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

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Chapter 7

Two-year survival of proximal ART restorations in relation to GIC brand and post-restoration meal consumption

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Abstract

Purpose: To investigate the influence of 3 glass ionomer cement (GIC) brands, their mixing and placement times, the ambient temperature and the post-restoration meal consumed, on the survival rate of proximal ART restorations.

Methods: 804 restorations were placed in primary molars by trained operators and assistants using 3 GIC brands and 2 tooth-isolation methods. The materials' mixing and placement times, the room temperature and the post-restoration meal consumed by the subjects were documented. The restorations were evaluated soon after placement and after two years by trained and calibrated evaluators.

Results: There were no statistical significant differences in the survival rate of the restorations in relation to GIC brand, mixing, placement times and the ambient temperature. The post-restoration meal taken that was of "hard-consistency" was associated with a significantly lower restoration-survival rate.

Conclusions: The consistency of the next meal consumed by the subjects after restoration significant influenced the survival rate of the proximal restorations.

Introduction

Dental caries is probably the most common chronic disease during childhood in spite of it being preventable [1]. Its prevalence continues to rise in the less developed nations due to a poor socioeconomic status, increasing refined-sugar consumption, poor oral-health habits and limited access to dental health care [2]. One way of treating dental carious lesions is through the placement of a restoration. When such a restoration is required, the operator makes a decision as to the choice of the restorative material and the technique to use. The Atraumatic Restorative Treatment (ART) approach is one of the techniques used in the management of dental caries, particularly because it is inexpensive and a tooth-tissue conservative approach. As a result of these attributes, the technique offers expanded opportunity for restorative dental treatment for underserved communities, dentally anxious patients and those with special health needs.

Glass ionomer cement (GIC) is the material of choice with the ART technique. GIC is preferred because of its satisfactory biological features, favourable processing and setting times, fluoride-release capability and its low cost. GIC material has also thermal compatibility features close to those of the tooth-enamel, forms stable bonds with the tooth tissues and remains stable under ambient oral conditions. However, GIC suffers from short-working and long-setting times, poor cohesive strength, low fracture-toughness, poor wear-resistance and it is also susceptible to moisture contamination or dehydration in its early setting stages [3, 4].

The strength of GIC is also affected by incorporated porosities during its mixing. Mechanical mixing tends to produce a good material-mixture, while hand-mixing is generally more favourable for high-viscosity cements in producing good material-mixture, but unfavourable for the low-viscosity cements [5]. The mechanical properties, the physico-chemical properties, the working and setting characteristics of GIC depend on the material formulation, the relative proportion of the constituents in the cement-mix and the mixing process. These features vary according to the brand of the GIC. Capsulated GIC brands contain pre-measured glass ionomer powder and liquid that ensures the correct ratio, a definite mixing-time, correct consistency of the mixture and predictable results, when compared to the hand-mixed GIC brands. Accordingly, the restorations placed out of the material-brands using different mixing-methods will have considerable variability in their mechanical and physico-chemical properties. Most of these factors are under the control of the manufacturer and vary for different brands, but other factors such as the mixing and handling processes are operator-controlled.

During the setting process of GIC, the alkaline glass powder and the unsaturated acid part react to result in a salt-gel that forms the bonding matrix. While water remains the reaction medium and an essential component of the salt gel, excessive or little amount of water can lead to a weaker bonding within the material matrix and with the tooth tissues. The proportionation, the mixing-technique, the mixing- and the restoration-times and the ambient temperature at which the material is processed, will consequently influence the integrity of the ART restorations. The maturation process of the material that follows after the mixing is crucial for the strength of the restoration. During this stage the dissolution of the material in water progressively lessens and its compressive strength is enhanced [6, 7]. The amount of occlusal forces applied on the restoration during the maturation stage can influence the survival rate of the restoration [5, 8]. It is on this basis that the patient is advised to avoid taking any food in the first one hour.

The extent of the effects of all these factors on the integrity of the restoration and particularly on proximal ART restorations is not clear. The purpose of the present study was to determine after two years, the influence of three brands of high viscosity GICs on the survival rate of proximal ART restorations placed using two tooth-isolation methods. In particular to determine the effects on the survival rate of proximal ART restorations, of three GIC brands, their mixing and restoration times, the ambient room temperature and the consistency of the post-restoration meal consumed by the subjects.

