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Chapter 5



Influence of different isolation methods on the survival of proximal ART restorations in primary molars after two years

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Abstract

Aim: This was to evaluate the influence of two methods of tooth-isolation on the survival rate of proximal ART restorations in the primary molars.

Methods: The study was conducted in two rural divisions in Kenya, with 7 operators randomly paired to a group of 8 assistants. A total of 804 children had each one proximal cavity in a primary molar restored using the ART approach. During the restoration 2 isolation methods, rubber dam or cotton wool rolls, and 3 brands of glass ionomer cements were randomly used by the operators. The restorations were then followed for a period of 2 years.

Statistics: SPSS 14.0 was used to analyze and relate the data obtained to the method of isolation used.

Results: After 2 years 30.8% of the ART restorations had survived. Higher survival rates of the restorations were obtained when using rubber dam irrespective of the GIC material or the operator.

Conclusions: Generally the survival rate of the proximal restorations in the present study was very low, but the use of rubber dam resulted in a higher survival rate of the restorations.

Introduction

The atraumatic restorative treatment (ART) approach has been described as simple to use due to its manual cleaning of dental cavities with just hand instruments and the use of an adhesive material such as glass ionomer cement (GIC) to restore them. The setting of GIC is basically an acid-base type of reaction. The calcium and aluminium-ion components react with polyacrylic ions to form cross-links between the polyacrylic chains, incorporating the silica particles to a solid mass. The calcium polyacrylic chains formed are soluble in water, and therefore, require protection from moisture contamination during the placement of the material in the cavity and shortly after completing the restoration [Sofar *et al.*, 1999, Frencken and Holmgren, 1999].

Cotton wool rolls and rubber dam have been used to isolate teeth requiring dental restorations. Matrix bands/strips with inter-dental wedge-retainers are additionally used, in the case of proximal cavities, to further enhance moisture-control and to reproduce the tooth-form [Tandon, 2001]. Some studies have suggested rubber dam to be superior to the cotton roll method [Knight *et al.*, 1993]. Other studies have found no merit in this assertion [Smales, 1992], and have associated the method with higher cost and is also cumbersome for routine application by most general dentists [Frencken and Holmgren, 1999].

While single-surface ART-restorations have shown very good survival rates in the short- and medium-term [Honkala *et al.*, 2003; Yu *et al.*, 2004,], the multi-surface ART restorations have been found to have unsatisfactorily high failure rates [Roeleveld *et al.*, 2006; van Gemert-Schriks *et al.*, 2007; van der Hoef and van Amerongen, 2007]. Failures of ART restorations, manifesting as 'wholly or partially missing', with 'fractures or gross marginal defects' [Taifour *et al.*, 2002] have commonly been associated with operator-inexperience, incomplete removal of dental caries and inadequate tooth-isolation [Yu *et al.*, 2004]. To what extent contamination during the application and initial setting of glass ionomer contribute to the high failure rate is unknown. Could the use of rubber dam improve the adhesion of the GIC to the tooth substance as well as the physical properties of the material? The purpose of this study was to compare the influence of rubber dam and cotton wool roll tooth-isolation methods on the survival results of proximal ART restorations after two-year period.

Materials and Methods

Study population: The present study formed part of a larger clinical intervention study to determine factors influencing the survival rate of proximal ART restorations described previous [Kemoli *et al.*, 2009]. A group of 6,002 children were selected in 30 out of 142 public primary schools in two rural divisions of Machakos district, Kenya. The selection-criteria included 6 to 8 year-olds, in good general health with a proximal carious-lesion in a primary molar having an occlusal access of approximately 0.5 mm to 1.0 mm in the bucco-lingual direction [Kemoli *et al.*, 2009]. The calculated sample size was 382 children but a higher study population was desirable to allow for the study loss over the 2-year study-period.

Operators: These were as in the previous report [Kemoli *et al.*, 2009] and briefly a paediatric dentist and two final-year Dutch dental students, who had been trained and pre-tested.

Randomization and restorative procedure: The 7 operators were randomly paired daily to a group of 8 assistants. They had been trained in their respective roles in applying the ART approach, based on a five-module WHO-recommended ART training program [Frencken *et al.*, 2000] as previously described [Kemoli *et al.* 2009]. Using random numbers, the children were assigned to an isolation method, material, operator and assistant. Each child had the restoration randomly placed in the primary molar in either mandibular or maxillary arch.

