Factor analysis in relation to survival rate of proximal ART restorations in primary molars
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Chapter 2

Study design
Introduction
Due to deficient finance and personnel resources, the prevalence of dental caries in the Less Developed Nations continue to rise, without the concurrent intervention and curative programmes to meet the trend. In Kenya, for example, the dental restorative needs for its child-population are unmet (1, 2) due to similar reasons. It is possible that the Atraumatic restorative treatment (ART) approach could aid in alleviating the present dental restorative needs of the Kenyan children, by augmenting the current dental health delivery system.

The ART approach involves manual cleaning of the dental cavity using only hand instruments and restoring the cavity and sealing the adjacent pits and fissures using an adhesive restorative material like glass ionomer. The survival results of class I ART restorations have shown comparable results with the traditional restoration techniques for both the primary and permanent dentition (3, 4, 5, 6, 7, 8, 9). However, the survival rates for the multiple-surface restorations placed in the both the primary and permanent dentitions using the ART approach are still very low and varied (9, 10, 11, 12, 13, 14), probably due to a variety of influencing factors (15, 16).

Clinical research is the most desirable and indispensable method of determining the mode of behaviour of a carious process, its prevention and the restoration of the cavity arising from the process, the behaviour of the restorative materials used and the quality of the restorations so placed. Yet such research can be extremely complicated, laborious to plan and execute particularly when being conducted in poor and remote areas where the ART technique is applicable. Visual/tactile inspection and radiographic methods have been employed in determining the quality of restorations. In the case of ART restorations, the quality of the restorations can be unpredictable, particularly during the first one month of post-placement. The flexural strength of GIC increases steadily to a maximum at about twenty-eight days, during which period the restoration can be vulnerable to fracture (17).

In the present clinical study, three high-viscosity GIC brands, recommended for use with the ART approach, were used with the approach to restore proximal carious lesions in the primary molars of 6 to 8 year-olds. Clinical (visual/tactile) and radiographic evaluations were done to determine the quality and subsequently the longevity of the restorations. The evaluation criteria used included the determination of the presence/absence of the restoration, fractures, marginal integrity, residual caries and secondary caries. The results of these evaluations were related to the cavity-sizes, the tooth-isolation method, the experience of the operator/assistant, the GIC brand used and its handling, the room temperature at the time of placing the restoration, the consistency of the next postoperative meal consumed by the child and the oral health of the child. Where a restoration was prematurely lost, the integrity of the surfaces of the cavity was also analyzed.

Aim of the study
The broad aim of the present study was to determine the factors influencing the survival rate of proximal ART restorations in the primary molars of 6 to 8 year-old children, with specific objectives as follows:
a. to evaluate and document the socio-demographic status of the study population, the oral health status as it relates to dental plaque index and the DMFT/dmft of the children in the study population,
b. to restore using the ART approach one proximal carious lesion in the primary molar of each child in the study, with either of the three available brands of GIC restorative materials, using ‘experienced/in-experienced’ operators and assistants under two different tooth-isolation methods,
c. to evaluate, longitudinally, the restorations placed in the study group soon after restoring, after one week, one month, five months, one year, one and a half years and two years, in order to ascertain the quality and longevity of the restorations,
d. to calculate the effects of different variables as mentioned above on the survival rate of the proximal restorations, and also other variables as the size of the cavity restored, the time taken to mix the materials and to complete the restoration process, the next post-operative meal taken, residual caries factor, restoration gaps and the oral hygiene status of the child,
e. and to investigate the effects of the combinations of these variables on the survival rate of the proximal ART restorations, and consequently, the survival of the restored tooth.

The Null hypothesis
There is no relationship between the survival rate of proximal ART restorations and the cavity-choice, the experience of the operator, the experience of the assistant, the method of tooth-isolation, the GIC brand used and its manipulation, the ambient temperature at the time of placing the restoration, the residual caries/restoration gaps, the next meal taken and the oral health status of the child.

