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TWO-YEAR SURVIVAL OF GLASS IONOMER SEALANTS PLACED AS PART OF PROXIMAL ATRAUMATIC RESTORATIVE TREATMENT RESTORATIONS
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TWO-YEAR SURVIVAL OF GLASS IONOMER SEALANTS PLACED AS PART OF PROXIMAL ATRAUMATIC RESTORATIVE TREATMENT RESTORATIONS

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ABSTRACT

Objective: **To evaluate after two years, the survival rate of glass ionomer cement (GIC) sealants placed in primary molars of six to eight year-olds and as part of proximal atraumatic restorative treatment (ART) restoration.**
Design: **A longitudinal clinical study.**
Setting: **Matungulu/Kangundo rural divisions, Machakos district, Kenya.**
***Subject*: A total of 804 six to eight year-olds from rural Kenya received a sealant as part of a proximal restoration placed in a primary molar using the atraumatic restorative treatment (ART) approach.**
Results: **The two-year cumulative survival of the sealants was 10.9%, and the survival of the sealants was not significantly affected by the GIC material brand and the tooth-isolation method used. However, slightly more sealants survived when Fuji IX and rubber dam tooth- isolation method were used.**
***Conclusion*: The two-year survival rate of the sealants was poor and was not significantly influenced by the GIC material or the tooth-isolation method used.**

INTRODUCTION

Atraumatic restorative treatment (ART) approach is a potentially viable technique for restoring carious teeth and sealing pits and fissures in both primary and permanent dentition in children (1-3). Glass ionomer cement which is used with this technique, is very sensitive to moisture contamination, and requires adequate tooth-isolation (4,5). The tooth-isolation can be achieved through the use of rubber dam or cotton rolls, but whether any of the methods offers superior tooth-isolation, is not exactly clear (6-8), although rubber dam method has been reported to be more costly and difficult to routinely apply by most general practiotioners (7).

There are reports that good marginal seals have been obtained with GIC sealants placed using the 'finger-press' method (9) as used with the ART approach. However, their failure rate has remained generally high (10). Premature loss of GIC sealants has been associated with, among other factors, inadequate cleaning of the pits and fissures and tooth-isolation prior to applying them (11), besides the low compressive strength of GIC materials (12). It is still unclear to what extent moisture contamination and the GIC material-brand affect the failure rate of these sealants. The aim of the present study was to evaluate after two years the survival rate of GIC sealants placed on occlusal surface of primary molar, as part of proximal ART restorations and when using 3 GIC-brands and 2 tooth-isolation methods.

MATERIALS AND METHODS

Sample selection: The study sample formed part of a larger two-year longitudinal study on factors influencing the longevity of proximal ART restorations in six to eight year-olds from 30 rural schools in Matungulu/Kangundo rural divisions in Machakos District, Kenya. The carious lesions were selected in primary molars, and had a bucco-lingual occlusal opening of 0.5 - 1.0 mm. The teeth selected had no signs or symptoms of periodontal disease, and clinically the carious lesions did not involve the dental pulp. The remaining caries-free occlusal surfaces of the teeth to be restored were to have at least some pits and fissures present. A total of 804 cavities in a similar number of children were selected and restored, with the adjacent pits and fissures being sealed at the same time using the 'finger press' method. All the participating children had all the other teeth documented for dental caries (13) and dental plaque (14). Three examiners did

the documentation after having been trained and calibrated by the principal investigator (a mean Kappa of 0.84 for caries and 0.88 for plaque). Prior to the commencement of the study, the parent/guardian gave a written informed consent and Ethical clearance for the study was obtained from the Ethical Committee of the Kenyatta National Hospital, Nairobi.

Clinical procedure: Two Dentists, four final-year dental students and one Community Oral Health Officer (COHO) as operators, restored the proximal cavities and placed the sealants on the remaining occlusal surface of the teeth. They were assisted by eight dental assistants, randomly paired to the operators, in such a manner that one assistant rested on each operative day. All the operators and assistants had been trained in their respective roles in applying the ART approach, and had also gained further experience with the technique prior to the start of the study (5, 15).

