Clinical Article

Two-year Survival Rates of Proximal Atraumatic Restorative Treatment Restorations in Relation to Glass Ionomer Cements and Postrestoration Meals Consumed

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Abstract: ***Purpose:*** *The purpose of this study was to investigate the influence of 3 glass ionomer cement (GIC) brands and the postrestoration meal consumed on the survival rate of proximal atraumatic restorative treatment (ART) restorations.* ***Methods:*** *A total of 804 proximal restorations were placed in primary molars by trained operators and assistants using 3 GIC brands. The materials' mixing/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 2 years by trained and calibrated evaluators.* ***Results:*** *After 2 years, approximately 31% of the restorations had survived. There were no statistically significant differences in the survival rate of the restorations in relation to the GIC brands. The postrestoration meal consumed, which was of "hard consistency," was associated with significantly lower survival rate of the restorations.* ***Conclusions:*** *The survival rate of the proximal restorations was not significantly affected by the glass ionomer cement brands used, but was significantly influenced by the consistency of the next meal consumed by each child.* *(Pediatr Dent 2011;33:246-51) Received November 4, 2009 / Last Revision January 28, 2010 / Accepted March 15, 2010*

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Dental caries is probably the most common chronic disease of childhood, in spite of it being preventable.[1] Its prevalence continues to rise in less-developed nations due to poor socioeconomic status, increasing refined sugar consumption, poor oral health habits, and limited access to dental health care.[2]

One way of treating carious lesions is by placing a restoration, during which time the operator decides on 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 an inexpensive and tooth tissue conservative approach. Due to these attributes, the technique offers opportunities for restorative dental treatment for underserved communities, dentally anxious patients, and children with special health needs (eg, mentally disabled and neurologically compromised patients).[3,4]

Glass ionomer cement (GIC) is commonly used together with the ART technique because of its satisfactory biological features, favorable processing and setting times, fluoride-release capability, and low cost. It has thermal compatibility features similar to enamel and forms stable bonds with tooth tissues under ambient oral conditions. GIC suffers, however, from shorter working and longer setting times. Its cohesive strength, fracture toughness, and wear resistance are poor, and GIC has a high susceptibility to moisture contamination/dehydration in its early setting stages.[5,6]

The porosities incorporated during GIC mixing can complicate the material's already poor strength. Mechanical mixing tends to produce a good material mixture with less porosity, while hand-mixing is generally favorable for high viscosity cements but not for low viscosity cements.[7] The mechanical/physicochemical properties and working/setting characteristics of GIC materials depend on the material formulation, the relative proportion of its constituents in the cement mix, and the mixing process. These features will tend to vary according to the GIC brand. Capsulated GIC brands contain premeasured GIC powder/liquid ratios that ensure definite mixing times, correct consistencies of the mix, and predictable results as compared to the hand-mixed GIC brands.[8] Most of the material-related factors are under the control of the manufacturer and vary by brand, but other factors, like the mixing and handling processes, are operator controlled.

During the setting process, GIC's alkaline glass powder and unsaturated acid react and form a salt gel as part of the bonding matrix. While water remains the reaction medium and an essential component of the salt gel, excessive or insufficient water can lead to weaker bonding within the material matrix and to the tooth tissues. The proportion, mixing technique, mixing/restoration times, and ambient temperature during the material handling will influence the integrity of the ART restoration. Even after mixing, the material

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goes through a maturation stage that can last several weeks, during which the dissolution of the material in water progressively lessens and its compressive strength enhances.[9-11] The amount of occlusal forces applied on the restoration, particularly in the early stages of its maturation, can influence the restoration's survival rate.[7,12,13]

The extent of the effects of all these factors on the integrity of proximal ART restorations is not clear. The purpose of the present study was to determine, after 2 years, the influence of 3 high-viscosity GIC brands on the survival rate of proximal atraumatic restorative treatment restorations, placed using 2 tooth isolation methods. Particularly observed were the: effects of mixing/restoration times of the materials; ambient room temperature during the material placement into the cavity; and consistency of the first postrestoration meal consumed by the subjects.

Methods

Study population and ethical issues. This study's data were obtained as part of a prospective clinical study on factors affecting the survival rate of proximal ART restorations in the primary molars. The present study was conducted in 2 rural divisions in Kenya, in May, 2006, 2 months after selecting the study population. Ethical approval was obtained from The University of Nairobi and The Kenyatta National Hospital Ethical Committees, Nairobi, Kenya.

Although the calculated prestudy sample size was 382, given the various factors in the study and in order to improve the statistical power, a larger study population was desirable. The subjects were drawn from 30 randomly selected schools, with 6,002 6- to 8-year-olds, out of the 142 public schools in an area with 22,105 children in the same age bracket. Only healthy 6- to 8-year-olds with at least 1 proximal cavity in a primary molar, and who assented and were provided written consent by their parents/guardians, were recruited into the study.

