tensile, compressive strength, and elastic modulus when compared with conventional glass ionomer.[4] The presence of photoinitiator systems in the resin-modified glass ionomer (RMGI) together with the light-curing system allowed a better controlling of the work and setting time, which is particularly important when used in pediatric dentistry approach.

With the development of nanotechnology, a novel RMGI has introduced in the market

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which classified as nano-filled RMGI (nano-ionomer). It is the first RMGIC with nanotechnology, combining the benefits of RMGIC and bonded nanofiller particles.[9] By using bonded nanofillers and nanocluster fillers along with fluoralumino silicate glass, nano-ionomer restorative has improved esthetic, adhesive, and mechanical properties, nevertheless, provides the benefits of glass ionomer such as fluoride release. Ketac N100 is a new paste/paste nano-ionomer with a filler composition of 69%. The glass component of Ketac N100 consists of nanofiller (5–25 nm) and nanofiller clusters (1–1.6 μm).

A recent addition to the list of hybrid restorative materials is the prereacted glass (PRG) ionomer composite (composite/giomer). Giomer is one such category based on prereacted filler technology (PRG) where PRG particles incorporated in the resin matrix. The manufacturers claim that the beneficial effects of GIC retained along with the superior physical and esthetic properties of resin composite materials.

So far, to our knowledge, the available literature does not show any studies comparing giomer with nano-ionomer and light-cured GIC (LC-GIC). Hence, this study was to evaluate and compare the clinical and radiographic success of giomer with nano-ionomer and LC-GIC in Class II lesions of the primary molars.

Materials and Methods

The present study was a prospective, single-centered, double-blinded randomized clinical trial conducted to evaluate and compare the clinical and radiographic success of giomer, nano-ionomer, and LC-GIC in Class II cavities of primary molars with a balanced allocation ratio of 1:1:1.

Considering the clinical success rate as the primary outcome, a level of significance set at 0.05, and power at 80%, a total sample size of 102 was essential.

The criterion for including the children for the study was age range of 4–8 years with a behavior rating of 3 or 4 on the Frankl Behavior Rating Scale,[10] having proximal caries diagnosed using the International Caries Detection and Assessment System criteria[11] as code 4, 5, and 6 as well as normal radiographic features of the lamina dura and periodontal space.

Children were excluded from the study if there was any systemic disease, known or suspected allergy to restorative material, history of bruxism as well as the teeth with discoloration or developmental defects needing endodontic treatment or extraction, and any history of pain experienced in the tooth excluded.

A detailed case history was recorded, and an oral examination was completed. Oral prophylaxis was performed to all the study children before the restorative treatment. A total of 102 primary molars (first/second, maxillary/mandibular) with carious lesions that indicated for restorative treatment were selected by specified inclusion criteria. Based on the type of restorative material, the teeth were randomly allocated to three groups (n = 34 in each group) – the distribution of the study participants shown in Figure 1.

- Giomer group (Group 1) – Proximal lesions restored with glucocorticoid receptors
- Nano-ionomer group (Group 2) – Proximal lesions restored with nano-ionomer based RMGIC
- LC-GIC group (Group 3) – Proximal lesions restored with LC RMGIC.

Soft caries was excavated using a sharp spoon excavator. Later, conservative cavities were prepared with a high-speed round diamond bur and water coolant by a single operator: rubber dam isolation and powerful suction used for moisture control after cavity preparation. Restorative materials were applied according to the manufacturer's directions by a single operator [Table 1]. After polymerization, finishing accomplished, and postrestorative instructions given to all the children.

The restorations were evaluated using the FDI criteria having esthetic, functional, and biological properties at 3, 6, and 12 months' interval both clinically and radiovisiographically (RVG), for their success. Evaluations were carried out by two specialist researchers who blinded to the study for all the three groups; five steps of grading