Materials and methods
Overall design of the study and the study area
This was a large intervention study designed to achieve its objective, and involved 6 to 8 year-olds with at least one appropriate proximal carious lesion. The study took place in Matungulu/Kangundo rural divisions in Machakos district, situated approximately sixty three kilometres south-east of Nairobi, Kenya (see figure 2.1 and 2.2). The 200,000 inhabitants of the area at the time of the study belong mainly to one ethnic tribe of low socio-economic status, with limited access to any properly organized oral health care. At the beginning of the study, there were about 30,000 children of ages 5 to 9 years (18). The only sub-district hospital in the area had one dental unit that provided mainly dental extraction and limited restorative dental treatment.
Figure 2.2: The geographical map of the study area where schools that participated in the study were drawn from.

Study population
A convenient sample of 804 children from 30 randomly selected primary schools in the two divisions participated in the study. To be included in the study, the child had to be 6 to 8 years of age, a resident of the area for at least one year prior to the study, in good general health, cooperative and with an appropriate proximal carious lesion in a primary molar restorable using the ART approach. One proximal cavity per child was preferred in order to reduce intra-patient dependencies that could affect the restoration placed. In case the child had more than one appropriate cavity, then the smallest of them all was selected. The mean age of the study population was 7.4 (SD 0.95) years, with a mode of 8 years and the male to female ratio of 1.3:1. The subjects had a mean plaque score of 2.3 (SD 0.46), a mean DMFT of 0.15 (SD 0.52) and dmft of 3.96 (SD 2.38).

Sampling procedure
Initially, a minimum pre-study sample-size was calculated based on the formula, \( N = \frac{Z^2P(1-P)}{E^2} \) (19) (\( N \) = the minimum study population, \( P \) = expected failure rate for such restorations, \( Z \) = normal standard deviation at 95% confidence level and \( E \) = significance level of 5%). The 54% failure rate for Fuji IX proximal restorations based on the study by Lo ECM et al (20) was used in this calculation and gave the required minimum number of cavities for the study of 382. However, given the various factors involved in the study and in order to improve on the statistical power, a larger study population was preferred.
Ethical approval to conduct the study was sought and obtained from the University of Nairobi and the Kenyatta National Hospital Research and Ethical Committees. Three trained examiners (a paediatric dentist and 2 final-year dental students), who did not take part in the operative stage, made the selection of the subjects with the appropriate proximal carious lesion during the months of March, 2006. All the 22,105 children of ages 6 to 8 years in the 142 public primary schools in Matungulu and Kangundo divisions had been targeted, provided the school had at least 50 eligible children. The eligible schools were then stratified, and using random numbers, thirty schools with a total of 6,002 eligible children were selected and examined for the appropriate proximal carious cavity in their primary molars. The selection process was to continue if the number of subjects required was unmet. At least 50 subjects had been envisaged for allocation to each final treatment category, after randomization process that included the combinations of the operator experience, assistant experience, isolation method and material brand used, to result in a total required number of at least 1,200 subjects (see figure 2.3). The participating children had to orally assent to the procedure, be available for the follow-ups that were scheduled after the restorative stage of the study and the parents/guardians had to provide written consent. Any child who did not meet the criteria was excluded.

**Figure: 2.3:** the randomization process for treatment of the study population.

With the child seated facing towards a natural light source, the examiner used a sterile mouth mirror and Michigan O with William’s markings periodontal probe to examine and select a carious proximal lesion in a primary molar, with an occluso-marginal ridge entry of approximately 0.5 to 1.0 mm in diameter. The periodontal probe (Michigan O probe with William’s markings) was also used for the estimation of the size of the dental cavity entrance. This size was preferred as it allowed for access into the cavity by at least the smallest dental excavator. The selected tooth was without signs or symptoms of pulpitis or mobility. A total of 1,560 cavities in a similar number of children from the 30 schools met the criteria, out of which number 804 cavities were restored during the operative stage of the study. The others had been excluded from the study as a result of failure to obtain the required parental consent (n= 280), anxiety (n= 25), pulpal exposure during
the caries excavation stage (n= 99), teeth having exfoliated/inappropriate cavity size, age discrepancy or transferrals to schools outside the area or voluntary abscondment (n= 352).

