Comparison of Clinical Efficacy of Glass Ionomer-based Sealant Using ART Protocol and Resin-based Sealant on Primary Molars in Children

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ABSTRACT

Aim: The present *in vivo* study aims to evaluate and compare the clinical efficacy and survival rate of resin-based composite sealant (Clinpro Sealant, 3M ESPE, Irvine, California, United States of America) with high viscosity glass ionomer (GI) (Equia Forte, GC India, Patancheru, Telangana, India) using atraumatic restorative treatment (ART) sealant protocol in primary molars.

Materials and methods: The design of the study was a clinical, prospective split-mouth study. A total of 100 contralateral primary molars were selected and divided into two groups. In group I, children received Equia Forte, and in group II, children received Clinpro Sealant. The follow-up examinations were performed in the 1st and 6th months. Simonsen's Criteria were used to check for retention. International Caries Assessment and Detection System II (ICDAS II) criteria were used to check for dental caries. The data obtained were subjected to statistical analysis.

Results: At 6 months, there was no statistically significant difference between the groups with regard to retention and caries preventive effect. **Conclusions:** High-viscosity GI sealants can be applied using the ART protocol and provide an alternative to resin-based sealants.

Clinical significance: There is a limited number of studies on the performance of ART sealants in primary molars. Thus, the clinical efficacy and survival rate of resin-based composite sealant (Clinpro Sealant, 3M ESPE, Irvine, California, United States of America) with high viscosity GI (Equia Forte, GC India, Patancheru, Telangana, India) using ART sealant protocol in primary molars were evaluated. The research concluded that high-viscosity GI sealants using ART protocol are effective sealants in primary molars.

Keywords: Atraumatic restorative treatment sealant, Glass ionomer sealant, Pit and fissure sealants, Primary molars, Resin-based sealant. International Journal of Clinical Pediatric Dentistry (2022): 10.5005/jp-journals-10005-2450

INTRODUCTION

Dental caries is site-specific and manifests predominantly in the pits and fissures of occlusal surfaces. The morphology of pits and fissures provides a location for the aggregation of food particles and microorganisms. Therefore, altering the morphology of retentive pits and fissures into a smooth, easy-to-clean surface by the placement of sealants is a good method to prevent dental caries.¹

Sealants are thin coatings applied to the grooves on the occlusal surface, which act as a physical barrier to prevent the collection of food particles and microorganisms. The most commonly used sealants are resin-based and GI based. Resin-based sealants are hydrophobic in nature.² However, GIs show decreased sensitivity to moisture contamination, adhesion to the tooth structure, and fluoride release. They can be placed *via* the ART technique in areas with limited resources and underdeveloped facilities.³

High-viscosity glass-ionomer materials have mainly been used in the ART approach. The placement of ART sealant is done *via* the "finger-press" technique.⁴ The GI sealants demonstrate better setting properties, better retention rates, and low solubility in oral fluids when compared to low-viscosity GIs.⁵ Newer formulations also show faster mixing times. These properties make high-viscosity glass-ionomer cement (GIC) a better alternative to the regularly used resin-based sealants.⁶

Several studies have compared the effectiveness of highviscosity GIC sealants and resin-based sealants. GIC sealants have shown higher retention rates than resin-based sealants.⁷ However, there is a paucity of studies on the performance of ART sealants ¹⁻³Department of Pedodontics and Preventive Dentistry, The Oxford Dental College, Bengaluru, Karnataka, India

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in primary molars. Thus, the aim of the present *in vivo* study is to evaluate and compare the clinical efficacy and survival rate of resin-based composite sealant (Clinpro Sealant, 3M ESPE, Irvine, California, United States of America) with high viscosity GI (Equia Forte, GC India, Patancheru, Telangana, India) using ART sealant protocol in primary molars.

MATERIALS AND METHODS

The present study was conducted on 3–6-year-old children who visited the Department of Pediatric and Preventive Dentistry. Ethical approval was obtained from The Institutional Ethics Committee and Review Board (Ethical committee Ref No: 179/ECAL/2019-20). The trial was registered under the Clinical Trials Registry of India (Reference Number: CTRI/2021/04/032999). The sample size was

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determined to be 50. After initial screening, children with teeth fulfilling the inclusion criteria were selected. Parents of the selected children were asked to sign an informed consent form.

The selected teeth were randomly allocated into group I–ART sealant (Equia Forte[®], GC Dental Pvt Ltd, Patancheru, Telangana, India) or group II–resin-based sealant (ClinproTM Sealant, 3M ESPE, Irvine, California, United States of America).