Isolation: Each tooth was isolated using either rubber dam (Medium-dark, Hygenic Dental Dam, HCM - Hygienic Corporation, Malaysia) or cotton wool rolls (Hartmann Celluron, De - Paul Hartmann AG - 89522, Heiderheim, Germany). The cotton wool rolls were placed buccally (maxillary teeth) or lingually and buccally (mandibular teeth), while the rubber dam was used to isolate the tooth to be restored. A 2-minute gingival application of a topical anaesthetic (Lidocaine 50mg/g cream) was used prior to the application of the rubber dam clamp (FIT - Kofferdam Klammer, U67, Hager & Werken GmbH & Co. KG Germany). No other local analgesic was used in the study, and none of the children allocated to the rubber dam isolation refused the method.

Cavity preparation and materials: A hatchet enlarged cavity access and a spoon excavator removed the soft carious materials [Kemoli *et al.*, 2009]. Pulpal-exposures were dressed and the children who were affected removed from the study and referred for further treatment to a local hospital. Rinsing and drying of the cavity was with wet and dry cotton pellets. Deep cavities were lined with a thin layer of calcium hydroxide (Caulk, Dycal). A small pre-curved steel matrix band (Union Broach Moyco) and wooden wedges (Sycomore Interdental wedges No. 823, Hawe Neos Dental, Switzerland) were used before restoring the cavity with either Fuji IX (GC Europe) or Ketac Molar Easymix or KME (3M ESPE AG); Ketac Molar Aplicap or KMA (3M ESPE AG). Fuji IX and KME were manually mixed and KMA mechanically mixed for 10 seconds (Degussa amalgamator at 4300 oscillations per minute). After pre-treating the cavity for 15 sec. with a diluted form of the mixing-liquid (Fuji IX) or the manufacturer's conditioner (Ketac Molar brands), each tooth was restored. Restorations were adjusted for occlusion and petroleum jelly applied for moisture protection. Each child had a bite-wing radiograph of the restored tooth taken and advised not to chew any food for an hour.

Follow-up evaluations: The restorations were evaluated using the criteria reported previously [Kemoli *et al.*, 2009] within two hours of restoring each tooth (4 final-year Dutch dental students) and after two years (2 postgraduate Dutch paediatric dental students). Other evaluations were completed at 1 week, 1, 5, 12, 18 and 24 months. The evaluators had not restored the cavities but had been trained and calibrated in the technique [Cohen, 1960]. Sterile mouth-mirrors and Michigan O periodontal probes with William's markings were employed during the evaluation of the restorations to establish their presence, marginal integrity, general material wear, fractures and secondary caries. The post-operative bitewing radiographs were evaluated by the chief investigator for the restorations' presence, marginal integrity (voids) and any residual caries.

Dental caries and restoration evaluations: The chief investigator (AK) had established a "gold" standard for the detection of dental caries with a local professor of paediatric dentistry (Kappa 0.84, n=60) and for the assessment of the restorations with an experienced dentist (Cohen's Kappa 0.92, n=20). AK then trained and calibrated the caries-examiners and restoration-evaluators. The mean Kappa for caries-detection

ranged from 0.84 to 0.86 (n= 20 – 26) with the inter- and intra-examiner mean repeatability of 0.84 (n=63) and 0.86 (n=52) for the first and last examination-groups respectively. The mean inter-evaluator repeatability for the evaluators was Kappa 0.82 and 0.92 for the first and second groups respectively, with the daily intra-examiner agreements on 10% of the restorations evaluated ranging from 0.80 to 1.0 for both groups. Bite-wing radiographs were evaluated by AK after calibrating with a local dental radiologist (mean inter-examiner Kappa, p= 0.83 (n=46 and intra-examiner Kappa 0.92, n= 10% of the radiographs examined).

Statistical analysis: The data obtained in the study were analyzed using SPSS 14.0 (SPSS Inc, Chicago, IL) computer programme and further details have been reported earlier [Kemoli *et al.* 2009].