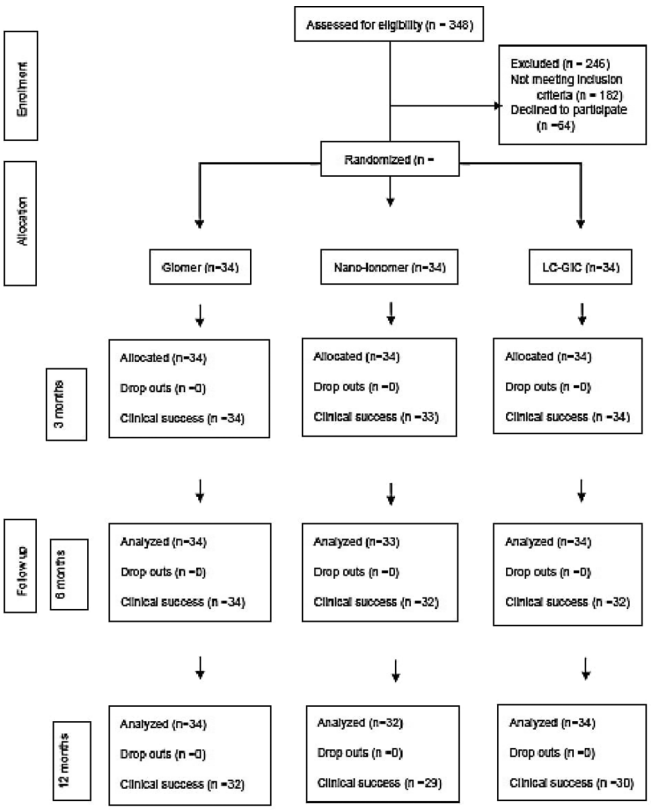

Figure 1: Distribution of study participants according to the consort flowchart

were used for the assessment: score 1 – excellent/very good, score 2 – good, score 3 – sufficient/satisfactory, score 4 – unsatisfactory, and score 5 – poor. Scores of 4 or 5 were considered as a failure.

Results

In this study, 102 primary molar Class II lesions (50 primary first molars and 52 primary second molars) in 51 children (28 boys and 23 girls) with an age range of 4–8 years were restored. All the participants attended the recalls (dropout rate: 0%). For each group, patient mean age (year) with standard deviation (%) was giomer – 5.794 ± 1.174, nano-ionomer – 5.911 ± 1.239, and LC-GIC – 6.058 ± 1.099.

During the study period, none of the restored teeth got exfoliated. The intra- and inter-examiner reliabilities were 0.96 and 0.94, respectively. Only one sample in the nano-ionomer group failed within the 3 months' interval and none in both the giomer and LC-GIC group. During 3–6 months' interval, three restorations (one – nano-ionomer and two – LC-GIC) were recorded as a failure. During 6–12 months' interval, seven restorations were recorded as failures (two – giomer, three – nano-ionomer, and two – LC-GIC).

Maximum failures of giomer and nano-ionomer were observed in the 12th month of the study period, whereas a homogeneous distribution of time-dependent breakdown was detected for LC-GIC during 6th and 12th months.

Intergroup comparison of clinical failure rate revealed that there was no statistically significant difference among the three groups [Table 2].

Intergroup comparison of radiographic failure rate revealed that there was no statistically significant difference among the three groups ($P > 0.05$) [Table 3].

Intergroup comparison of total failure rate revealed that there was no statistically significant difference among the three groups ($P > 0.05$) [Table 4].

When evaluation factors compared among the restorative material groups after 12 months, it found that there was no statistically significant difference [Table 5].

At 3 months' clinical failure [Figure 2a], radiographic failure at 12 months [Figure 2c] and clinical failure at 12 months [Figure 2b] are shown in Figure 2.

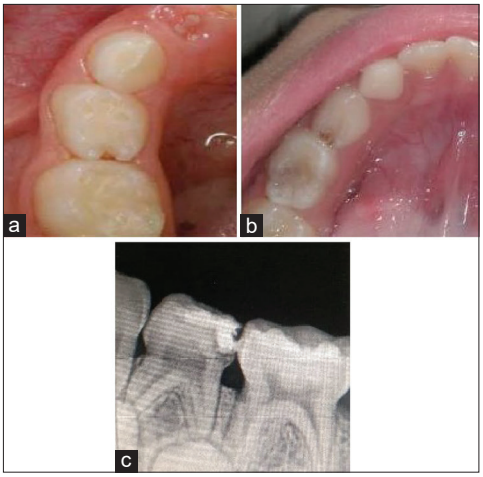

Figure 2: Clinical failure at 3 months (a), and clinical failure at 12 months (b) radiographic failure at 12 months (c)

Table 1: Materials, Composition, manufacturer, and instructions for use

Material	Composition	Manufacturer	Instructions for use
Beautifil II Lot 060854	S-PRG glass filler, fluoride-containing fluoro-boro-aluminosilicate glass filler particles, TEGDMA, Bis-GMA	Shofu, Kyoto, Japan.	-20s cure
Ketac N 100 (light-curing nano-ionomer restorative)	Deionized water, blend, including HEMA, a methacrylate-modified polyalkenoic acid Filler content: methacrylate functional-fluoroaluminosilicate glass and nanomeres and nanoclusters	Ketac™ N 100; 3M ESPE, St Paul, MN, USA	-mix the pastes together for 20 seconds -maximum depth of the material for light curing should not exceed 2 mm. -20s cure
LC-GIC	Powder: Aluminosilicate glass. Liquid: Polyacrylic acid, HEMA, 2,2,4, trimethyl hexamethylene dicarbonate, TEGDMA	GC Gold Label, GC Corporation, Japan	- mix for 10s - insert into the cavity -Light cure for 20s
Tetric N Bond Self-Etch	Bis-acrylamide derivative, bismethacrylamide dihydrogen phosphate, amino acid-acrylamide, water, nanofillers, hydroxyalkyl methacrylamide	Ivoclar Vivadent, Liechtenstein	- 20s application - Gently air dry for 5s - Light cure for 10s