Inclusion Criteria

- Otherwise, healthy cooperative children with fully erupted primary molars.
- Deep pits and fissures are present in these primary molars (ICDAS II code 00).
- Initial occlusal carious lesions involving the pits and fissures of enamel (ICDAS II code 01).
- Incipient carious lesion involving enamel (ICDAS II code 02 and 03).⁸

Exclusion Criteria

- Uncooperative child.
- Children whose parents did not give consent for the study.
- Children with systemic disorders.

Equia Forte was applied on a primary molar in one quadrant, and Clinpro Sealant was applied on the contralateral primary molar of the same dental arch. Prior to the placement of sealant, ICDAS Il scores were assessed. Plaque and debris were removed from enamel surfaces and fissures. Teeth were rinsed thoroughly with water, dried, and isolated. Both of the materials were applied as per the manufacturer's instructions. After application, Equia Forte was pressed with slight finger pressure using a vaseline-coated gloved index finger (ART technique).¹ The patient was instructed not to eat for at least 1 hour after the procedure.^{9,10}

The follow-up examinations were conducted in the 1st and 6th month. At each recall visit, Simonsen's Criteria were used to check for the retention of sealants using a CPI Probe. In case of sealant loss, ICDAS II was used to check for caries.

Statistical Analysis

The data obtained were subjected to statistical analysis using Statistical Package for the Social Sciences for Windows, version 22.0, Released 2013, Armonk, New York, United States of America: IBM Corp. Chi-square analysis assessed the retention and ICDAS scores between different sealants at different times. Friedman's test evaluated the ICDAS scores. *Post hoc* Wilcoxon signed-rank test analyzed ICDAS Scores at different time intervals.

RESULTS

A total of 37 participants were included in the study. Of the 37, 15 (40%) were males and 22 (60%) were females. The mean age of the sample population was 5.04 ± 1.16 years. At 1 month, there was an attrition of seven pairs of teeth. At 6 months, there was an attrition of nine pairs of teeth.

Chi-square analysis revealed that group I had a statistically significant higher complete retention (67.4%) than group II at 1 month of following. Group II had a statistically significant higher number of no retention cases at 1 month of following (75%). Chi-square analysis revealed no statistically significant difference between Group A and Group B among retention scores at 6 months (Table 1).

Friedman's test displays a statistically significant difference in ICDAS scores at baseline, 1 and 6 months among group I sealant and no statistically significant difference in ICDAS scores at baseline, 1 and 6 months among group II sealant (Tables 2 and 3). Chi-square analysis displayed no statistically significant difference between group I and group II among ICDAS scores at baseline, 1 and 6 months (Table 4).

DISCUSSION

Pit and fissure sealants establish a seal that prevents nutrients from reaching microflora in the fissures.¹¹ Resin-based sealants are technique sensitive.¹⁰ Their hydrophobic nature makes application particularly difficult in young children. The proper placement of sealants thus requires a certain level of cooperation from the child.^{12,13}

Table 1: Comparison of retention scores between group I and II at baseline, 1 and 6 months

			Groups		. Chi-sauare	
			Group I	Group II	value	p-value
Retention at 1 month	Sound	Ν	0	0	11.7	0.008*
		%	0.00%	0.00%		
	Complete retention	Ν	29	14		
		%	67.40%	32.60%		
	Partial retention	Ν	8	11		
		%	42.10%	57.90%		
	No retention	Ν	6	18		
		%	25.00%	75.00%		
Retention at 6 months	Sound	Ν	0	0	2.25	0.521
		%	0.00%	0.00%		
	Complete retention	Ν	14	8		
		%	63.60%	36.40%		
	Partial retention	Ν	7	8		
		%	46.70%	53.30%		
	No retention	Ν	20	25		
		%	44.40%	55.60%		

*Statistical significance set at 0.05; N, number of samples; Chi-square value: Chi-square value

among group i sealant				among group	ng group il sealant		
	Mean rank	Chi ² -square	p-value		Mean rank		
Baseline	2.19	11.437	0.003*	Baseline	2.09		
1 month	1.79			1 month	1.91		
6 months	2.01			6 months	2		

 Table 2:
 Comparison of ICDAS scores between baseline, 1 and 6 months among group I sealant

Table 3: Comparison of ICDAS scores between baseline, 1 and 6 months among group II sealant

	Mean rank	Chi ² -square	p-value	
Baseline	2.09	4	0.135	
1 month	1.91			
6 months	2			
*Statistical significance set at 0.05				

