Comparative Evaluation of GIC Based Sealant with Nano-Filled Resin Coating versus Filled Resin Sealant: A Randomized Clinical Trial

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Objective: *To evaluate and compare the retention of GIC based sealant with nano-filled resin coating and filled resin sealant at specified time intervals.* ***Study Design****: It was a split mouth design in which 248 mandibular first permanent molars were divided into two groups i.e. Group 1 (124): treated with glass ionomer sealant followed by light cured nano-filled resin coating and Group 2 (124): treated with acid etching followed by resin filled sealant. Clinical evaluation was done at 1,3,6,9 and 12 months as per modified categorization by Weiwei Z et al. Data was analyzed using Pearson's chi-square test to evaluate the success of both treatment procedures (p<0.05).* ***Results:*** *At 12 months, overall retention rate of glass ionomer sealant with nano-filled resin coating was found to be superior (84.7%) as compared to filled resin sealant (74.3%); but no significant difference was noted (p>0.05).* ***Conclusions:*** *Nano-filled resin coating application over glass ionomer sealant provides enhanced longevity and cariostatic benefits; hence, can be used as a viable alternative in place of resin sealants.*

Keywords*: Glass ionomer sealant, Nano-filled resin coating, Resin based sealant.*

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INTRODUCTION

In 1960's, researchers introduced pit and fissure sealants as a gold standard for prevention of fissure caries.[1] When placed in the occlusal surface of early, non cavitated carious lesions and sound healthy teeth; thwart carious lesions in primary and permanent molars, consequently, cost effective. They provide a thin, physical, and protective barrier on the tooth structure against food and bacteria in the oral environment therefore, reducing the risk of dental caries.[2] Despite its substantial use in preventive dentistry, long term success of sealants depend on several properties including biocompatibility, anti cariogenicity, adequate bond strength , good marginal integrity, enamel conditioning, morphology of pit and fissures, resistance to abrasion and wear, viscosity of sealant.[3]

Selectively, fissure sealants can be categorized as: Resin based and Glass ionomer based sealant. [4] Resin based sealant form a micromechanical bonded resin layer that acts as a palisade between the enamel surface and the oral environment, while glass ionomer based sealant provides a chemo-mechanical adhesion and fluoride release.[5]

Glass ionomer based sealants are an effective choice for partially erupted molars with inadequate moisture control;[4,5] while lack of rigidity, initial water sensitivity, low adhesive resistance and low retention rates are some of the dearth's associated with the same.[6] In order to overcome these drawbacks of chemically cured sealants, numerous modifications have been made, one of which is glass ionomer sealant GC Fuji VII (GC Corporation, Tokyo, Japan), available in white and pink color.[7] This white color, low viscosity

product was the sealant of choice. According to manufacturer, this type of GIC sealant provides six times more fluoride release up to 24 hours than other sealant. Fuji VII also possesses antibacterial property, free-flowing consistency, and improved adherence to enamel.[8]

Multitude of protecting agents have been recommended to increase the lifespan of sealants like petroleum jelly, cocoa butter, water proof varnishes, methyl- methacrylate and light polymerized resin coatings. But, with time, these coatings are lost by oral masticatory forces and local environmental conditions.[9] To overcome these impediments, a new generation of low viscosity, nanofilled resin coating (particle size of 40 nm) (G-coat Plus GC Europe, Leuven, Belgium) has been propagated. The main difference between this material (G-Coat plus) and the previous generations of coat for GIC is the content of nano-filler particles.[10] This neoteric material intends to bring adequate mechanical properties, and enhance aesthetic in terms of smoothness, polishability and precision of shade characterization.[11]

The current literature revealed that previously used sealants undergo abrasive wear over a period of time. Hence, filler particles have been added to augment the retention, wear and abrasion resistance in newly invented sealants.[3] The most reframe Grandioseal (Voco, Germany), a highly filled nano-hybrid sealant, with excellent flow properties has claimed to enhance micromechanical bond strength, well adherence to tooth structure, outstanding abrasion resistance provide paramount longevity in the oral cavity.[12,13]

To the best of our knowledge, there is no study available in the present literature comparing the clinical performance of glass ionomer based sealant along with nano-filled resin coating versus a nano-hybrid filled resin sealant.