The appropriate proximal cavity had an occlusal access of approximately 0.5 mm to 1.0 mm in the buccolingual direction, in a tooth without signs and symptoms of periodontal disease or pulpal involvement. The cavity size allowed for easy access of the smallest excavator. Only 1 proximal carious lesion, considered to be the smallest, was selected in each child. Initially, 1,560 cavities were selected, but due to absenteeism, school transfers, lack of parental consent, and pulpal exposure during the excavation stage, only 804 cavities were restored over a 3-week period.

Personnel and training. One pediatric dentist and 2 trained and pretested final-year dental students selected the appropriate proximal cavities. Seven operators [2 dentists, 4 final-year dental students and 1 community oral health officer (**COHO**)] and 8 assistants [1 COHO and 7 dental assistants] restored the cavities using ART. The operators and assistants were blinded to the material in the study (labeled only as A, B, and C), in spite of Ketac Molar Aplicap (**KMA**, 3M ESPE, Seefeld, Germany) being the only encapsulated material. One operator had failed to participate in the operative stage. That left 7 operators to be randomly paired daily to the 8 assistants in such a manner that 1 assistant rested on each operative day. All of them received appropriate training (theory and practice) based on the 5-module, World Health Organization-recommended ART training program contained on a compact disc by Frencken et al.[14] Over a period of approximately 3 months, the evaluators were pretested and calibrated in their roles in applying the ART and undertook further supervised and documented clinical sessions with the technique for the purpose of gaining more experience. They used materials similar to those used in the study.

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 conducted at each school, with the child lying supine on a table facing toward a natural light source. A battery-powered headlamp augmented the lighting within the oral cavity.

The operators isolated the teeth using rubber dam or cotton rolls (see Figure 1). Dental hatchets were used to enlarge the cavity entrances and to remove enamel overhangs, while spoon excavators were used 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 appropriate referral to the local hospital for further management. Deep and unexposed cavities were lined with calcium hydroxide (Dycal, Dentsply, York, Pa) to provide pulpal protection. A slightly contoured matrix band (Union Broach Moyco, Moyco Technologies Inc, York, Pa) was adapted around the tooth and held in place with a wooden wedge (Sycomore Interdental Wedges, no. 823, Hawe Neos Dental, Bern, Switzerland) prior to restoring the cavity.

Fuji IX (GC Europe, Netherlands and KMA and Ketac Molar Easymix (**KME**, 3M ESPE, Seefeld, Germany) GICs were used to restore the teeth. A 15-second pretreatment of the cavity was done using a diluted liquid portion of the GIC (Fuji IX) and the manufacturer's conditioner (Ketac Molar brands). The operator and the assistant handled the materials in accordance with the manufacturers' instructions. The assistant manually mixed Fuji IX and mechanically mixed KME and KMA for 10 seconds (Duomat 2 amalgamator, Dental und Goldhalbzeug, 600 Frankfurt, Germany), and recorded the mixing/total restoration times (from mixing of material to completion of restoration process) using Oregon scientific clocks. The room temperature at the end of the restoration process was also taken using an ordinary Celsius thermometer (Brannun, London, UK). The child was asked to avoid taking any food within 1 hour after restoring the tooth.

Evaluation of the restorations. Four dental undergraduate students and 2 postgraduate students, respectively, evaluated the restorations soon after placement and after 2 years. They had been trained using GIC restorations photographs, extracted teeth with GIC restorations and children with GIC restorations on their molars. During the evaluation,

Table 1. QUALITY OF THE RESTORATIONS

Score	Condition of the restorations	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 gone	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	Undiagnosable	Censored
9	Presence of secondary caries related to the restoration	Failed

the evaluators used sterile mouth mirrors and periodontal probes (Michigan O probes with Williams markings, HufriedyMfg. Co. Inc, Chicago, USA) to evaluate the restorations under natural light augmented with a headlamp. They evaluated the restorations for their presence, marginal integrity, wear, fractures, and secondary caries (see Table 1). A day after placing the restorations, a record of the type and consistency of the next meal (lunch, snacks, or dinner) was provided by the child.

Calibrations. Cohen's kappa coefficient[15] was used to determine 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. Good agreements were obtained. In the case of the evaluations soon after placement and after 2 years, the mean weekly results between the chief investigator and the first group of evaluators was kappa=0.84 (N=63) and with the second group was kappa=0.86 (N=52). The mean interevaluator value within each group was kappa=0.82 (N=48) for the first group and 0.92 (N=52) for the second group. The daily intraexaminer agreements for 10% of the evaluated restorations ranged from kappa=0.80 to 1.0 for both groups.