Methods

The study population and ethical issues

The data in this study were obtained as part of a prospective clinical study on factors affecting the survival rate of proximal ART restorations in the primary molars. The study was conducted in Matungulu and Kangundo divisions in Kenya, in May, 2006, two months after selecting the study population. Ethical approval to conduct the study was obtained from The University of Nairobi and The Kenyatta National Hospital Ethical Committees. After receiving all the information concerning the possible risks and benefits of the treatment, the parents/guardians of the children provided written consents for the inclusion of their children in the study. Although the calculated pre-study sample size was 382, given the various factors in the study and in order to improve on the statistical power, a larger study-population was preferred. The subjects were drawn from 30 randomly selected schools out of the 142 public schools in the area. They comprised children aged 6 to 8 years, with an ART restorable proximal cavity restorable using the ART approach, in good general health, who assented to the procedures and whose parents/guardians provided a written consent for their participation.

The workforce for the study

The operators, who were randomly paired daily with the assistants, restored the proximal cavities using the ART approach. The operators and the assistants were blinded to the material in the study (labelled only as A, B and C). One of the operators had failed to participate during the operative stage, leaving 7 operators to be randomly paired daily with 8 assistants, in such a manner that one assistant rested on each operative day. The operators were 2 dentists, 4 final-year dental students and one community Oral Health Officer (COHO). The assistants comprised of one COHO and 7 dental assistants. Prior to the study, the operators and the assistants received appropriate training (theory and practice) based on the five-module WHO recommended ART training program contained on a compact disk by Frencken *et al* [9]. Over a period of three months they were pre-tested in their various roles in applying the ART. The operators were taken through the process of detection and selection of the appropriate carious lesions for restoration. The operators and the assistants also undertook further supervised and documented clinical sessions using the ART technique for the purpose of gaining more experience with the technique. They used similar materials as those that were used during the study. Evaluators were also trained and calibrated in the technique for assessing the restorations done during the study. The evaluation group consisted of Final-year undergraduate Dutch dental students and Paediatric postgraduate Dutch dental students.

The restoration process

Random numbers were used to assign each child to an operator, an assistant, a GIC material brand and an isolation method. The treatment of the children was done at site, with each child lying supine on a table facing towards a natural light source. A battery-powered headlamp augmented the lighting within the oral cavity. The operators randomly isolated the teeth using rubber dam or cotton rolls. They then used dental hatchets to enlarge the cavity-entrances and to remove enamel overhangs, and spoon excavators to remove the soft carious dentinal materials aided by a caries-detector dye (private label from ACTA, the Netherlands based on acid red). Wet and dry cotton pellets were appropriately used to rinse and dry the cavity. If pulpal exposure occurred during the excavation of caries, the child was disqualified from the study, but given emergency treatment and an appropriate referral to the local hospital for further management. Deep and unexposed cavities had their bases lined with calcium hydroxide (Caulk, Dycal) to provide pulpal protection. A slightly contoured matrix band (Union Broach Moyco) was adapted around the tooth and held in place with a wooden wedge (Sycomore Interdental wedges No. 823, Hawe Neos Dental, Switzerland).

Fuji IX (GC Europe), Ketac Molar Easymix and Ketac Molar Aplicap (3M, ESPE Germany) glass cements were used to restore the teeth and apply the sealant to adjacent pits and fissures. A fifteen-second pre-treatment of the cavity and the adjacent fissures was done using a diluted liquid portion of the GIC (Fuji IX) and the manufacturer's conditioner (Ketac Molar brands). The operators and their assistants manipulated the materials in accordance with the manufacturer's instructions. The assistants recorded the mixing time and the total time taken to restore the cavity using timers (Oregon scientific clocks). They also recorded the room temperature at the time of completing the placement of the restoration using an ordinary Celsius thermometer (Brannun, England). The child was asked not to take any food within one hour after restoring the tooth.

Four dental undergraduate students and two postgraduate students evaluated the restorations and the adjacent sealants, soon after placement and after two years respectively. They examined the restorations under natural light augmented with artificial lighting using a headlamp. Sterile mouth-mirrors and periodontal probes (Michigan O probes with Williams markings) were used during the examination, and the restorations were evaluated for their presence, marginal integrity, wear, fractures and secondary caries (see Tables 7.1 and 7.2). A day after placing the restorations, a record of the type and consistency of the next meal taken by the child after restoring the cavity was documented. This was either lunch (for morning treatment sessions) or dinner (for afternoon treatment sessions).