MATERIALS AND METHOD

The investigation protocol was permitted through Ethics Committee of Teerthanker Mahaveer Dental College & Research Centre, Moradabad, Utter Pradesh, India. Total 321 children were screened at Department of Pedodontics and Preventive Dentistry, and 124 children who met the inclusion criteria were involved in the study using stratified sampling method. It was a split mouth design in which 248 first permanent mandibular molars in 124 children were equally allocated to Group 1 and Group 2, based on the randomization protocol and all the procedures were performed and evaluated by a single operator (Z.P).[14] Calculation of the sample size was done following power analysis which was 95% for this study. After parents' consent, children of 6 to 8 years old with behaviour rating of Frankel Rating 3 and Frankel Rating 4 without any systemic disease, with presence of contralateral mandibular first permanent molars with deep occlusal morphology, without any developmental defects were included in the study.[3] After rubber dam isolation of selected tooth, pits and fissures of permanent first molars were cleaned by using pumice powder (fluoride free) mixed with glycerine on a glass slab with cement spatula and washed with distilled water. In group 1, GC dentine conditioner was applied on the occlusal surface of isolated and cleaned tooth for 20 seconds followed by 20 seconds water rinsing, further blotted dry. The glass ionomer based sealant (GC Fuji VII, GC Corporation, Tokyo, Japan) was mixed according to the manufacturer's instructions and applied to the occlusal surface and excess was removed with the help of restorative instrument before the final setting of the material. A single layer of nanofilled surface coating (G-coat plus, GC Corporation Tokyo, Japan,) was then applied using micro brush applicator tip on the top of GIC sealant followed by photopolymerization for 20 seconds.

In group 2, the occlusal surface of the isolated and cleaned tooth was etched with 37% phosphoric acid for 15 seconds followed by washing with distilled water. The surface was dried with oil free compressed air using pressure syringe for 20 seconds; and etching was confirmed by the frosty appearance of the involved pits and fissures. A resin based sealant (Grandioseal, Voco Gmbh, Cuxhaven, Germany) was then applied on the tooth surface and excess was removed with the help of teflon coated instrument followed by photopolymerization for 20 seconds. After procedure completion, both the groups were followed clinically at 1,3,6,9, and 12 months respectively according to modified categorization as described by Weiwei Z et al [15] in 2017 as completely retained, partially retained, completely lost and were analyzed statistically. In the conventional categorization, completely and partially retained sealants were classified as success, whilst the missing sealants were grouped as unsuccessful. The drawback of the conventional categorization is inability to assess the exact performance of a sealant longitudinally; hence, modification of the conventional categorization was done. Three sections of occlusal surface (mesial, central and distal) were divided to evaluate the retention rate and evaluated separately. A lost sealant in this category is defined as one occlusal section no longer covered with sealant material, which modifies the definition of a partially retained sealant. Hence, both sealant groups depicted lower retention rate in modified categorization.[15] In this study, partially retained sealants observed in any of the follow up period, were neither repaired nor excluded but kept under follow up till 12 months. Completely lost cases were considered as failure at any given point of time, the sealant was reapplied and the tooth was excluded from the study.

The data obtained was subjected to statistical analysis using Statistical Package for Social Sciences Software version 24 for Windows (IBM Corporation U.S.A). The success of both treatment procedures was compared using Pearson's chi-square test. The level of significance was set at $p<0.05$.