Data analysis. SPSS 14.0 (SPSS Inc, Chicago, Ill) was used to analyze the data and relate the results to: the material, its mixing time/restoration times; the room temperature; and the consistency of the postrestoration food taken using descriptive statistics. Chi-square, Kaplan-Meier, Cox proportional hazards regression model (**Cox PHRM**), and multiple-logistic regression model tests, with the significance limit pegged at less than 5%, also were used to test the results of the analysis.

Results

The mean age for the 804 participants was 7.4 (±0.95 SD) years old, and the male-to-female ratio was 1.3:1. Except for 3 improperly documented cases, a total of 244 (~31%), 281 (35%), and 276 (~34%) restorations were placed using KMA, KME, and Fuji IX, respectively. There were twice as many restorations placed in the first molars compared to the second molars, with most being disto-occlusal and mesio-occlusal restorations in the first and second molars, respectively. There also were a near equal number of restorations placed using the 2 methods of tooth isolation (see Table 2). A total of 404 restorations were placed using the rubber dam tooth-isolation method, while 397 restorations were placed using cotton roll tooth-isolation method. Three teeth that were restored were not included due to failure to document the method of tooth-isolation used.

Table 2. DISTRIBUTION OF THE PROXIMAL RESTORATIONS IN RELATION TO THE METHOD OF ISOLATION, TOOTH TYPE, AND CAVITY

Isolation method	Cavity type restored	First molar	Second molar	Total
Rubber dam	Disto-occlusal	193	22	215
	Mesio-occlusal	19	170	189
Cotton wool roll	Disto-occlusal	197	25	222
	Mesio-occlusal	39	136	175
Total		**448**	**353**	**801**

At the initial evaluation (within 2 hours of restoring the tooth), 38 (~5%) restorations were not evaluated due to truancy by the children. After 2 years, there were dropouts (N=86), transfers to other schools outside the study area (N=69), and death (N=1), resulting in only 648 (~81%) restorations being evaluated. At this moment, approximately 31% of them have survived. The survival rate of the restorations was not significantly influenced by the type of cavity restored (chi-square, $P>.05$).

GIC brands and restoration survival. Figure 1 shows the Kaplan-Meier survival plots for the restorations in relation to the GICs used. The 2-year survival rate did not

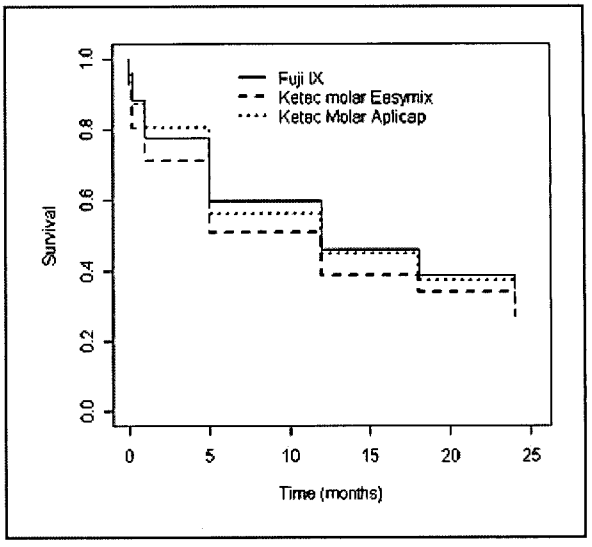

Figure 1. The two year Kaplan Meler survival plots for the restorations in relation to the material used.

show any significant differences in relation to the GIC brand used (chi-square; $P>.05$). KMA and Fuji IX restorations had the highest survival rate compared to KME restorations. In regard to the mixing times of the materials, the mean mixing time for the 3 brands of GICs was 30 (±0.25) seconds. A higher 2-year survival rate of the restorations was observed for the mixing times of less than 60 seconds, but the difference when related to the mixing times above 60 seconds was not significant (Cox PHRM= -0.112±0.607; chi-square=0.034; $P>.85$). Additionally, a higher 2-year survival rate was recorded when the total restoration time for all the GIC brands was less than 3 minutes, (Cox PHRM=-0.11±0.61; chi-square=0.03; $P=.85$), and Fuji IX restorations had higher survival rates, followed by KMA and KME.

When the survival rate of the restorations was related to the ambient room temperature during the restoration of the teeth, higher survival rates of the restorations were recorded for temperatures below 25°C, and they tended to decrease (not statistically significant) with increasing temperatures (Cox PHRM=0.02±0.01; chi-square=1.86; $P=.17$). Fuji IX restorations were higher, followed by KMA and KME, at all temperatures recorded.

Postoperative meal consumed and restoration survival. Only 536 (~67%) children provided the information regarding the inquiry on the first postrestoration meal taken (see Table 3). The children, who ingested "hard" consistency foods, had a lower survival rate of their restorations at the initial evaluation moment and also after 2 years. The difference in the 2-year survival rate of the restorations, in relation to food of a "hard" consistency and the "soft foods," was statistically significant (chi-square = 8.34, $P=0.002$).