Pre-operative evaluation
All the children recruited in the study were evaluated at baseline. The evaluation included a record of the gender, oral health status using their dmft/DMFT (1997 WHO dental survey criteria (25) and dental plaque levels (Greene and Vermillion index (26), and the socio-economic status of the family. All the data collected by the examiners recorded for each child by trained assistants, on each individual child’s record form.

Trial design
A three-week trial-run was undertaken to standardize the procedures and calibrate the personnel. Eight operators and eight assistants were recruited and trained in the ART technique using the WHO-recommended training protocol (21). One of the operators, a Community Oral Health Officer (COHO), was already familiar with the ART technique, while the others were new to the technique. The COHO had previously placed many ART restorations prior to the study and not as part of the present study. Nonetheless, this operator participated in the training. After the training and further varied but supervised and documented clinical sessions, all the operators were grouped into ‘experienced’ group (operators who had done at least 50 ART restorations with at least 25 of them as multi-surface restorations), and ‘inexperienced’ group (operators who had made between 5 and 10 ART restorations of any class). The same criteria applied to the assistants but based on the number of restorations each had assisted an operator to place, irrespective of the type of cavity restored.

All the operators were either dentists or Community Oral Health Officers (COHO) or final-year dental students. The assistants were either trained dental assistants or COHO. At the commencement of the operative stage of the study, one ‘experienced’ operator was excluded from the study for personal reasons, leaving three ‘experienced’ (two dentists and one COHO) and four ‘inexperienced’ (ACTA final-year students) operators assisted by four ‘experienced’ (three dental assistants and one COHO) and four ‘inexperienced’ assistants (all dental assistants). The experienced assistants had longer experiences as general dental assistants, while the ‘inexperienced’ assistants had just completed their dental assistant course.

Materials used during the operative stage of the study
Fuji IX (GC Corporation, Europe, Lot 0505021), Ketac Molar Easymix (3M ESPE AG, Germany, Lot 213513) and Ketac Molar Aplicap (3M ESPE AG, Germany, Lot 219562) were used to restore the cavities. They were labelled A, B and C to blind the patient, the operator and the assistant. Even though KMA was the only capsulated material, it still had a label placed on it. Rubber dam and cotton rolls were used randomly to isolate the tooth selected for restoration, while Calcium Hydroxide (Caulk, Dycal) was applied to the cavity-bases of deep cavities as a protection to the pulp prior to the placement of the restorative material. Vaseline petroleum jelly was applied over the restorations to protect them from wetness.

Restoration procedure step by step
Using random numbers, the subjects were allocated to a brand of GIC restorative material, a tooth-isolation method, an operator and an assistant. A preoperative
diagnostic bitewing X-ray of the tooth was taken by a portable X-ray machine (Philips Oralix 50, 65kV 7.5mA, set at 0.3s), using *kwik-bite* with a ring-centring film-holder (Pinnacle product Inc, USA part no. 270 US). The ring-centring film-holder allowed for the taking of almost similar radiographs of the teeth of all the children who underwent this procedure.