Using random numbers, the children were assigned to an isolation method and GIC material brand. The treatment was done at each school, with the child lying on a table. The selected tooth was isolated with rubber dam (Medium - dark, Hygenic Dental Dam, HCM - Hygienic Corporation, Malaysia) or cotton wool rolls (Hartmann Celluron, De - Paul Hartmann AG89522, Heiderheim, Germany). During the use of rubber dam, a two-minute gingival application three of a topical anaesthetic (Lidocaine 50mg/g cream) was first done prior to placing the rubber dam clamp FIT - Kofferdam Klammer, U67, (Hager & Werken GmbH & Co. KG Germany). The cotton wool rolls were placed buccally (maxillary teeth) or lingually and buccally (mandibular teeth) to isolate the tooth. No other local anaesthetic was used in the study and no child refused any of the tooth-isolation method used in the study. Either a disto-occlusal or mesio-occlusal cavity in a first or second primary molar was restored in either the upper or lower dental arch. The restoration was placed after plaque and debris were removed from the tooth-surfaces with a probe (Duflex - SS White) and the surfaces cleaned and dried with cotton pellets. The cavity and fissure surfaces were pre-treated for 15 seconds (diluted part of the mixing liquid for Fuji IX and the manufacturer's conditioner for Ketac brands) and then rinsed and dried again in the same manner as described before. Fuji IX (GC Europe) or Ketac Molar Easymix or KME (3M ESPE AG), Ketac Molar Aplicap or KMA (3M ESPE AG) GIC brands were used to restore the cavities. The assistants mixed the GIC materials in accordance with the manufacturer's instructions and the operator applied the materials in the prepared cavities. A thin coating of petroleum jelly on a gloved finger was used to press the excess restorative material into pits and fissures adjacent to the proximal restoration. Any further excess material was removed with an excavator. After one minute, the conclusion was checked with a blue articulating paper (Bausch Articulating paper (Nashua, NH03060, US) and if necessary adjusted. Petroleum jelly was applied over both the restoration and the sealant to protect them from moisture contamination, and the child advised not to chew any food for an hour.

Evaluations and calibration process: The sealants were evaluated soon after placement (within two hours) and after two years by four final-year dental students and two postgraduate paediatric dental students respectively, using the criteria given in Table 1.

Table: 1

The quality of the fissure sealants was based on the following guidelines:

Score	Evaluation criteria	Comment
0	Present, good	Successful
1	Present, marginal defects, no repair needed.	Successful
2	Present gross defects, repairs needed.	Failed
3	Not present, almost/completely disappeared, to re-do.	Failed
4	Not present, other treatment done	Censored
5	Not present, tooth extracted/exfoliated	Censore
6	Un-diagnosable	Censu

Similarly, other evaluations were done at one week and again at one, five, twelve and eighteen months. All the evaluators had been trained and calibrated by the principal investigator. Their training and calibration involved the use of intra-oral photographs of GIC sealants, GIC sealants in extracted teeth and in teeth of children who had received GIC sealants but who were not part of the study population. Using the intra-oral photographs of GIC sealants the evaluators were trained to recognise and to score (using the criteria in Table 1) good sealants, those that showed loss or marginal defects on them. The evaluators also used extracted teeth with GIC sealants and teeth with GIC sealants in a selected

group of children, to similarly evaluate and score the sealants using the same criteria for the evaluation of the sealants, aided by sterile mouth- mirrors and Michigan 0 periodontal probes with William's markings.

Initially, a 'gold' standard for inter-evaluator consistency was established between the principal investigator (PI) and an experienced Dentist using the Cohen Kappa coefficient (16) (Kappa 0.92, n=20), before the PI calibrated all the evaluators of the sealants. The mean inter- evaluator reproducibility was Kappa 0.82 and 0.92 for those evaluating the sealants soon after placement and after two years respectively. The intra-evaluator agreements for the two groups of evaluators on 10% of their evaluated sealants ranged from Kappa 0.80 to 1.0. Also done after two years was the documentation of dental caries (including secondary caries on the restored teeth) and plaque in the participating children, in the same manner as initially done before treating the children. The documentation was done by the two post-graduate students who had been trained and calibrated in the technique by the pricipal investigator. Their mean Kappa Co-efficient was 0.86 for caries detection and 0.92 for plaque detection.

Statistical analysis: The data collected were analysed using SPSS 14.0 (SPSS Inc, Chicago, IL) computer programme, and the results related to the method of isolation, the GIC material- brand and also to the dental arch in which the sealants were placed. Kaplan-Meier survival, Cox Proportional Hazard model (Cox PH), multiple logistic regression model and Chi-square tests were used to validate the results, with p-value of less than 5% being statistically significant.

