Factor analysis in relation to survival rate of proximal ART restorations in primary molars

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Publication date
2011

Chapter 8

Effects of plaque, residual caries and cervical marginal gaps on the 2-year survival rate of proximal ART restorations

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Journal of Dentistry for children (Submitted for consideration)

Abstract

Aim: To investigate the effects of oral hygiene, residual caries and cervical marginal-gaps on the survival rate of proximal restorations placed in primary molars using the atraumatic restorative treatment (ART) approach.

Materials and methods: A total of 804 children participated in the study. They had their dental plaque levels assessed at baseline and after two years by trained examiners. Each of the children also had one proximal carious lesion in a primary molar restored by trained operators and their assistants using the ART approach, 3 brands of glass ionomer cements and 2 tooth-isolation methods. The restorations were clinically evaluated soon after placement and after 2 years. Post-operative bite-wing radiographs were also taken immediately after restoring the teeth and evaluated. The data collected were analyzed using SPSS version 14.

Results: The cumulative survival of the restorations decreased from 94.4% soon after placement to 30.8% after 2 years. The plaque index changed from 2.34 (SD 0.46) at baseline to 1.92 (SD 2.1) after 2 years. Higher plaque indices were associated with higher restoration failure.

Only 507 bite-wing radiographs out of the possible 804 of the restored teeth were of good quality for the study. A total of 48 (9.5%) restorations had residual caries, 63 (12.4%) cervical marginal gaps and 9 (1.8%) both residual caries and cervical marginal gaps related to them. The survival rate of the restorations with both residual caries and cervical marginal gaps was significantly lower (Chi-square, p= 0.003) when related to the restorations that did not have any.

Conclusions: Low survival rate of proximal restorations in the study was associated with the presence of cervical marginal restoration gaps.

Introduction

Earlier stages of dental caries can be managed using non-invasive methods, but when the process is in its advanced stages a restoration becomes necessary (1). Without a clear demarcation, clinically a carious lesion has an inner layer which is sensitive and partly demineralized and an outer layer that is insensitive, highly demineralised with lots of bacteria (2, 3). Atraumatic restorative treatment (ART) approach, a minimally invasive technique for managing dental caries, relies on the removal of this outer layer of the carious lesion with hand instruments and sealing the prepared cavity with an adhesive material (4, 5, 6). While using hand instruments to remove caries, some residual carious material and/or cariogenic bacteria tend to remain behind (7, 8). This residual carious material can partly contribute to poor cavo-material bonding leading to marginal gap-formation, besides those cervical marginal-gaps that are formed due to poor application of the restorative material. The cervical marginal gaps can predispose the tooth to secondary caries. On the other hand, the remnant bacteria can be presumed to unlikely survive during the placement of the material, or be unable to reactivate the caries if adequate hermetic seal is achieved during the restoration process (9, 10, 11). The hermetic-seal prevents gap-formation and so deprive the remnant bacteria of the needed vital nutrients for their metabolism (12). Combined presence of cervical gaps and residual caries can, therefore, cause considerable influence on the integrity of a restoration (13, 14).

Single-surface ART restorations have been reported to have relatively higher survival rates than the multi-surface ART restorations (15). Failures of the ART restorations have, in general, been associated with poor material handling and inadequate removal of caries during the caries excavation stage (16), besides poor oral hygiene (17). The purpose of the present study was to evaluate the effects of oral hygiene status, residual caries and marginal cervical gaps on the survival rate of proximal ART restorations placed in the primary molars, using 3 brands of GIC and 2 methods of tooth-isolation. The null hypothesis was that the survival rate of proximal ART restorations is not influenced by the oral hygiene, residual caries or marginal gaps.

Materials and method

Subjects and setting: The present study formed part of a 2-year clinical investigation on factors influencing the quality of proximal ART restorations. The 804 children who participated in the study were drawn from 30 randomly selected schools out of the 142 public schools in Matungulu and Kangundo divisions, Machakos district, Kenya. In spite of the pre-study sample-size calculation of 382 children, a larger number of subjects was desirable to cater for the number of factors that were under investigation (18). Ethical approval was obtained from Nairobi University Ethical Committee and the eligibility criteria followed was as that used by Kemoli *et al* (18).