*Statistical significance set at 0.05

Table 4: Comparison of ICDAS scores between group I and II at baseline, 1 and 6 months

			Groups			
			Group I	Group II	χ^2 -value	p-value
ICDAS score	Sound	Ν	24	23	0.806	0.848
		%	51.10%	48.90%		
	First visual change in enamel	Ν	7	9		
		%	43.80%	56.20%		
	Distinct visual change in enamel	Ν	14	15		
		%	48.30%	51.70%		
	Localized enamel breakdown	Ν	5	3		
		%	62.50%	37.50%		
ICDAS score at 1 month	Sound	Ν	40	31	6.84	0.144
		%	56.30%	43.70%		
	First visual change in enamel	Ν	1	6		
		%	14.30%	85.70%		
	Distinct visual change in enamel	Ν	1	4		
		%	20.00%	80.00%		
	Localized enamel breakdown	Ν	1	2		
		%	33.30%	66.70%		
ICDAS score at 6 months	Sound	Ν	30	27	6.61	0.251
		%	52.60%	47.40%		
	First visual change in enamel	Ν	2	9		
		%	18.20%	81.80%		
	Distinct visual change in enamel	Ν	6	3		
		%	66.70%	33.30%		
	Localized enamel breakdown	Ν	2	2		
		%	50.00%	50.00%		
	Underlying dark shadow from dentin	Ν	1	0		
		%	100.00%	0.00%		
		%	50.00%	50.00%		

*Statistical significance set at 0.05; N, number of samples; χ^2 -value, χ -square value

Glass ionomer (GI) sealants are hydrophilic. GI sealants also act as a fluoride reservoir even after the visible loss of sealant material.³ Remnants of sealant material are left behind in the deeper parts of pits and fissures and provide a caries-preventive effect over a long period. These remnants are probably present because GI fractures cohesively, whereas resin-based materials fracture adhesively.^{12,14} Furthermore, newer high-viscosity GIs demonstrate better physical properties making them an alternative to resin-based sealants.⁶

Several studies have utilized high-viscosity glass-ionomer as sealant material through the ART approach and have compared the effectiveness of high-viscosity GIC sealants and resin-based sealants. Evidence suggests that high-viscosity GI sealants and resin-based sealants are equally effective in preventing dentine lesion development.^{12,15,16} However, studies conducted on primary

molars were limited in number. Thus, this study assessed the clinical efficacy and survival rate of resin-based composite sealant (Clinpro Sealant, 3M ESPE, Irvine, California, United States of America) with high viscosity GI (Equia Forte, GC Dental Pvt Ltd, Patancheru, Telangana, India) using ART sealant protocol in primary molars.

The resin-based sealant utilized in this study was Clinpro Sealant. It is a light-cured and fluoride-releasing sealant with a color-changing ability. The color is initially pink and aids dental professionals in placement. After curing, the color changes to off-white. The addition of color also improves visibility at recall visits and decreases chairside evaluation time. The sealant is also clearly visible to the parent and child, thereby encouraging them to observe for sealant loss.¹⁷

Equia Forte Fil is a newly introduced high-viscosity GIC formulated by integrating ultrafine, highly reactive glass particles



into the conventional GI structure. It has several advantageous physical properties, such as fast placement, fast set, and hydrophilic nature. These features make the material apt for pediatric and high-caries-risk patients.¹⁸ To our knowledge, to date, no study has compared Equia Forte Fil with resin-based sealants. Thus, a comparison of the results with other studies which have utilized Equia Forte is not possible. The results were compared with other studies which have applied high-viscosity GICs or GI ART sealants.

In the present study, partial isolation was performed using cotton rolls. Absolute isolation *via* rubber dam was not preferred as it would be challenging in the selected age group. Studies have also stated that isolation by cotton rolls is equally effective to that of rubber dam.¹⁹⁻²²

The GI mixture was pressed into the pits and fissures (press-finger technique).¹² High-viscosity GICs, when placed using the "press finger" technique, may penetrate into pits and fissures and remain adhered long enough to provide a clinically important benefit to the patient.²³ A study showed that the fissure penetration depth and marginal leakage of ART sealants (using "finger pressure") were not significantly different from that of resin-based sealants.¹²

Assessment of sealants was performed at 1 and 6 months. In the present study, there was an attrition of the samples. Due to the COVID-19 pandemic, a few participants moved back to their hometowns from Bengaluru city. Schools were closed, and therefore the children could not return for subsequent follow-up visits. However, attrition was not considered a major problem in this study as subjects and molars lost to follow-up probably did not differ from those that were followed.²⁴

In this study, Equia Forte had higher complete retention (67.4%) than Clinpro at 1-month follow-up. The majority (75%) of Clinpro Sealant did not show retention at 1 month. However, at 6 months, there was no statistically significant difference between the groups.