RESULTS

The mean age of the children participated in this study was 7.21 ± 0.81 years. A total of 69 boys and 55 girls received the treatment. Figure-1 shows the distribution of teeth at 1,3,6,9 & 12 months. Each group comprised of 124 children with two contralateral first permanent molars (total 248 teeth) was considered, at baseline. At the end of 12 months, 104 teeth were left in group 1 and 102 teeth were left in group 2 due to exclusion of completely lost sealant (failure) and dropouts. Failure (Completely lost) was excluded at next follow up period and drop out was excluded in the same follow up period. Table-1 shows the comparison in the retention rate of both groups at 1,3,6,9 and 12 months.Table-2 revealed that 84.7% sealants in group 1 and 74.3% sealants in group 2 were completely retained which depicts that overall retention rate of group 1 was higher than group 2 at 12 months, but it was also statistically not-significant.

Figure-1 Distribution of teeth at various follow up periods i.e 1, 3, 6, 9 and 12 months.

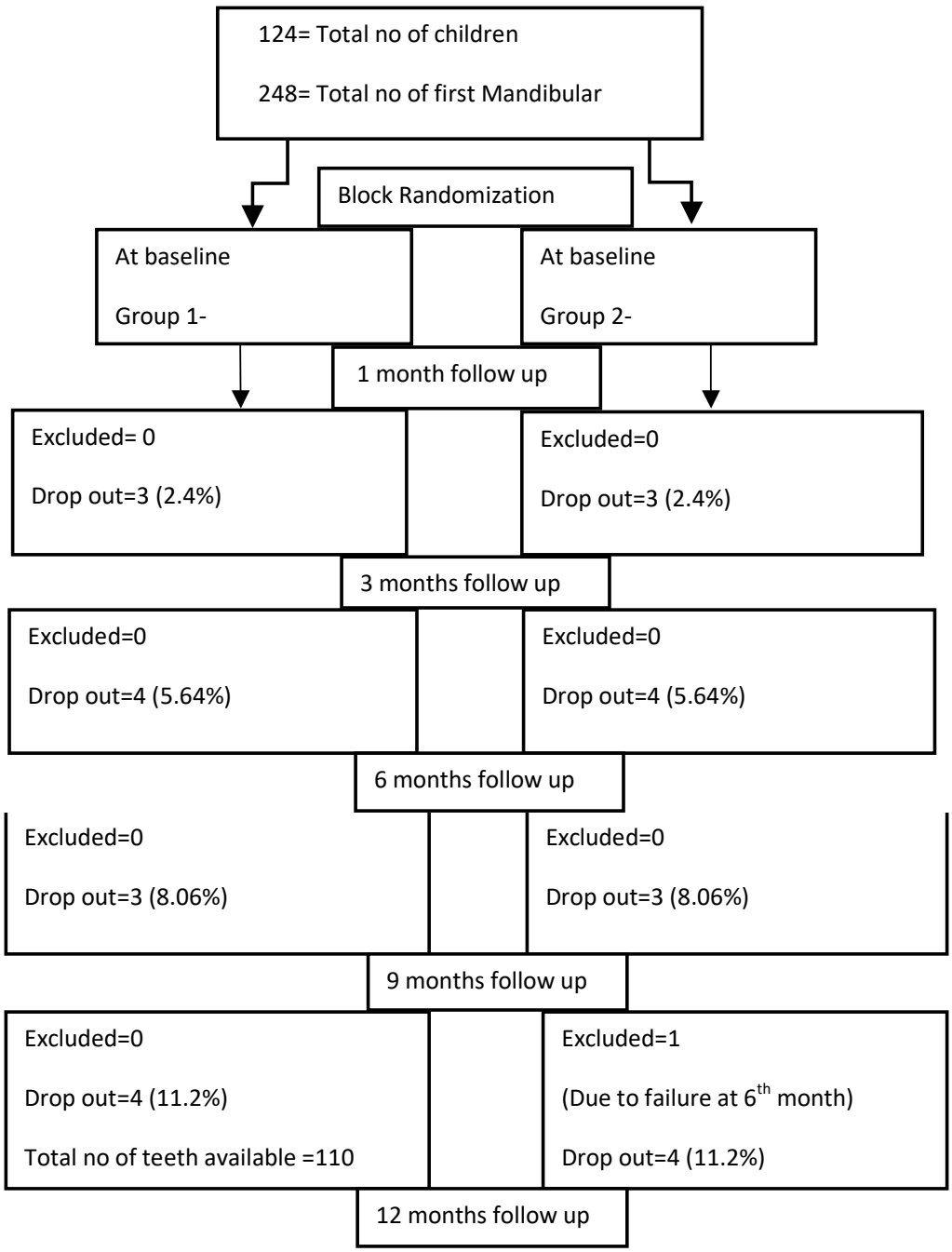

Table 1. Retention rate of both the groups at 1, 3, 6, 9 and 12 months respectively.

Retention rate Group 1		Groups Group 2		Total	Value	df	P value
1 month	CR	119 (98.3%)	116 (95.9%)	235 (97.1%)	1.32	1	0.250 (N.S)
	PR	2 (1.7%)	5 (4.1%)	7 (2.9%)			
	CL	0 (0.00%)	0 (0.00%)	0 (0.00%)			
	Total	121	121	242			
3 months	CR	112 (95.7%)	107 (91.5%)	219 (93.6%)	1.78	1	0.182 (N.S)
	PR	5 (4.3%)	10 (8.5%)	15 (6.4%)			
	CL	0 (0.00%)	0 (0.00%)	0 (0.00%)			
	Total	117	117	234			