To adjust for the effect of other variables and to predict the best survival outcome, a multiple-logistic regression model test was applied to the restoration survival results. The variables included the operator, material, isolation method, and the next meal taken after placing the restoration. Except for the next postrestoration meal that was taken (chi-square= 0.34; $P<.001$), the GIC brands did not have any statistically significant effect, but there was a significant effect with the rubber dam isolation method (chi-square=3.84, $P=0.026$) and the operator (chi-square=15.83; $P<.001$) on the survival rates of the restorations.

Discussion

High-viscosity GICs, like those used in the present study, were designed as alternatives to amalgam restorations, particularly for Class I restorations,[16] which have shown comparable survival rates,[17,18] unlike for multisurface restorations.[5,18-21] In the present study, Fuji IX restorations had higher survival rates, followed closely by KMA, with KME restorations having the lowest. The approximately 31% 2-year cumulative survival of the restorations in the present study was still very low when compared to the 46% or more reported in other studies using similar materials.[13,14] It was, however, higher than the approximately 12% of restorations reported in another study.[5]

Table 3. TYPE AND CONSISTENCY OF THE POST-RESTORATION FOOD CONSUMED BY PARTICIPANTS

Meal name	Consistency of food	No. of children	Percentage (%)
Githeri	Hard	248	31
Rice	Soft	66	8
Ugali	Soft	200	25
Others	Mixture	22	3
Not stated	Unavailable	268	33

The quality and survival of a restoration can be determined by many factors. Some of the factors are related to the restorative material's physical properties, flow rate, and consistency.[22] Restorations placed using mechanically mixed materials generally have better properties than those that are hand-mixed and which usually end up with varying consistencies.[8,14] This is because the mechanically mixed type has the correct powder/liquid ratio that results in a consistent mixture with predictable results.

In the present study, although KMA was mechanically mixed and Fuji IX and KME were manually mixed, the 2-year survival rates of Fuji IX and KMA were higher and almost similar, and KME restorations were much lower. There were, however, other factors involved than the mixing process[23,24] or probably, the hand-mixing of Fuji IX had been done rather well. Longer or shorter mixing times also can affect the properties of the GIC material, with possible air entrapments or poor bonding that weakens the restoration's strength.[10] The manufacturers' recommended mixing and working times at 23°C to 25°C, however, were: 15 seconds and 270 seconds for KMA; 30 seconds and 140 seconds for Fuji IX; and 30 seconds and 5 minutes for KME. While the mean mixing time in the present study was 30 seconds, a mixing time of less than 60 seconds and a total restoration time of approximately 3 minutes gave rise to higher survival results of the restorations.

The total restoration time, expressed as the time the mixing started to the completion and adjustment of the restoration, can affect the restoration's survival rate, especially when there is undue delay in placing the material into the cavity.[25] This delay could lead to the material being placed in the cavity during an advanced setting stage and result in poor adhesion to the tooth surfaces.[10,23] In the present study, the restorations placed within the recommended time by the manufacturer had higher survival rates.

The restorations placed at temperatures recommended by the manufacturers (23°C to 25°C) had the highest survival rates. The acid base reaction of GICs can be affected by temperature changes.[26] In the present study, higher ambient room temperatures tended to result in restorations with lower survival rates. By the time the material was placed into the cavity, the setting process possibly was already advanced, leading to poor material flow, void formation, and poor cavo material bonding—thus reducing the restorations' survival rates.[14,23]

It would be difficult to ensure that every child complied with the instruction not to chew any food in the first 1 hour postrestoration. The next meal consumed, however, had a significant effect on the restorations' survival rate, with "hard" consistency foods having a considerable negative effect. GICs take several weeks to mature and reach their full compressive strength,[7,18] making the restorations vulnerable to failure if high forces are applied to them early. It is not clear from the study whether the next meal eaten was representative of the regular meals normally consumed by the children, as all children who had consumed hard consistency foods had restorations with significantly lower survival rates. It is possible that high masticatory forces required to crush these foods could have affected the survival of these restorations, given the low compressive strength of the GIC materials.

Conclusions

Based on this study's results, the following conclusions can be made:

1. The 2-year survival rate of the proximal atraumatic restorative treatment restorations placed using Fuji IX, Ketac Molar Aplicap, and Ketac Molar Easymix was low.
2. The glass ionomer cement brands did not affect the survival rate of the proximal restorations. KMA, however, had a consistent mixing time. Higher survival rates (not statistically significant) were observed when the material mixing time for the other 2 GIC brands was less than 60 seconds. The total restoration time for all the materials was less than 3 minutes.
3. The next "harder" consistency meal was associated with significantly lower survival rates among the proximal ART restorations.

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