Table 7.1: The quality of the fissure sealants was determined using the following criteria.

Score	Condition of the sealants	Comments
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	Censored
6	Un-diagnosable	Censored

Table 7.2: The quality of the restorations was evaluated according the following criteria.

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

Calibrations

Cohen's Kappa Coefficient [10] was used to calculate the repeatability of the evaluators. Initially, the chief investigator and an experienced dentist established the "gold standard" by examining several ART restorations (Kappa 0.92, n=20). The chief investigator then trained and calibrated all the evaluators.

Data analysis

SPSS version 14.0 (SPSS Inc., Chicago, IL, USA) was used to analyze the data. Descriptive statistics, Chi-square, Kaplan-Meier (KM) survival tests, Cox proportional hazards regression model (Cox PH model) analysis and Multiple-logistic regression model tests, with the significance limit pegged at less than 5% were used to analyze and test the survival rates of the restorations. The results were related to the material used, mixing time, restoration time, the room temperature and the consistency of the food taken after the placement of the restorations.

Results

A total of 804 restorations were placed in the primary molars of 6 to 8 year-olds during the operative stage of the study. The mean age of the participants was 7.4 (SD 0.95) years and the male to female ratio was1.3:1. Except for the 3 cases that were improperly documented, a total of 244 (30.3%), 281 (35.0%) and 276 (34.3%) restorations were placed using KMA, KME and Fuji IX respectively. In total 38 (4.8%) restorations were not evaluated soon after placement (within 2 hours of restoring the tooth) due to truancy by the children. At the end of 2 years, there were voluntary drop-outs or drop-out resulting from irregular school attendance (n=86), transfers to other schools outside the study area (n= 69) and death (n= 1). Only 648 (80.6%) restorations were available for evaluation, and 30.8% of the restorations and 10.9% of the sealants adjacent to the restorations had survived.

The results of the calibration showed good agreements with a mean weekly value between the chief investigator with the first group of evaluators of Kappa 0.84 (n=63), and with the second group of Kappa 0.86 (n=52). The mean inter-evaluator value within each group was Kappa 0.82 (n=48) for first group and 0.92 (n= 52) for the second group, and a daily intra-examiner agreements on 10% of the evaluated restorations ranging from Kappa 0.80 to 1.0 for both groups.

Survival of the restorations and the GIC brands

The Kaplan-Meier survival plots for the sealants and restorations in relation to the material used are shown in Figures 7.1 and 7.2. After two years, there were no significant differences in the survival rates of the restorations in relation to the material used the operators who placed them (Chi-square, $p > 0.05$). Nonetheless, the restorations and the sealants adjacent to the restorations had higher rate when rubber dam tooth-isolation method was used and not the cotton rolls. KMA and Fuji IX sealants and restorations had the highest survival rates compared to those of KME, but the differences were not statistically significant (Chi-square, $p > 0.05$).

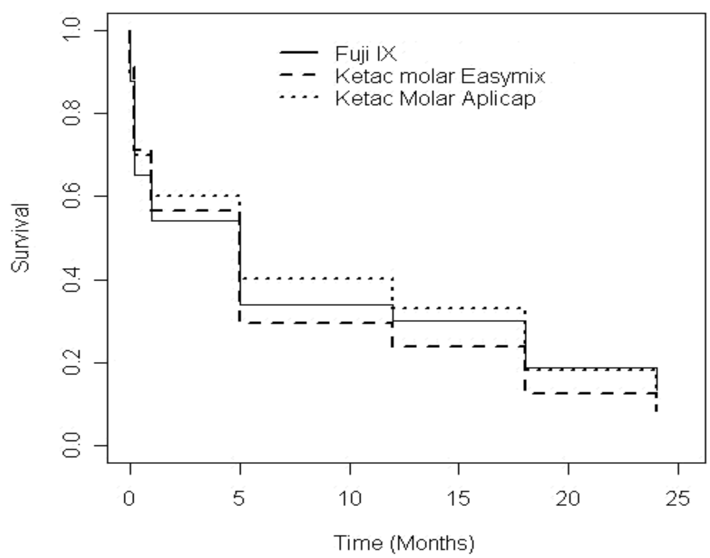

Figure 7.1: The two-year Kaplan-Meier survival plots for the ART sealants.