6 months	CR	106 (93.0%)	98 (86.0%)	204 (89.47%)	2.369	1	0.124 (N.S)
	PR	8 (7.0%)	15 (13.20%)	23 (10.10%)			
	CL	0 (0.00%)	1 (0.8%)	1 (0.4%)			
	Total	114	114	228			
9 months	CR	98 (89.1%)	89 (81.6%)	187 (85.0%)	3.12	2	0.210 (N.S)
	PR	11 (10.0%)	18 (16.5%)	29 (13.2%)			
	CL	1 (0.9%)	2 (1.8%)	3 (1.3%)			
	Total	110	109	219			
12 months	CR	89 (85.5%)	78 (76.4%)	167 (81.06%)	3.61	2	0.165 (N.S)
	PR	13 (12.5%)	21 (20.5%)	34 (16.5%)			
	CL	2 (1.9%)	3 (2.9%)	5 (2.4%)			
	Total	104	102	206			

CR= Completely retained, PR= Partially retained, CL=Completely lost, N.S= Not significant.

Group	No of success at 12 months/ Total no of teeth at 12 month	Success %	Pearson chi square	p value
Group1	89 /105	84.7%	3.54	0.060 (N.S)
Group 2	78/105	74.3%		
Total	167/210	79.52%		

N.S=No significant

Table 2- Overall retention rate at 12 months

DISCUSSION

Dental caries have evolved as a pandemic issue worldwide. Owing to the tedious morphology, pit and fissures of the occlusal surface are eight times more prone to caries as compared to smooth surface.[14] Intricate morphology of deep pit and fissures are responsible for increase incidence of caries in children.[16] The tortuous pattern of pit and fissures in addition to the hampered cleaning of erupting first permanent molars, pave these sites for accumulation of food debris and bacterial plaque resulting in caries.[14] Myriad of techniques like fissurotomy, odontomy has been implicated in the past to prevent the pit and fissure caries. Bunocore[17], in 1970's described the use of BIS-GMA containing resins, which laid the cornerstone of adhesive dentistry.