Results

A total of 1,560 cavities met the criteria, but only 804 cavities were successfully restored. The remainder were lost due to absenteeism, transfer to other schools outside the study area or for other reasons (n=352), lack of parental consent (n=280), pulpal exposure at the excavation stage (n=99) and child anxiety (n=25). A total of 244 (30.4 %) and 560 (69.6%) restorations were placed in the maxillary and mandibular arches respectively. Save for 3 cases that were improperly documented, distribution of restorations to the method of tooth-isolation and GIC material used is shown in Table 5.1. A total of 244 (30.5%), 279 (34.8%) and 278 (34.7%) restorations were made using KMA, KME and Fuji IX GIC respectively. Rubber dam was used for 404 (50.2%) and cotton rolls for 397 (49.4%) of the restorations (Table 5.1).

Table 5.1: The distribution of the ART proximal restorations in relation to GIC materials, isolation-method and the dental arch where they were placed.

Type of GIC	Method of isolation	Restorations in mandible	Restorations in maxilla	Total
Fuji IX	Rubber dam	39	105	144
	Cotton roll	51	83	134
	Sub-total	90	188	278 (34.7%)
Ketac Molar	Rubber dam	34	104	138
	Cotton roll	53	88	141
	Sub-total	87	192	279 (34.8%)
Easy mix	Rubber dam	28	94	122
	Cotton roll	37	85	122
	Sub-total	65	179	244 (30.5%)

The 7 operators had their restorations distributed as 104 (13%), 100 (12.5%), 92 (11.5%), 104 (13%), 131(16.4%), 128 (16%) and 142 (17.7%), with the assistants almost equally distributed in relation to these restorations that they helped to place. Because of truancy 38 (4.7%) of the restorations the 801 documented cases could not be evaluated soon after placement, leaving only 763 restorations to be evaluated. Due to the study-population attrition resulting from drop-outs, school-transferees, absentees and one death, only 648 (80.9%) children could be evaluated at the end of 2 years.

A total of 132 (16.5%) teeth were found to have secondary caries at final evaluation. The survival rate of the restorations declined from 94.4% soon after placement to 30.8%

after 2 years. At the end of the study the survival rate of the restorations placed using the rubber dam was significantly higher compared with the cotton roll method (Cox PH model, Est = -0.224, SE = 0.10, Chi-square = 4.93, p = 0.026). Comparing the method of isolation and the material used, the survival rate of the restorations did not show any significant difference. But, KMA restorations had slightly higher survival rate followed by Fuji IX with KME having the least survivals. The cotton roll method gave the lowest survival rate for the restorations, and then Fuji IX restorations had a higher survival rate followed by KMA and KME (Figure 5.1).

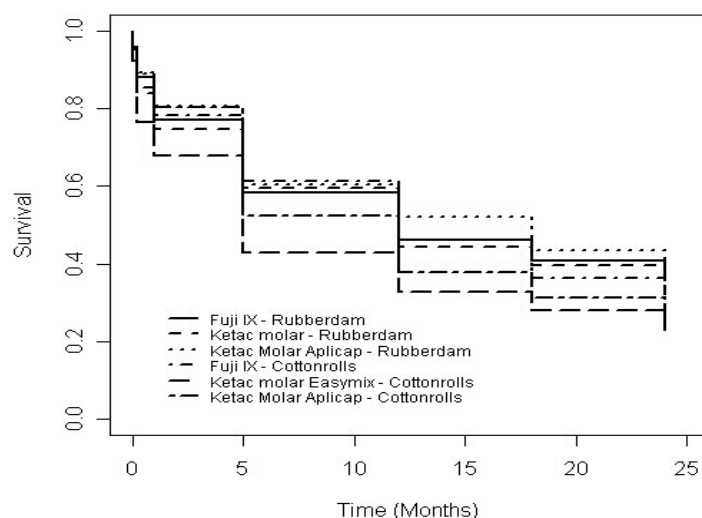


Figure 5.1: Kaplan-Meier plot for the survival of the restorations, method of isolation and the materials used.

In relation to the dental arches, the 2-year survival rate of the restorations was higher in the mandible when rubber dam isolation method was used (Est 0.091, SE= 0.105, p=0.402), but the difference with cotton rolls method was not significant (Cox Proportional Hazard model test, Est -0.042, Se=0.102, p=0.677). The restorations placed in the maxilla using the cotton roll method had a slightly higher survival rate than the rubber dam method, but again the difference was not significant statistically (Chi-square, p =0.423).