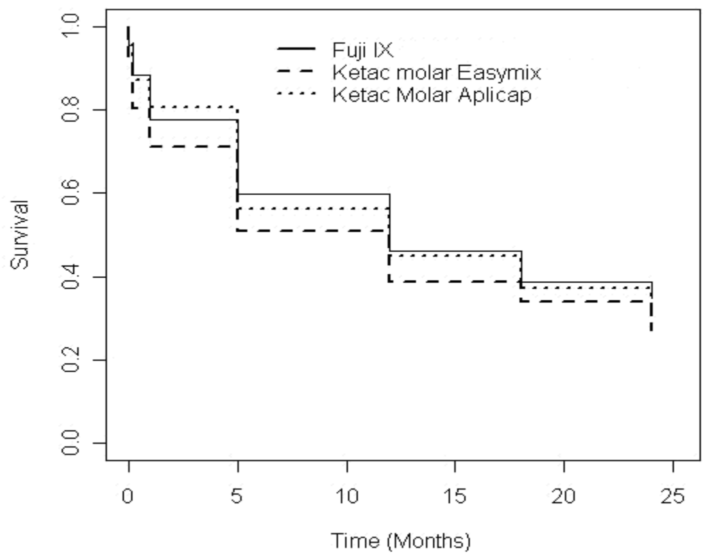

Figure 7.2: The two-year Kaplan-Meier survival plots for the proximal ART restorations.

In regard to the mixing times of the materials, the mean mixing times for the three brands of GIC used in the present study was 30 (SD 0.25) seconds. After two years, higher survival rates of the restorations and the adjacent sealants were observed for the mixing times of less than 60 seconds compared to the times that were higher. The differences were, however, not statistically significant for sealants (Cox PH model, Est= -0.585, SE=0.484, Chi-square= 1.456, p=0.228) or for the restorations (Cox PH model, Est = -0.112, SE= 0.607, Ch-square= 0.034, p= 0.853). The survival rate after two years of the restorations and the adjacent sealants of all the material brands was higher when the total restoration time was 3 minutes or less. Fuji IX restorations had the highest survival rate followed by KMA and KME. The difference in the survival rates of the restorations in comparison to the restoration-times of higher or lower than 3 minutes was not statistically significant for the restorations (Cox PH model, Est = -0.11, SE = 0.61, Chi-square = 0.03, p = 0.85) and for the adjacent sealants (Cox PH model, Est = -0.58, SE = 0.48, Chi-square = 1.46, p=0.23).

When the survival rates of the restorations were related to the material used and the ambient temperature at the time of restoring the teeth, higher survival rates were recorded for restorations placed at temperatures less than 25°C. The survival rates tended to decrease with increasing temperatures, although the differences were not statistically significant for the restorations (Cox PH model, Est = 0.02, SE== 0.01, Chi-square = 1.86, p=0.17) and the adjacent sealants (Cox PH model, Est = 0.006, SE = 0.013, Chi-square = 0.232, p=0.630). Nonetheless, the restorations placed using Fuji IX had the highest survival rate followed by KMA and KME at all temperatures.

Survival of the restorations and post-operative meal consumed

Only 536 (66.7%) children provided the information on the enquiry on the next meal taken after placing the restorations. The type and consistency of the food consumed were recorded and grouped as shown in Table 7.3. Those children, who took food that was of 'hard' consistency as their next meal, had a lower survival rate of their restorations and the adjacent sealants at the initial evaluation moment and also after two years. The difference in the survival rates after two years for the children who had food of a 'hard' consistency and those who took 'soft foods' was statistically significant for both sealants (Chi-square, $p = 0.0006$) and restorations (Chi-square, $p= 0.0019$).

Table 7.3: The results for the meals consumed by the children were categorized as follows:

Name of the meal	Consistence of food	Number of children	Percentage
Githeri	Hard	248	30.8
Rice	Soft	66	8.2
Ugali	Soft	200	24.9
Others	Mixture	22	2.7
Not stated	unavailable	268	33.3

To adjust for the effect of other variables, a multiple-logistic regression model was applied to the survival results obtained in order to predict for the best survival outcome. The variables included the operator, isolation method, material used, mixing time, placement time, room temperature and the next-meal taken after placing the restoration. The results showed that all these factors, except for the next-meal that was taken, did not have any statistical significant effects (Cox PH model test, $p > 0.05$) on the survival rates of the restorations and the adjacent sealant in relation to the materials used. The next-meal taken soon after placing the restoration had a significant effect on the survival rate of the restorations (Chi-square = 0.34, p = 0001) and the adjacent sealants (Chi-square = 1.62, $p = 0.004$).