RESULTS

At baseline, the male / female ratio of the subjects was 1.3: 1 and the mean age was 7.4 (SD ± 0.9) years. The DMFT and dmft of the study population changed from 0.15 (SD 0.52) and 3.96 (SD 2.38) at baseline to 0.19 (SD 0.42) and 3.24 (SD 2.18) after two years respectively. The mean plaque index changed from 2.34 (SD 0.46) at baseline to 1.92 (SD 2.1) after two years. A total of 244 (30.4 %) and 560 (69.6%) sealants were placed in the maxillary and mandibular arches respectively, with 450 (56%9 in first molars and 354 (44%) in the second molars. Save for three improperly documented cases, the distribution of the sealants in relation to the method of tooth-isolation, the GIC material and the dental arch in which they were placed was as shown in Table 2. The distribution of the sealants per operator ranged from 92 to 142 sealants.

Table 2

The distribution of the sealants in relation to the GIC-brand, tooth-isolation method and the dental arch.

Type of GIC	Method of isolation	Sealants in maxillary arch	Sealants in mandibular arch	Total
	Rubber dam	39	105	144
Fuji IX	Cotton roll	51	83	134
	Sub-total	90	188	278
				(34.7%)
	Rubber dam	34	104	138
Ketac Molar	Cotton roll	53	88	141
Easy mix	Sub-total	87	192	279
				(34.8%)
	Rubber dam	27	95	122
Ketac Molar	Cotton roll	37	85	122
Aplicap	Sub-total	64	180	244
				(30.5%)

Thirty-eight (4.7%) of the sealants could not be evaluated soon after placement due to truancy by the children, leaving 763 sealants for evaluation. Due to the study-population attrition of 19 (2.5%) drop-outs, 64 (8.4%) school-transferees, 31 (4.1 %) absentees and one death, 648 (84.9%) sealants were available for evaluation at the end of two years. The cumulative survival of the sealants had declined from 89.4% at the initial evaluation stage to 10.9% when evaluated after two years. A total of 39 sealants were still intact on first primary molars while only 32 sealants were found to be still intact on the second primary molars after two years. The rest of the sealants had failed with a total of 132 (17.3%) teeth with sealants having experienced secondary caries. Of the teeth with secondary caries, 11.4% (n=15) had involved the sealed surfaces. There was no significant statistical difference between the survival rate of the sealants when related to the first and the second primary molars (Chi-square, p=1.06), although slightly more sealants were surviving on the first primary molars than on the second primary molars

The survival rate of the sealants varied among the operators. However, survival rate of the sealants that were placed using the rubber dam isolation-method did not show any significant statistical difference with those placed using the cotton wool rolls method (Cox PH Model, Est = -0.005, SE=0.094, Chi-square = 0.003, p=0.96). There were no significant statistical differences with the survival rate of the sealants when related to the material brand used (Cox PH model test, Est = -0.009, SE = 0.091, p = 0.923) (Figure l) or to the dental arches in which they were placed (Cox PH model test, Est = 0.213, SE = 0.108, p = 0.402) (Figure 2). However, there were more sealants placed in the mandibular arch compared to the maxillary arch, and this skewed situation could be something to consider in this result. Nonetheless, the sealants placed using Fuji IX had a relatively higher survival rate, followedby KMA and lastly by KME

Figure 1

Kaplan-Meier plot for the survival of sealants in relation to the GIC- brand and the method of tooth - isolation