The child was laid supine on a table with the operator seated at the head of the table. A battery-powered headlamp augmented the natural light in illuminating the oral cavity. The operators used cotton rolls or rubber dam isolation methods randomly to isolate the tooth to be restored. Except for the surface analgesia (Lidocaine 50mg/g cream) applied for 2 minutes on the gingiva around the targeted tooth prior to the placement of the rubber dam clamp (22), no other local anaesthetic was used. Plaque and food debris were removed from the tooth surface using a probe before rinsing and drying it using wet and dry cotton pellets respectively. If necessary, a hatchet was used to widen the cavity entrance and to remove the enamel overhangs. Aided by a caries detector-dye (private label based on acid red, by ACTA, the Netherlands), a spoon excavator was used to remove the soft dentinal material within the cavity (23, 24). A slightly curved matrix band was then applied round the tooth and held interdentally by a wooden wedge. For very deep cavities, a thin layer of calcium hydroxide was applied at the very deepest point. Measurement in millimetres of the size of the cavity was taken using the graduations on the Michigan O probe with William's markings periodontal probe, to determine the mesio-distal distance, the bucco-lingual distance and the depth of the cavity through the centre of the cavity. The cavity was conditioned for 15 seconds using diluted solution of the mixing liquid (Fuji IX), or the manufacturer’s conditioner (Ketac Molar Easymix and Ketac Molar Aplicap). After rinsing and drying of the cavity using cotton pellets, the cavity was ready for restoration.

The assistant mixed the restorative material manually for Fuji IX and Ketac Molar Easymix and mechanically for 10 seconds (Dumat 2 amalgamator, Germany) for Ketac Molar Aplicap, in accordance with the manufacturer’s instructions. The assistant also recorded the time taken (Oregon scientific clock) to mix the materials (included was the KMA which in any case had a constant mixing time), to apply the material and also to complete the restoration process. The restoration was considered finished after the completion of the ‘press-finger’ technique for sealant application, the adjustment of the occlusion aided by an articulating paper and the application of Vaseline petroleum jelly over the restoration. The room temperature taken in degrees Celsius using an ordinary thermometer (Brannun, England) at the time of completing the restoration process was recorded. The child was also advised to avoid eating within the next hour. A bite-wing x-ray was taken (within 2 hours post-placement) in the same manner as the first radiograph, for later evaluation. On the following day, each child provided information on the type of food that had been consumed after receiving the restoration.

Each child was coded and documented in relation to the type and size of the cavity restored, the operator, the assistant, the tooth-isolation method, the brand of material used, the mixing and placement times for the material, room temperature, the consistency of the first meal taken after the restoration and the oral health status (plaque and DMFT/dmft). Tables 2.1 and 2.2 show the distribution of the 804 restorations that were placed in the primary molars of the children who participated in the study, and how they related to the operator/assistant experiences and the method of isolation applied.
Table 2.1: Distribution of the restorations/sealants placed in the primary molars in relation to the operator/assistant and material used.

<table>
<thead>
<tr>
<th>Operator/Assistant experience</th>
<th>Percentage distribution of the glass ionomer cement used for restoration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Fuji IX</td>
</tr>
<tr>
<td>“experienced” operators</td>
<td>34.7</td>
</tr>
<tr>
<td>“inexperienced” operators</td>
<td>34.3</td>
</tr>
<tr>
<td>“experienced” assistants</td>
<td>35.2</td>
</tr>
<tr>
<td>“inexperienced” assistants</td>
<td>33.7</td>
</tr>
</tbody>
</table>

Table 2.2: Distribution of the glass ionomer cements and the isolation method used to restore the cavities (notice 3 cavities were left out due to improper documentation).

<table>
<thead>
<tr>
<th>Method of isolation</th>
<th>Material used</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Fuji IX</td>
</tr>
<tr>
<td>Rubberdam</td>
<td>142</td>
</tr>
<tr>
<td>Cotton rolls</td>
<td>134</td>
</tr>
<tr>
<td>Total</td>
<td>276</td>
</tr>
</tbody>
</table>

Postoperative Evaluation
The restorations were independently evaluated within 2 hours (using visual and tactile methods) and the post-restorative radiographs taken were also assessed for quality of the restorations. The visual/tactile evaluations were repeated after one week, one month, five months, one year, one and a half year and two years, in all cases using the criteria given below for both the restorations and the sealants adjacent to them. In the case of the restorations, it was possible that a single tooth could have two valid evaluation codes. An example is in the case of code 2 and code 6 in which case only code 2 would be recorded. The DMFT/dmft and the plaque evaluations of the children were similarly repeated after two years using the same WHO criteria (25).