Demographic data and oral hygiene: Using a questionnaire, baseline information on family history and the oral hygiene of the subjects was provided by the children's parent/guardian. Trained paediatric dentist and two final-year dental students, paired with an equal number of trained dental assistants, assessed the baseline oral hygiene (represented by plaque index) of each child. They used the Greene and Vermillion criteria (19) to register the dental plaque indices. The same paediatric dentist and dental assistants, but with two postgraduate dental students similarly repeated the process after two years.

Calibration of examiners of dental plaque: Cohen's Coefficient (20) was used to calculate the examiner-agreement in the documentation of plaque, and the values were Kappa 0.85, n= 28) for the group that did the baseline evaluation and Kappa 0.86, n= 24 for the group that did the evaluation after two years. The mean inter- and intra-examiner repeatability for all the examiners ranged from Kappa 0.80 to 1.0, n= 32 - 40. The examiners were unaware of the previous oral health status, the teeth that had been restored, the condition of the tooth or the restoration placed in the children.

Restoration procedure: At baseline, 7 operators and 8 assistants who were randomly allocated to each other, restored the 804 proximal carious lesions in the primary molars. The operators and assistants had all initially received adequate training in their relevant roles in applying the ART technique, as per the WHO approved ART manual (21). Prior to the start of the study, they also undertook further practical experience with the ART technique. Using random numbers, the children were assigned to an operator/assistant, an isolation method (rubber dam or cotton wool rolls) and to a glass ionomer cement material (Fuji IX (GC Europe), Ketac Molar Easymix (3M ESPE AG, Germany) or Ketac Molar Aplicap (3M ESPE AG, Germany). Each child received one proximal restoration in any one of the primary molars that had been selected using the ART approach. The restoration was done without the use of local anaesthesia, except in the case of rubber dam tooth-isolation, when Lidocaine (50mg/g cream) was applied for 2 minutes on the gingiva prior to placing the rubber dam clamp.

As much of the carious material within the cavity was removed with light excavation forces using spoon excavators, aided by a caries-detector dye (private label based on acid red from Academic Centre for Dentistry Amsterdam (ACTA), the Netherlands). The cavity was then cleaned and dried using cotton pellets. Deep cavities were lined with calcium hydroxide (Dycal, Caulk-Dentsply, USA). If the pulp was exposed, emergency dressing was done before the child was referred for definitive treatment at the local hospital, but such participant was excluded from the study. A post-operative bite-wing radiograph that included the restored tooth was taken soon after placing the restoration, and the child released with the advice not to chew any food within the next hour. Oral health education was provided regularly to the participating children by the dental assistants over the two-year period of follow-up. Due to the technical difficulties experienced in taking radiographs in the field, it was not possible to take other sets of radiographs after 2 years.

Post-operative evaluation process: Trained and calibrated examiners, who did not have any knowledge of the previous oral health or tooth/restorations status of the child, clinically evaluated the restorations, soon after placement (within 2 hours) and after two years using the same criteria used by Kemoli *et al* (18). Due to truancy, 38 of the 804 children in the study failed to present themselves for the initial evaluation, leaving 766 restorations to be evaluated soon after placement. The post-operative radiographs taken were evaluated by the chief investigator in accordance with the criteria that had been set (Table 1). As a result of irregular school attendance, drop-outs, transfers to schools outside the study area and one death, only 648 restorations were evaluated in a similar manner after 2 years.

Calibration of the examiners of the restorations and the radiographs: The chief investigator who had established a 'gold' standard with an experienced dentist (Kappa 0.92, n=20) calibrated the examiners of the restorations. The mean weekly

reproducibility for the evaluation of the restoration was Kappa 0.84, n=63 (for the examiners at the initial evaluation period) and Kappa 0.86, n=52 (for the examiners after 2 years). The mean inter-examiner reproducibility for the same procedure was Kappa 0.82 (n=48) and 0.92 (n= 52 for the two groups respectively, with the intra-examiner agreement range on a re-examination of 10% of the restorations of Kappa 0.80 to 1.0 for both groups. After calibrating with a radiologist (Kappa, p= 0.88, n= 50), the chief investigator evaluated all the radiographs, and had a mean intra-examiner repeatability of kappa 1.0.