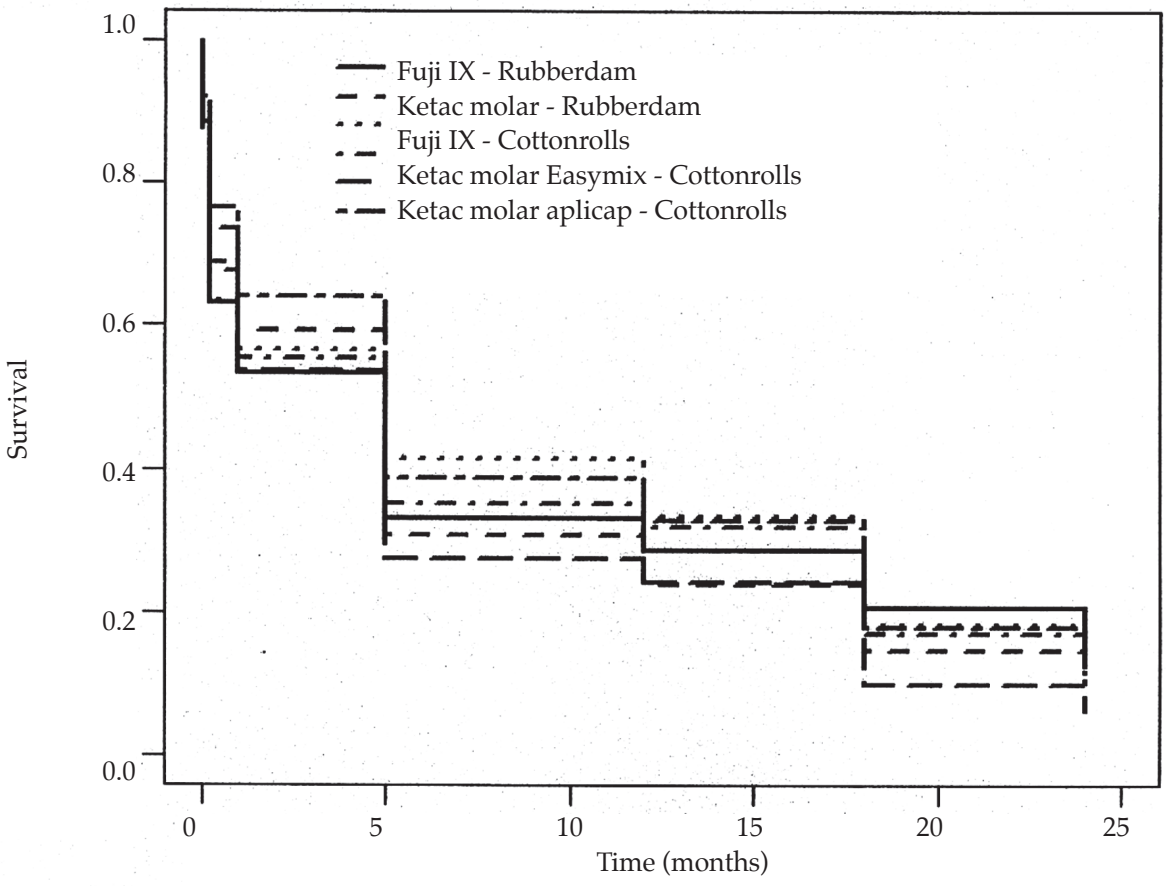

Figure 2
Kaplan-Meier plot for the survival of sealants in relation to the isolation method and the arch in which they were placed

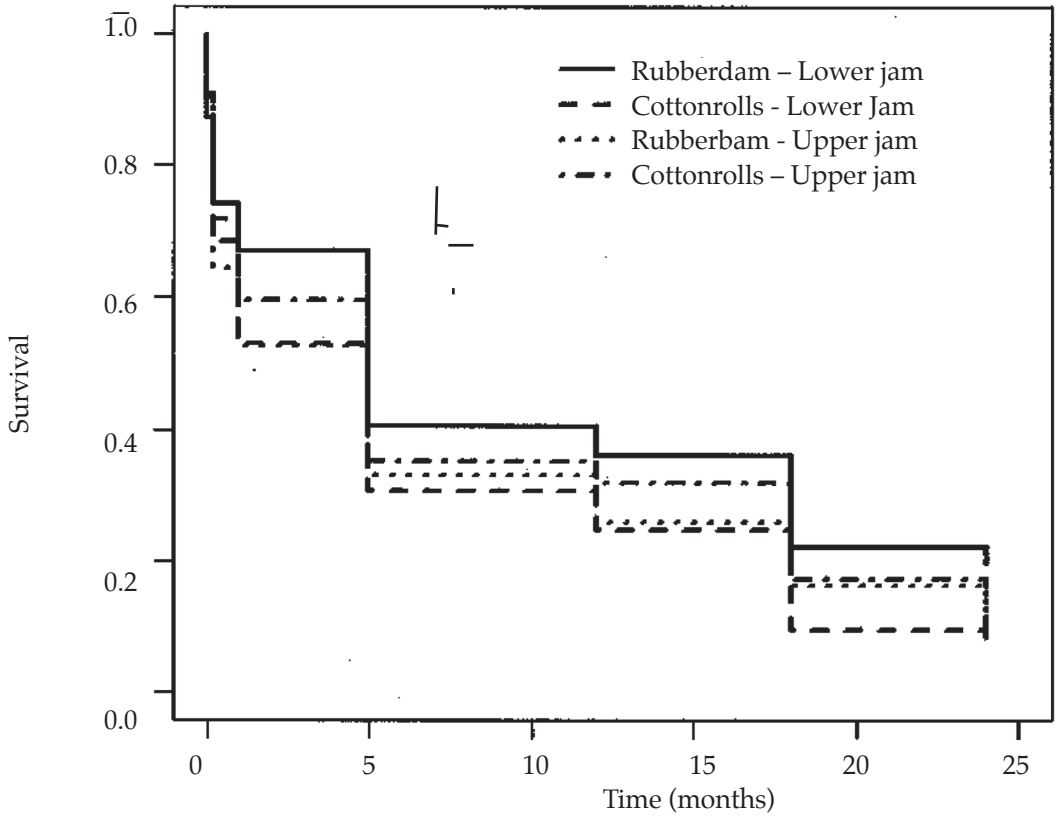

Table 3
The multi-logistic regression test results for the best model of survival rate for the sealants in relationship to the operator, material and isolation-related variables.