After the inception of glass ionomer cement; it has found in an array of dental applications. Glass ionomer adheres chemically to enamel and dentin; possess enhanced biocompatibility, and fluoride release. Based on these properties it was believed to be useful product for sealant application.[18] In contrast, many studies suggested that glass ionomer sealant exhibited lower retention rate.[19-21] However, the clinical efficacy of sealants depend on several factors such as duration, material's ability to retain, fluoride release and degree of sealant retention to the tooth structure. Early contamination of GIC based sealant can lead to their inadequate adhesion and retention to the tooth structure.[14]

In the present study, conventional low viscosity glass ionomer Fuji VII sealant was selected because it is easy to apply and claim to possess cariostatic effect due to more fluoride release. Nonetheless, it is critical to protect glass ionomer sealant in the initial stages of setting reaction;[22] thus, nano filled surface coating G-coat plus was applied over the glass ionomer sealant. This coating enhances retention of glass ionomer sealant due to inclusion of nano filler particles which provide mechanical lock with the tooth and restoration.[10]

Some of the previous studies[19,7,21] have revealed lower retention rate of glass ionomer sealant Fuji VII as compared to resin based sealant. So, in order to fetch the cariostatic benefits of GIC based sealants; longevity of these sealants needs to be augmented. Hence, the present study was undertaken to compare the retention of glass ionomer Fuji VII sealant along with application nanofilled surface coating versus the most neoteric resin based sealant (Grandioseal).

At the end of 12 months follow up, Group 1 showed (84.7% teeth- completely retained), while Group 2 (74.3% teeth-completely retained). No significant difference was found in both groups at 12 months follow up ($p > 0.05$). In this study, resin based sealants exhibited less percentage of retained sealants than glass ionomer sealant. Synonymous results were obtained by Arrow *et al* [23] and Ulusoy *et al* [22] who demonstrated significantly greater retention rate of GIC sealants as compared to resin based sealants; but it was statistically non-significant at 12 months. However, contrary results were depicted in a study by Antonson *et al* [24], Subramanian *et al* [7], Mejare and Mjor[25] and Paulsen *et al* [26], who reported very low retention rate for glass ionomer based sealant at 12 months.

Lack of moisture control, incomplete sealing of pits and fissures, ineffective rinsing and drying, material wear, non sealant failure (extraction of tooth, proximal caries, and exfoliation); failure due to amalgamation of all or some of these factors and also presence of a prismatic layer over newly erupted teeth are some of the factors cited for failure of resin based sealants in present study.[27]

One of the main reasons for loss of some of glass ionomer sealants could be inadequate adhesion of the cement to the enamel surface due to erratic topographic pattern of the occlusal surface. Thus, there might be the possibility of entrapment of air voids due to jagged surface which lowers the strength of the adhesive joints.[25,7]

This study showed that overall retention rate of glass ionomer sealant with nanofilled resin coating was superior (84.7%) to that of resin based sealant (74.3%). It indicates that glass ionomer sealant with light cured nanofilled surface coating can act as a substitute to that of resin based sealant because it acts as a protective lamination to glass ionomer. Homogenous findings were found by Sukumaran *et al* [9], where samples coated with G-coat plus presented higher values of mechanical strength as compared to the unprotected samples. Nano-filled resin coating's hydrophilicity united with a tremendous low viscosity, offers perfect seal to GIC surface. Ulusoy *et al* [22] also reported higher retention rate of Fuji VII (19%) with G coat plus as compared to the samples coated with helioseal over Fuji VII (17%).

This study is no without any limitations. Follow-up time considered being quite short, but this period was selected to reduce the risk of too many dropouts. The same operator performing and assessing the sealant over different observation periods can also be cited as one of the limitation of this study. Therefore, further consideration is proposed to assess the success of sealants by evaluating the clinical performance and caries risk assessment of glass ionomer sealant with and without nanofilled coating in primary mandibular molars in a prospective longitudinal study. In-vitro studies can also be conducted to assess the adhesive and cohesive failure of samples coated with nanofilled resin coating in simulated oral conditions.

CONCLUSIONS

The success rate of glass ionomer sealant with nanofilled surface coating was higher as compared to resin based sealant respectively at the end of 12 months; but it was statistically non significant.

Glass ionomer sealant with nanofilled surface coating provides enhanced longevity and cariostatic benefits; hence, can be used as a viable alternative in place of resin based sealants.

Further long term clinical trials are recommended to establish the results of this study.

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