The post-restorative radiographic evaluation did not show any statistical significant difference for the quality of restorations placed using the two methods of isolation (Chi-square, p = 0.98). The marginal gaps detected in the radiographs were slightly more for restorations made using cotton rolls and not rubber dam. Restorations with marginal gaps proved to have the poorest survival rate after 2 years (Pearson Chi-square, p=0.005). A multiple logistic model test for the best model of the survival of the restorations as related to the isolation method, GIC material, dental arch and operator was done and the results tabulated (Table 5.2). The use of rubber dam and the operator emerged as significant determining factors in the survival rate of the restorations, irrespective of the other factors.

Table 5.2: The Logistic regression analysis results for the best model with the variables shown in relation to the two-year survival rate of the restorations.

Parameter	Odds ratio estimate	Standard Error	95% confidence interval	Chi-square test p-value	Statistical significance
Operator	0.203	0.085	1.321- 21.543	0.017	significant
Fuji IX	0.094	0.134	1.083 - 6.157	0.482	not significant
KMA	0.212	1.137	2.721 - 5.168	0.123	not significant
KME	-0.088	0.354	1.062 - 9.168	0.805	not significant
Rubber dam	-0.188	0.086	1.074 - 5.013	0.037	significant
Cotton roll	-0.167	0.085	1.070 - 7.342	0.068	not significant
Dental arch	-0.020	0.019	3.678 - 17.475	0.280	not significant

Discussion

Improvement in the survival rate of proximal ART restorations would lead to a greater use of the technique. If either of the two isolation methods used resulted in higher retention rate of these restorations, it would be advantageous.

In the present study, the survival rate as clinically evaluated soon after placement was lower than expected probably because of early restoration-losses, gross marginal failures or failure by the child to abstain from eating within the first one hour. The present 2-year survival results of 30.8% for the restorations, though still very low, were a little higher compared with results from previous studies using similar materials [Roeleveld *et al.*, 2006; van Gemert-Schriks *et al.*, 2007; van der Hoef and van Amerongen, 2007]. However, the study -population and the environment in which the studies were carried out might have been different.

Proximal carious lesions present specific isolation-challenges due to proximity to the gingival sulcus. In addition, there are difficulties related to the access and to the moisture control for these cavities when using the ART approach [Sofar, 1999]. Even though the use of rubber dam has been associated with higher restoration-survival rates [Smales, 1992], other reports have contradicted this [Smales, 1992; Raskin *et al.*, 2000]. In the present study, the use of rubber dam gave rise to proximal restorations with a relatively higher survival rate when compared with cotton wool rolls.

In general the present study had higher survival outcomes for both restorations of Fuji IX and KMA but not for KME, probably a result of their individual material-characteristics rather than the method of isolation [Barghi *et al.*, 1991]. GIC materials used in the present study were high viscosity GICs recommended for use with the ART. The quality of the fillings depends on many other factors such as mixing technique, manipulation of the mixture by operators and other handling conditions [Grossman and Mackenautsch, 2002, Kemoli *et al.*, 2009]. In the present study the use of any of the GICs did not give rise to any significant influence on the survival rate of the restorations.

Teeth in the mandible should be harder to adequately isolate than those in the maxilla, due to the saliva bathing effect [Frencken and Holmgren]. At the end of the 2 years, rubber dam isolation gave rise to restorations with significantly higher survival rate in the mandibular arch, but not in the maxillary arch where the cotton roll method proved a

little better. Probably the advantages offered by the rubber dam could have been more pronounced in the mandibular arch where the saliva bathing is higher than in the maxillary arch.

Overall, the results obtained in the present study were still very low for a technique that could be used routinely to conserve proximal caries in the primary molars. An operator has a duty to evaluate a given situation where a proximal ART restoration is needed and to make a decision as to the method and the technique to apply in placing a restoration. Consideration needs to be given to other available options that might lead to increased longevity of the restorations, for example the Hall's technique [Innes et al., 2006] which, compared to the present method used in this study, has the advantage of using preformed metal crowns. This approach allows for the use of GIC as a cementing material while at the same time providing the tooth with all the advantages of the GIC material in relation to control and prevention of dental caries. There is a need to further investigate the two techniques in order to find a long term solution to the management of large dental carious lesions in the primary molars.

Conclusions

The survival rate of proximal ART restorations after two years was very low. A higher survival rate of the restorations was observed when the rubber dam isolation-method was used, with the difference between rubber dam and cotton roll methods being statistically significant.

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