Data analysis: The data was analyzed using SPSS version 14.0 (SPSS Inc., Chicago, IL, USA) computer programme. The results of the survival rate of the proximal restorations were related to the variables in the study and tested using Pearson's correlation, Cox Proportional Hazards regression analysis (Cox PH) and Multiple Logistic regression models tests, with the statistical significance set at less than 5%.

Results

Initially, only 766 children had their restorations evaluated soon after placement (see Table 8.1), the rest (n= 38) having played truancy during this initial examination. Of the restorations that were evaluated soon after placement, 94.4% had survived (Table 8.1). After 2 years, 648 restorations out of the original 804 restorations were available for evaluation and 30.8% of them had survived (as shown in Table 8.1).

Table 8.1: The clinical evaluation scores for the proximal restorations soon after placement and after 2 years.

Evaluation criteria for the Restoration	Survival soon after placement	Survival after 2 years	Comments
Present, good	681(88.9%)	105 (16.4%)	survived
Present, cervical marginal defects ≤ 0.5 mm in depth	39 (5.1%)	60 (9.5%)	survived
Present with cervical marginal defects > 0.5 mm deep	5 (0.7%)	11 (1.6%)	Failed
Not present, restoration almost or completely disappeared	35 (4.7%)	38 (5.8%)	Failed
Not present, other restoration present	0 (0%)	1 (0.2%)	Censored
Not present, tooth extracted/exfoliated	0 (0%)	232 (35.7%)	Censored
Present, general wear over the restoration of ≤ 0.5 mm at the deepest point	3 (0.4%)	32 (4.9%)	Survived
Present, general wear over the restoration of > 0.5 mm. at deepest point	3 (0.4%)	28 (4.3%)	Failed
Un-diagnosable	0 (0%)	9 (1.4%)	Censored
Presence of secondary caries related to the restoration	0 (0%)	132(20.3%)	Failed
Total	**766 (100%)**	**648 (100%)**	

Survival of restorations and plaque index: A total of 766 children of the 804 who were treated were validly documented for plaque at baseline, and their mean plaque index was 2.26 (SD 0.46), with 587 (76.6%) having a plaque index of 1.5 or over. More males (n= 332) than females (n= 288) had a plaque index of over 1.5. After two years, the 648 children were evaluated and they had a mean plaque index of 1.9 (SD 2.1), with more males having higher plaque indices than the females (Chi-square, p= 0.07).

The plaque indices were grouped as: (a) 0 - 1.5, (b) 1.51 and over, and related to the survival rate of the restorations. The plaque indices that were lower than 1.5 were associated with a higher survival rate of the restorations than for those with plaque index above 1.5, but the difference was not statistically significant (Chi-square, $p > 0.5$). More males than females recorded higher failure-rate but the difference was also not statistically significant (Chi-square, $p = 0.57$).

Survival of restorations and radiographic findings: Due to frequent break-downs of the X-ray machines during the restorative phase and poor quality of some radiographs, in addition to truancy by some of the children, the number of radiographs were fewer than expected. Only 507 of the possible 804 restorations (63.1%) restorations had good quality radiographs for the study. Nevertheless, this number could be considered to form reasonable representative sample for the study population, allowing for a valid assessment of the quality of the restorations and their survival rates. The results of the radiographic assessment are shown in Table 8.2. Most of the restorations that failed after two years were for children whose oral hygiene was poor at baseline and after two years. A total of 48 (9.5%) of the 507 restorations had residual caries, and after two years, two-thirds of these restorations (32 or 67%) had survived. The restorations that had residual caries were fewer in children of ages 7 years and older. Most of the restorations that had only marginal gaps at baseline (n= 63) ended up clinically having secondary caries adjacent to them (n = 38), while some of them exfoliated earlier (n= 16), and only a few were still present after two years (n = 9).

Table 8.2: The evaluation criteria and the results of the post-restorative bite-wing radiographs and the oral hygiene of the children. Note: S=Survived, F= Failed.