parameter	Odds ratio estimate	Standard Error	95% confidence interval	Chi-square test p-value	Statistical significant
Operator	0.5419	0.0963	1.4261 - 12.4351	<0.0001	significant
Fuji IX	0.2314	0.1051	0.0832 - 4.2430	0.3102	not significant
KMA	0.2143	2.2340	2.6231 - 4.2132	0.1320	not significant
KME	-0.088	0.6123	1.0721 - 5.0162	0.5481	not significant
Mixing time by assistants of less than 30 seconds	0.5846	0.4884	3.2413 - 5.1274	0.2313	not significant
Rubber dam	-0.0049	0.0943	1.0341-4.0123	0.9582	not significant
Cotton roll	-0.2130	0.1201	1.0562 - 6.3627	0.6482	not significant
Dental arch	-0.0992	0.1034	3.7781 - 9.3573	0.3377	not Significant

A multiple logistic regression model test for the best model of the survival of the sealants as related to the isolation method, GIC material, dental arch and operator was done and the results tabulated (Table 3). Apart from the operator factor, there were no other significant determining factors noted in relation to the survival rate of the sealants.

DISCUSSION

Whenever possible, a sealant is usually placed on the remaining pits and fissures of a tooth receiving a restoration when using the ART approach. Since the selection process for the appropriate teeth with the proximal cavities was done carefully and using the criteria that had initially been set, all the selected teeth were restored and also received a sealant. Subsequently, a determination was made of the longevity of such sealants placed together with proximal ART restorations. An analysis of the data obtained showed that a number of the sealants had already failed at the initial evaluation stage (within two hours of post-placement).

This early loss could have been caused by gross marginal failures, failure by the child to abstain from chewing food within the first one hour or as a result of shallow pits and fissures, a common feature for the type of dentition in the study. At the end of two years most of the sealants had virtually failed, with only 10.9% of the sealants surviving.

The quality of the GIC sealants depends on many factors, for example, material- mixing / manipulation technique (15) and the method of tooth-isolation at the time of placing the sealant. Even though rubber dam tooth-isolation is not a routine method for use when using the ART approach, its use in this study gave rise to a higher survival rate of the sealants when related to the cotton roll method, though not statistically significant.

The lower dental arch should be more challenging than the upper arch to adequately isolate (5), due to the presence of the saliva bathing effects. But in the present study, there were no statistically significant differences observed in relation to the survival of the sealants and the dental arches where they were placed. Although in the study there were more sealants placed in the mandibular arch than in the maxillary arch, and this could have probably affected the outcome. Since the sealants were applied on the occlusal surfaces of the teeth away from the gingiva or floor of the oral cavity, it is also possible that the saliva contamination-effect might have been less pronounced. Fuji IX and KMA materials had higher survival outcomes for their sealants than the KME material, irrespective of the isolation method used. This might be a pointer to the effects of individual material-characteristics rather than any other factor considered in the study (17).

There was obviously a high failure rate of the sealants in this study, as previously reported in other studies (18). However, the affected teeth appeared less susceptible to new carious lesions, probably there are extra benefits from the presence of the sealants and even after their loss. There were lower numbers of the restored teeth in the present study that were found to have secondary cariers on the surfaces that had been sealed. It is plausible to presume that the sealants might have had some caries-preventive effects. Nonetheless, there is still a need to research more on various factors that could help improve the longevity or the long-term effects of GIC sealants placed using the 'press-finger' technique used in applying the sealants when using the ART approach. The high rate of failure in the present study could have also been affected by the type of dentition that was used. The pits and fissures in the primary dentition are rather shallow, and there is also a higher rate of dental attrition in this dentition.

There is a possibility all these factors could have affected the outcome. This is, therefore, a consideration to be taken care of in future research. Nonetheless, the poor survival rate found in the present study calls for more research in finding more ways of improving the survival rate of these sealants, that have the possibility of helping to preserve the dentition of children particularly from areas that lack basic dental health facilities.

In conclusion the two-year survival rate of the GIC-sealants placed as part of proximal ART restorations in the primary molars was very low, and was not significantly influenced by the GIC-brand or the tooth-isolation method used.

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