The sealants applied to the pits and fissures adjacent to the restorations were evaluated and scored as shown below, with scores 0 and 1 as successful, 2 and 3 as failures and 4, 5 and 6 as censored:

0 = Present, good.
1 = Present, marginal defects, no repair needed.
2 = Present gross defects, repairs needed.
3 = Not present, almost/completely disappeared, to re-do.
4 = Not present, other treatment done.
5 = Not present, tooth extracted/exfoliated.
6 = Un-diagnosable.

The proximal restorations were evaluated and scored as follows, with scores 0, 1 and 6 as successful, 2, 3, 7 and 9 as failures and 4, 5 and 8 as censored:

0 = Present, good.
1 = Present, marginal defects ≤ 0.5 mm in depth.
2 = Present, marginal defects > 0.5 mm deep.
3 = Not present, restoration almost or completely disappeared.
4 = Not present, other restoration present.
5 = Not present, tooth extracted/exfoliated.
6 = Present, general wear over the restoration of $\leq 0.5$ mm at the deepest point.
7 = Present, general wear over the restoration of $> 0.5$ mm at the deepest point.
8 = Un-diagnosable.
9 = Presence of secondary caries related to the restoration.

The criteria for radiographic evaluation of the restorations were as follows:
0 = Good restoration not involving the pulp.
1 = Presence of residual caries under the restoration.
2 = Presence of marginal gaps.
3 = Presence of residual caries and marginal gaps.
4 = Restoration involving the pulp.
5 = Restoration absent.

**Validity and reliability**

Prior to commencing the study, several pre-tests were carried out to standardize the plaque detection, caries detection, appropriate proximal cavity selection, documentation of the data, the restoration process of the proximal cavities and the evaluation method for the proximal restorations used and the sealants adjacent to these restorations. In the course of the study, calibrations were repeatedly carried out using the Cohen’s Kappa Coefficient (27) to establish and re-establish the inter-examiner and intra-examiner repeatability. Initially, the chief investigator and a local professor of paediatric dentistry established a ‘gold’ standard for the caries and plaque evaluations (Kappa 0.78, n = 60). The chief investigator also established another ‘gold’ standard with an experienced dentist in the ART approach for the evaluation of the ART restoration (Kappa 0.92, n=20). The chief investigator then trained and calibrated all the examiners and evaluators involved in the study. A random re-examination was also carried out for stabilization of intra- and inter-examiner repeatability. Good clinical practice was maintained during the study period.

The mean weekly results of the calibrations between the examiners of the carious dental cavities and dental plaque were Kappa 0.85 for dental caries and 0.88 for dental plaque. The mean range between the chief investigator and the evaluators for the evaluation of the proximal ART restorations was Kappa 0.78 to 0.95 (mean n= 25 to 63) and the mean inter-evaluator values ranged from Kappa 0.84 to 0.86 (mean n= 20 to 63). The daily intra-examiner agreements on 10% of the restorations evaluated ranged from Kappa 0.80 to 1.0 for all the evaluators. The results of the calibration between the local dental radiologist and the chief investigator who evaluated the radiographs was Kappa 0.88, n=50) and a mean intra-examiner Kappa of 1.00.

**Data Analysis and presentation of the results**

All the data collected were entered in the computer and processed using SPSS version 14 (SPSS Inc., Chicago, IL, USA) computer programme. Use of descriptive statistics, Pearson’s Chi-square, Kaplan-Meier (KM) survival tests, Cox proportional hazards regression model (Cox PH model) test and multiple-logistic regression model test with the significant limit pegged at less than 5%, were employed during the analysis of the data. The results of the analysis relating to the various factors that were considered in the study were presented in the form of tables and figures.
Discussion
The present clinical study had the size of the cavity, the method of tooth isolation, the operator and assistant experience and the GIC material-brand as the primary variables. The secondary variables included confounding factors as the time taken to mix and apply the material, room temperature, the consistency of the first meal taken after the placement of the restoration and the oral health status of the child.