Evaluation criteria	Total number of restorations radiographically evaluated	Distribution of restorations at 2-year evaluation	Distribution of restoration at 2 years in children with good oral hygiene at baseline and after 2 years	Distribution of restoration at 2 years in children with good oral hygiene at baseline but poor at 2 year	Distribution of restorations at 2 years in children with poor oral hygiene at baseline but good at 2 years	Distribution of restoration at 2 years in children with poor oral hygiene at baseline and at 2 years
Good restoration not involving the pulp	348 (68.6%)	124 (S) 224 (F)	67 (S) 46 (F)	4 (S) 6 (F)	30 (S) 59 (F)	23 (S) 113 (F)
Presence of residual caries under the restoration	48 (9.5%)	32 (S) 16 (F)	24 (S) 3 (F)	0 (S) 1 (F)	3 (S) 4 (F)	5 (S) 8 (F)
Presence of cervical marginal gaps	63 (12.4%)	9 (S) 54 (F)	3 (S) 11 (F)	0 (S) 0 (F)	2(S) 17 (F)	4 (S) 26 (F)
Presence of residual caries and cervical gaps	9 (1.8%)	0 (S) 9 (F)	0 (S) 1 (F)	0 (S) 0 (F)	0 (S) 2 (S)	0 (S) 6 (F)
Restoration involving the pulp	32 (6.3%)	0 (S) 32 (F)	0 (S) 9 (F)	0 (S) 2 (F)	0 (S) 7 (F)	0 (S) 14 (F)
Restoration absent	7 (1.4%)	0 (S) 7(F)	0 (S) 2 (F)	0 (S) 0(F)	0 (S) 1 (F)	0 (S) 4(F)
Total	**507(100%)**	**507**	**166**	**13**	**125**	**203**

When the two-year survival rate of the restorations were related to the results of the post-restoration radiographic evaluation (Table 8.2), there were no statistical significant differences between the survival rate of the restorations that had residual caries and those that didn't (Cox PH, Chi-square 19.14, 14 df, p=0.16). The 9 (1.8%) restorations that had both residual caries and gaps had failed at the end of two years. The differences in the two-year survival rate of the restorations with and without cervical marginal gaps and those with both residual caries and marginal gaps was statistically significant (Ch-square, p = 0.0001 and 0.003 respectively).

When the two factors (residual caries and marginal gaps) were related to the operator who placed the restorations, there were almost an equal number of restoration-gaps and residual caries present for restorations placed by all operators, except for one operator, who had reportedly more experience with the ART before the commencement of the study. The difference in the survival of the restorations placed by this particular operator and all the other 6 operators was statistically significant (chi-square, $p < 0.05$). All the operators using the rubber dam isolation method produced restorations that had less

restoration gaps, and with a survival rate that was significantly higher when related to those restorations placed using cotton wool roll method (Chi-square, $p< 0.05$). There was no evidence that the type of material used had any predilection to cervical marginal gap-formation.

The plaque indices were again re-categorized into two groups: Indices 1.5 and below for good oral hygiene and above 1.5 for bad oral hygiene. The results were then related to the radiographic findings and the survival of the restorations at baseline and after two years (see Table 8.2). There were more failures for all restorations in children who had poor oral hygiene at any one stage of evaluation, when related to the subjects with good oral hygiene at both evaluation stages. The difference was, however, not significant statistically (Chi-square, $p=0.06$). All the children with both cervical gaps and residual caries, did not have any surviving restorations after two years, irrespective of their oral hygiene status. A Pearson correlation test was carried to relate the survival rate of the restorations to the radiographic findings. The results showed: in relation to residual caries ($X^2=0.96$, 2 df, $p=1.68$), cervical marginal gaps (Pearson, $X^2=1.47$, 3 df, $p=0.03$, both cervical marginal gaps and residual caries (Pearson, $X^2=3.36$, 1df, $p=0.0024$).

Multiple regression model tests was also used to 'adjust' for the effects on the survival rate of the restorations for the other variables in the study as material brand and the method of isolation besides the effects of the residual caries, marginal gaps and the oral hygiene. The results obtained indicated that while the residual caries and oral hygiene did not show any significant effect on the survival rate of the restorations, the restoration-gaps and the method of isolation had a significant effect on the survival rate of the restorations ($p< 0.05$).