Discussions

The high-viscosity GIC's, like those used in the study, were designed as alternatives to amalgam restorations, particularly for class I restorations [11] which have been reported to be comparable in survival rates [12, 13]. In the present study, Fuji IX brand of GIC material had higher survival rates for the restorations and the adjacent sealants, followed closely by KMA. KME had the lowest survival rates for both sealants and restorations. With a survival rate in the present study of 30.8% for restorations and 10.9% for the adjacent sealants after two years, this was still very low when compared to the 46% or more restorations reported by some studies (13, 14), and yet higher than the 12.2% of restorations reported by another study [3].

The survival rates of the single-surface ART restorations have been acceptable, but the multi-surface ART restorations have not demonstrated similar results [3, 13, 14, 15, 16]**.** The quality of a restoration and its survival rate can be determined by many factors. One of the factors is the material used for the restoration, its physical properties, flow rate and consistency [17]. The restorations placed after mechanically mixing the material have generally got better properties than those placed with the assistant-proportioned and hand-mixed materials that may usually have varying consistencies [9, 18]. This is because the mechanically mixed type has the correct ratio of powder and liquid with consistent mixing and predictable results. In this study, KMA was mechanically mixed and Fuji IX and KME were manually mixed. The results showed Fuji IX and KMA had sealants and restorations that had almost similar survival rates, and which were higher than those of KME. Probably there were other factors involved other than the mixing process [10, 19] or the hand-mixing of Fuji IX had been done rather well. Longer or shorter mixing times can also affect the properties of the GIC material, with possible air-entrapments or poor bonding that weakens the strength of the restoration [10]. Although the manufacturers' recommended mixing and working times at 23 °C to 25 °C were 15 seconds and 4 minutes and 30 seconds for KMA, 30 seconds and 2 minutes and 20 seconds for Fuji IX and 30 seconds and 5 minutes for KME. In the present study the mean mixing time was 30 seconds, and the mixing done at less than 60 seconds, with a total restoration time of about 3 minutes gave rise to higher survival results of the restorations.

The total restoration time, expressed as time span from the moment the mixing starts to the completion of the placement and the adjustment of the restoration, can also affect the survival rate of the restorations particularly when there is undue delay in placing the material into the cavity [20]. This can lead to reduced flow rate, poor material adherence to the cavity-surfaces, and disturbance in the initial maturation process that can subsequently give rise to weaker material bonding. In the present study, the restorations that were placed within the recommended time by the manufacturer had higher survival rates.

The restorations that were placed at the temperatures that were around that recommended by the manufacturers of 23 °C to 25 °C had the highest survival rates. The reaction of GIC being an acid-base reaction can be affected by temperature changes [21]. Although in the present study higher temperatures tended to give rise to restorations with lower survival rates, the results did not show any statistical significance. Possibly, by the time the material was placed into the cavity the setting process of the material was advanced, leading to poor material flow, void-formation, poor cavo-material bonding and subsequently reduced survival rates of the restorations [9, 18].

It would be difficult to be completely sure if all the children adhered to the instructions given not to consume any food in the first one hour after the placement of the restoration. However, the next meal taken by these children had a significant effect on the survival rate of the restorations. The foods that were of 'hard' consistency had a considerable negative effect on the survival rate of these restorations. It is probable that the 'hard' foods affected the restorations leading to increased failures. GIC takes varying periods of time to reach their full compressive strength through a maturing process [7, 18]. It is not clear from the study as to whether the next meal taken by the children was representative of the actual regular meal the child normally took at home. However, after 2 years the survival rate of the restorations associated with the 'hard' consistency food-intake was significantly lower. It is possible that high masticatory forces exerted during the chewing of this food affected the survival of these restorations, given the low compressive strength of the GIC materials when related to the dental enamel.

Conclusions

1. Although the survival rate of the proximal ART restorations placed in the primary molars using the three GIC brands (Fuji IX, KMA, and KME) was low in the present study, the KME restorations recorded the lowest survival rates after 2 years.
2. Excluding KMA that had a consistent mixing time, higher survival rates were obtained with the mixing times of the materials of less than 60 seconds, and when the total restoration time was less than 3 minutes for the three brands of GIC used in the present study.

3. The next meal of ‘harder’ consistency was associated with significantly lower survival rates of the proximal ART restorations and the adjacent sealants.

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