It was believed that the success of sealants is assessed by retention rate and caries prevention.⁸ Selwitz et al. stated that the preventive effectiveness of sealants is directly associated with their retention ability.²⁵ However, a recent systematic review claimed that complete retention of sealants should not be a method of assessing caries prevention. The preventive effect of sealants is more important than their survival.²⁶

As per clinical evidence, sealant loss occurs in two phases. Initial loss is due to faulty technique. The faulty technique includes moisture contamination, not sealing all pits/fissures, inadequate etching, inadequate rinsing and drying, and insufficient curing time. Sealant loss at a later time (second loss) is associated with material wear under forces of occlusion. Sealant failure can occur due to any of these reasons or a combination of these reasons.²⁷ Another variable that affects sealant failure is the age of the patient.¹⁴

High levels of sealant loss may be due to difficulty in moisture control caused by the young age of the participants.^{1,28} It may also be due to the failure of participants to follow instructions and avoid eating for 1 hour after the procedure. In this study, the children were not supervised after the placement of sealants. Thus, their adherence to the instructions was not analyzed.⁹ Another reason is the placement of sealants without chairside assistance.¹

Increased levels of sealant loss were noted in other studies as well, and similar reasons were cited.^{1,28} These studies evaluated ART sealants in young Syrian children for a period of 5 years. The cumulative survival rate in these studies was only 12% for ART sealants and 14% for resin-based sealants after 5 years. Upon using

Fuji III, Poulsen et al. obtained <10% complete retention after 3 years in a field setting, and Boksman et al. reported only 2% of sealants were completely retained after 5 years.^{29,30}

However, high levels of sealant survival were reported by Holmgren et al. Their study reported a 59% survival of ART sealants after 6 years. These results could have been obtained as the mean age of the children was 12.5 years.⁵ The age might have further aided in the easier application and in reducing the problems associated with saliva control.¹ Another study also reported a 50% survival of ART sealants after 3 years.⁴ This could be due to the use of a faster setting, stronger, and more wear-resistant GI.

Glass ionomer (GI) ART sealants showed better retention in this study. Other studies have also reported similar findings and suggested that GI ART sealants can be used as an alternative to resin-based sealants.^{5,31} The study further advocates the use of GI sealants in cases of partially erupted teeth, as isolation is difficult.³¹ Due to the hydrophilic nature of GI sealants, even with some amount of salivary contamination, retention was better.

On comparison of ICDAS scores between the different time durations in each group. Equia Forte group showed a statistically significant difference. Clinpro Sealant did not show a statistically significant difference.

On comparison of ICDAS scores between the two groups at baseline, 1 and 6 months, Chi-square analysis displayed no statistically significant difference. Thus, there was no statistically significant difference with regard to the caries-preventive effect in this study. This might have occurred as both types of sealants used in this study are fluoride-releasing materials.²⁴ These findings are similar to other studies which reported that GI ART sealants have caries preventive effect and are effective in preventing dentine caries lesions.^{5,32–34} Certain studies stated that caries preventive effect of GI sealants persists even after they are missing from the tooth surface.^{29,35}

The main limitation of the study is the increased material wastage and treatment costs associated with the use of Equia Forte. To overcome these limitations, manufacturers can investigate the possibility of smaller dose sizes specifically for ART sealants which would reduce the cost of the sealants.⁵ Furthermore, additional longitudinal studies are needed to establish the results.

CONCLUSION

High-viscosity GI sealants are more retentive and equally caries preventive as resin-based sealants in young children. High-viscosity GI sealants can be applied using the ART protocol and provide a useful alternative to resin-based sealants, especially in situations where conventional dental equipment might not be available, minimal armamentarium is present, or in field settings. They are also good alternatives in situations where moisture control is difficult.

DECLARATIONS

Ethical Approval and Consent to Participate

- Ethical approval was obtained from The Institutional Ethics Committee and Review Board (Ethical committee Ref No: 179/ECAL/2019-20).
- The trial was registered under the Clinical Trials Registry of India (Reference Number: CTRI/2021/04/032999).
- Informed consent was obtained from all parents or caregivers of the participants included in the study.

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