Discussion

In the present longitudinal study, two clinical evaluations of the restorations placed in the primary molars were carried out soon after placement (within 2 hours) and after two years. In addition, a post-operative radiographic evaluation of the restored tooth was undertaken. The clinical evaluation method, though appearing to be simple, unlike the United States Public Health Science (USPH) criteria by Ryge and Snyder (22) that is often used to evaluate dental restorations, the results of this method has been tested before and found to be plausible. The one-year survival rates of ART restorations in the primary dentition have averaged 75.3% to 100% for the single-surface and 42.9% to 93.7% for the multi-surface ART restorations (23). The 30.8% 2-year survival results in the present study was still very low, although other studies have reported much lower results after two years of follow-up (24)

Influence of oral hygiene on the survival of the restorations: ART approach encompasses good dietary and good oral hygiene habits as part of the important facets of preserving the good health of the dentition (25). In the present study, poor oral hygiene was associated with poor survival rate of their restorations. Children who had good oral hygiene at baseline and after two years had higher survival rate of their proximal ART restorations (16), which appear to imply that the oral health of the child had some influence on the survival of the restorations, though not significant statistically.

Radiographic findings: Previous studies have reported no significant difference in the survival rates of restorations with or without residual caries if a cavo-material hermetic-seal is achieved (12). A study using 3 treatment methods, reported 33% of the proximal

restorations had residual caries and 16% to 18% had cervical gaps (7), as compared to the 48 (9.5%) of the restorations with residual caries in the present study, 63 (12.5%) with cervical marginal gaps and 9 (1.8%) with both. The reasons for this discrepancy could have been due to the difference in the study population, the oral hygiene habits of the study population and other patient and/or operator-related factors that were not documented. The two-year cumulative survival of 67% of the restorations in the present study that had residual caries could be considered reasonably good (7, 9), and compares with similar results reported by Roeleveld *et al* (13) in which the presence of residual caries did not significantly affect the survival rate of the proximal restorations.

Most restoration failures have been attributed to marginal leakage as a result of poor cavo-material bonding, cracks in the enamel due to restoration setting stress or fracture of the tooth substance at the restoration-cavity interface probably due to unsupported enamel overhangs and moisture contamination (26). Although the use of caries-detector remains a controversial issue in dental practice (27), its application in the study was to help the operator visualize and remove as much of the carious material using the hand instruments. Additionally, inadequate cavity conditioning, poor mixing of the material and inadequate adhesion of the material to the cavity walls can also lead to restoration-gaps hence marginal leakages (4, 28). The presence of restoration-gaps weakens the restoration and makes it susceptible to early failure (14). In spite of the operators and their assistants in the present study having been adequately trained and having had further experience with the technique after training, it is apparent that the phenomena appeared to have occurred in the present study, leading to the cervical marginal gaps that were observed and the low survival rate of the restorations with both residual caries and the gaps (13). Since the presence of restoration gaps together with residual caries is a panacea for early restoration failure, adequate tooth-isolation during the placement of a restoration might lead to a reduction in moisture contamination and probably void/gap-formation (29). Though not significant statistically, poor oral hygiene seems to worsen the survival rate of the restorations, and more so when the restorations had cervical marginal gaps.

Influence of other factors: Due to the similarity in the coefficient of thermal expansion of GIC and the dental hard tissues, good margin adaptation of glass ionomer restorations to the tooth hard-tissues has been cited (30, 31). However, the material properties can also be influenced by the patient- and operator-related factors. As one operator with a possible longer experience with ART had less number of restorations with cervical marginal gaps and residual caries, this could suggest that experience is a possible factor in achieving quality restorations and a higher survival rate (32, 33).

Conclusions

The null hypothesis in the present study that the survival rate of proximal ART restorations in primary molars is not influenced by the oral hygiene, residual caries and marginal gaps. The null hypothesis could not be rejected in relation with residual caries and oral hygiene factors, but could be rejected in the case of marginal gaps and marginal gaps in combination with residual caries. However, more conclusive research is needed to evaluate further the effect of oral hygiene of the child on proximal ART restorations

Acknowledgement

The authors acknowledge the financial and material support from Netherlands Universities' Foundation for International Cooperation (NUFFIC), GC Europe, 3M ESPE

Germany, the University of Nairobi (Deans Committee) and the dedication to the study of the school children, their parents and teachers, ACTA (Dutch) students, the Kenyan doctors, Community Oral Health Officers (COHOs), assistants and the support staff.

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