Discussion

In proximal cavities, where the cavosurface margins are facing two surfaces, enamel and dentin; this increases the difficulty in placement of the restorative materials.[12] The anatomy of primary teeth includes the constricted neck, broad-gingivally located contact areas, and marked decrease in the thickness of enamel and dentin in the proximal region; this may explain the difficulty in achieving adhesion in this area and increase the tendency of microleakage,[13,14] which may fail the restoration.

FDI evaluation of a restoration used in this study consists of three groups: esthetic, functional, and biological criteria. Each group has subcategories to score, numbered 1–5 (1 – clinically excellent/very good; 2 – clinically good; 3 – clinically sufficient/satisfactory; 4 – clinically unsatisfactory; and 5 – clinically poor). When restoration receives a score of 4 or 5, it was recorded as a failure. The overall rating is determined by the subcategory scores, with the final score in each group being dictated by the most severe score among all the subscores. For example, if one property/category is unacceptable, the last, overall score of this restoration is also unacceptable. Therefore, when summarizing the three groups (esthetic, functional, and biological) in one overall rating, the worst score prevails and gives the final score.

The present study included 51 children of age 4–8 years, of which 28 were boys and 23 were girls. It reported that if teeth restored at an earlier age, longevity would be lower. Barr-Agholme *et al*. reported that although the caries activity of children does not have a significant impact on restoration success, the lower caries risk level may have positively affected the survival of restoration.[15] Sengul and Gurbuz reported that even though the difference between the mean age values of the materials was not statistically significant in their study, the survival rates and average survival times

Table 2: Comparison of clinical failure rate among Giomer, Nano-ionomer and LC-GIC groups

Material group	3months	6months	12months	*P*
Giomer	0	0	2 (5.9%)	-
Nano-ionomer	1	2	5 (14.7%)	0.197
LC-GIC	0	2	4 (11.8%)	0.414

Table 3: Comparison of radiographic failure rate among Giomer, Nano-ionomer and LC-GIC groups

Material group	3months	6months	12months	*P*
Giomer	0	0	1 (2.9%)	-
Nano-ionomer	1	2	4 (11.8%)	0.368
LC-GIC	0	0	1 (2.9%)	-

Table 4: Comparison of total failure rate among Giomer, Nano-ionomer and LC-GIC groups

	Giomer	Nano-ionomer	LC-GIC	*P*
3months	0	1	0	-
6months	0	2	2	1.000
12months	2 (5.9%)	5 (14.7%)	4 (11.8%)	0.529

Table 5: Comparison of restorative material failure rate (%) over clinical evaluation criteria at 12 months

Evaluation criteria	Restorative material groups			
	Giomer (*n*=34)	Nano-ionomer (34)	LC-GIC (34)	*P*
Aesthetic				
Surface luster	2	3	2	0.867
Surface/marginal staining	2	3	2	0.867
Color stability and translucency	2	3	2	0.867
Anatomic form	2	3	2	0.867
Total	2	3	2	0.867
Functional				
Fractures and retention	1	4	2	0.368
Marginal adaptation	1	3	2	0.607
Contact point	1	2	3	0.607
Radiographic examination	1	2	3	0.607
Patients view	0	1	0	-
Total	1	4	3	0.417
Biological				
(Hyper) sensitivity, tooth vitality	1	1	1	1.000
Recurrence of caries	0	2	1	0.564
Tooth integrity	1	1	0	1.000
Periodontal response	2	0	0	-
Adjacent mucosa	0	0	0	-
Oral and general health	0	0	0	-
Total	1	2	1	0.779
Total	2 (5.9%)	5 (14.7%)	4 (11.8%)	0.529

increased in direct proportion with age.[16] In contrary, the survival of the restorative material was not affected by the patients' age in the present study that is attributable to the relatively different mean age distribution of children. Regarding gender variations, the failure rate was found to be high in boys (63.6%) when compared to the girls (36.4%).

At 3 months' evaluation interval, one of the restorations in the nano-ionomer group was found to be a failure clinically and radiographically, whereas none of the restorations were recorded as a failure in the giomer and LC-GIC groups, clinically or radiographically.