The area where the study took place was considered to be appropriate for the application of the ART approach. This is because the children in this area had unmet restorative needs, limited access to any oral health programme and were from a rural community with very high poverty levels. The selection process that had been applied produced an approximate representative sample of the 6 to 8 year-olds in the 142 public primary schools in the area.

Initially the operative stage had been arranged to take place over a period of one and a half months in split sessions, with one week pause between the first and the second operative weeks, and two weeks between the second and the third operative weeks. After the trial-run, it became clear that a three-week continuous operative stage would be more suitable. Although eight operators (four ‘experienced’ and four ‘inexperienced’) had been expected to participate in the study, one ‘experienced’ operator dropped out due to personal reasons. The eight assistants were, therefore, randomly allocated to the seven operators on a daily basis in such a manner that one of the assistant rested on any given day. It should also be noted that although the operators had been grouped as ‘experienced’ or ‘inexperienced’, all of the operators belonged to a group of workers who had received adequate training and had acquired adequate practical skills in the management of dental caries. In view of the drop-out of one of the operators, the projected number of 1,200 children that were to be treated could not be attained. Further, the unexpected high rate of irregular school attendance by the participating children compounded the problem.

The dental health status of the participants was determined by the plaque and DMFT/dmft indices of the child. The baseline information of the study population showed a high caries incidence (mean DMFT of 0.15 ±0.52) and the dmft as 3.96 ± 2.38) and poor oral hygiene (plaque index of 2.23 ± 0.98). The mean DMFT/dmft that was found in the present study was not representative for the study area but for the study population. The figures obtained might have been higher or even lower than the area’s average for the children in the same age-group. The reasons for such discrepancy could only arise from the fact that the participating children were selected primarily on the basis of having at least one appropriate proximal carious lesion. There were other children who were left out of the study due to having inappropriate carious cavities, non-proximal cavities or for lack of any carious cavities. Notwithstanding this, the children who were included in the study had negligible restorative treatment, and overall, this study population that was primarily of a rural population had higher than expected carious incidence. The ART approach has been reported to be atraumatic (28, 29), and in the present study, a mere 2% of the children showed anxiety towards the procedure. This was a clear indication that very few children were anxious about the operation.

Other than for one initial radiographic evaluation of the restorations, all the post-operative evaluations were done using visual and tactile methods with the help of a standard Michigan O probe with William's markings, as a simple tool for assessing these
Restorations. This method has plausible results and has been approved by World Health Organization for evaluation of ART restorations, though it is not as detailed as the USPHS method for the evaluation of dental restorations (30). The initial clinical and radiographic evaluations of the restorations were done to determine the presence of any marginal adaptation defects/gaps, material loss and fractures of the restorations soon after restoring the cavities (within 2 hours after placement). The same visual procedure was repeated for the sealants adjacent to the restorations. The two forms of evaluations constituted the important methods for determining the quality and integrity of the restorations and the sealants adjacent to the restorations, soon after restoring. Further clinical evaluations were used to determine the quality of the restorations and the adjoining sealants at one week, five months, one year, one and a half years and two years. The initial short-duration of spacing was considered on the basis of the fact that glass ionomer restorations and sealants have been reported to have very short survival span (31). A clinical hardness test was also carried out on the surfaces of the cavities that had premature loss of their restorations, in order to determine any effects of the restoration to these surfaces. The data obtained from the various evaluations were analysed using a computer, and various statistical tests were carried out to establish the factors influencing the quality and survival rate of the proximal restorations placed in the primary molars using the ART approach.
Reference