At 6 months' evaluation interval, clinically, one restoration and radiographically two restorations were observed as a failure in the nano-ionomer group, whereas two restorations in the LC-GIC group were found to be failures clinically and no failures were found radiographically. However, none of the restorations were observed as the failure in the giomer group either clinically or radiographically.

At 12 months' evaluation interval, in the nano-ionomer group, it was observed that two restorations were recorded as failure clinically and one radiographically, whereas in giomer and LC-GIC groups, only one was documented as a failure both clinically and radiographically.

Sengul and Gurbuz evaluated the clinical success of primary teeth Class II lesions and reported the 1-year success rate of restorative material fracture and retention as follows: 89.5% for giomer, 99% for nano-ionomer, and 95% for LC-GIC.[16] In the present study, the determined success rate for LC-GIC (94.1%) was almost comparable with the reported findings: giomer (97.1%) was above and nano-ionomer (88.2%) was under these findings. The differences may be due to the dissimilarities in the participants' mean age and the size of the cavity. It reported that marginal sealing of the cavity governs the longevity of the restoration.[17] Thus, the ability of restoration to maintain proper marginal adaptation that minimizes the microleakage extending at the tooth/restoration interface is important in predicting its clinical success.[18] This supports the present study; the nano-ionomer group with the highest clinical failure rate showed 8.8% of failures in marginal adaptation, which was high when compared to giomer (2.9%) and LC-GIC (5.9%) groups at 12 months' interval. The nano-filled RMGI showing higher microleakage scores may be explained by the resin content increasing the polymerization shrinkage.[18] Since the resin component is responsible for the polymerization shrinkage of light-cured glass ionomers, it may produce polymerization shrinkage which could adversely affect marginal adaptation.[19,20]

Radiographically, none of the restorations were found to be failures, at 3 and 6 months' interval among the three groups. However, four restorations in the nano-ionomer group and one restoration in both giomer and LC-GIC groups showed failure at 12 months' interval.

Based on the results of the radiographic evaluation of the present study, there was no statistically significant difference found between the material groups at 3, 6, and 12 months' interval. Although there was no statistically significant difference, nano-ionomer was found to be the weakest material, with a failure rate of 11.8% at 12 months' interval. However, the failure rates for giomer and LC-GIC groups were found similar, i.e. 2.9% at 12 months. It reported that restoration or tooth fracture was the prime reason, while apical pathology was the secondary reason for radiographic failures.[16] In the present study, in addition to the restoration or tooth fracture and apical pathology, secondary caries was also the major contributing factor for the radiographic failure, as the radiographic failure observed in all the secondary caries cases in this study. Paterson *et al*. reported that the loss of marginal integrity could result in secondary caries.[21] In this study, secondary caries was observed in 42.8% of the restorations exhibiting fracture and adhesion failure. However, giomer (n = 0%) and LC-GIC (n = 1%) displayed low secondary caries rate, which is probably due to their high success rate at fractures and retention criterion. Sengul and Gurbuz evaluated the clinical success of primary teeth Class II lesions restored with giomer and LC-GIC and reported a success rate of 100% and 92% for giomer and LC–GIC, respectively, in the evaluation of secondary caries.[16] Konde *et al*. clinically evaluated the nano-ionomer and reported a 100% success rate in the evaluation of secondary caries.[22] In our study, the success rates of giomer group, nano-ionomer group, and LC-GIC group were 100%, 94%, and 97%, respectively, at 12 months. With 94%, nano-ionomer had the lowest success rate in secondary caries.

At 12 months, the highest clinical success rate was found for the giomer group followed by LC-GIC group and least for nano-ionomer group. However, about radiographic evaluation, the highest success rate was found for giomer as well as the LC-GIC groups and lowest for nano-ionomer group. Limitations of the present study were the evaluation was by the naked eye, which may have the weakness in perceiving subtle changes because some clinical evaluation criteria such as surface roughness and wear cannot be measured accurately without the use of sophisticated tools. The radiographs were not standardized because of the young age.

Conclusion

These are the conclusions that can draw from the present study: At 3 months, the highest clinical and radiographic success rate was found for giomer as well as LC-GIC groups and lowest for nano-ionomer group. At 6 months, the highest clinical success rate was observed for giomer group and lowest for nano-ionomer as well as LC-GIC groups, whereas the highest radiographic success rate was found for giomer and LC-GIC groups and lowest for the nano-ionomer group. At 12 months, the highest clinical

success rate was found for the giomer group followed by LC-GIC group and least for nano-ionomer group, whereas the highest radiographic success rate was found for giomer as well as LC-GIC groups and lowest for nano-ionomer group.

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Conflicts of interest

There are no conflicts of interest.

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