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Influence of the cavity-size on the survival rate of proximal ART restorations in primary molars

ARTHUR MUSAKULU KEMOLI[1] & WILLEM EVERT VAN AMERONGEN[2]

[1]Department of Paediatric Dentistry/Orthodontics University of Nairobi, Kenya, and [2]Department of Cariology, Endodontology, Pedodontology Academic Centre for Dentistry Amsterdam (ACTA), Amsterdam, the Netherlands

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Aim. To evaluate the influence of the size of proximal cavities on the survival rate of the atraumatic restorative treatment (ART) restorations.

Design. A total of 804 children, aged 6–8 years, from a low socio-economic community, with an ART restorable proximal carious lesion in their primary molars, participated. Over a 3-week period, three 'experienced' and four 'inexperienced' operators randomly paired with four 'experienced' and four 'inexperienced' assistants, made the restorations at site using hand instruments. They randomly used Fuji IX, Ketac Molar Easymix and Ketac Molar Aplicap glass ionomer cements to restore the cavities, under randomly selected rubber dam and cotton roll isolation methods. The fillings were independently evaluated by nine trained and calibrated evaluators.

Results. After 1 year, the survival rate of the fillings evaluated in the study was 44.8%. Irrespective of the other factors involved, restorations with the highest survival rate were of size between 2 and 3 mm (mesio-distal, bucco-lingual, and depth) or volumes 10.0–19.9 mm^3 (Chi-square, $P = 0.002$, KM mean survival of 345 days).

Conclusions. While the survival rates for class II ART restorations were still low, the choice of medium-sized proximal cavities gave better survival rates for this technique.

Introduction

From GV Black's cavity preparation concept regarding maximum intervention for prevention and mechanical retention, new concepts of minimal cavity preparation (MCP) techniques have emerged. They are minimally invasive and focus on the preservation of the hard tissues of the tooth and the promotion of re-mineralisation of the affected dentine below the carious lesion[1,2]. The atraumatic restorative treatment (ART), an MCP technique, employs hand instruments in the cavity preparation and an adhesive restorative material like glass ionomer cement (GIC)[3]. As the ART technique can be applied without the need for sophisticated equipment, running water or electricity, it offers the opportunity for restorative work in children from poor communities[4].

Correspondence to:
Arthur M. Kemoli, Department of Paediatric Dentistry/Orthodontics University of Nairobi, Kenya, PO Box 34848, 00100 Nairobi, Kenya.
E-mail: musakulu@gmail.com

The ART technique has been recommended for small-sized cavities, and therefore, correct cavity selection is an important consideration. A good cavity-choice enables the operator to adequately remove dental caries using the hand instruments and to achieve adequate cavo-material adhesion during the placement of the restorative material[5]. Achieving accurate diagnosis of suitable cavities for the ART approach can be difficult, especially, for multi-surface cavities in the primary dentition. Because of the thinner enamel and dentine layers of the primary dentition, larger multi-surface cavities are susceptible to pulpal exposure with concomitant pulpal reaction effect[6]. In addition, multi-surface restorations are susceptible to marginal failures, restoration-overhangs and contouring/carving deficiencies[7]. Caries-detection dyes can assist the operator in visualising the extent of the carious material and its removal, but their usefulness is debatable[8,9]. Radiographs can provide prior indication of the extent of the carious lesion, but this method is expensive and difficult to accurately elucidate the true extent of the lesion in the earlier stages of caries development.

Nonetheless, ART remains an advantageous technique for use in children, as it is reportedly atraumatic[10]. While the survival rates after a year of the single-surface ART restorations are acceptable and range from 65% to 96%, those of the multi-surface restorations are rather low with a range of 31% to 76.15%[11–14]. Failures of ART restorations, diagnosed as partial or complete loss of the restorations, have been associated with incorrect indication, poor operator skills and performance during the restoration process, poor quality of the restorative material, and secondary dental caries[15]. Whereas only limited studies have been carried out in regard to the multi-surface ART restorations, the poor survival rates reported from the studies available may not form an absolute basis for not using the ART approach in these indications. ART can still be regarded as a beneficial treatment option for many children from poor communities with high risks to dental caries and without access to any dental health programme. Possibly, further research needs to be undertaken to find the best way to apply ART as multi-surface restorations.

The aim of this particular study was to investigate the influence of the cavity-size on the survival rate of proximal restorations placed in primary molars of 6- to 8-year-old children, using the ART approach.

Material and methods

This study formed part of a clinical research on factors influencing the survival rate of proximal ART restorations in primary molars of 6- to 8-year-old children from Matungulu/Kangundo divisions, Kenya. The study received ethical approval from the University of Nairobi and Kenyatta National Hospital Research and Ethical Committees. Written consents were obtained from the parents/guardians of the participating children.

Selection criteria

A total of 22 105 children from 142 public primary schools in the two divisions were targeted. The schools were initially selected provided they had 50 or more children of ages 6–8 years. The selected schools were then stratified in accordance to their division. Using random numbers to select the schools alternately from each division, an initial number of 30 schools with 6002 eligible children were selected for examination. The selection process was to continue if the required number of 1200 children with ART-restorable dental cavities was not attained. Three examiners (two final-year dental students and one paediatric dental specialist) examined the children on the basis of having a suitable proximal cavity for restoration using the ART approach. All the examiners were trained and calibrated regarding the selection of cavities (kappa coefficient range of 0.78–0.82), treatment procedures and practice of ART before the study. During the examination of the children, only one proximal carious lesion, considered to be the most appropriate, was selected for restoration in each child. If the child had more than one appropriate cavity, the examiner was required to choose only one, the smallest of them all. Besides, a written consent provided by the parent/guardian, the child was to be in good general health and assent to the examination. The proximal carious lesion in the primary molar was to have an occlusal access of approximately 0.5–1.0 mm in the bucco-lingual direction. The tooth selected did not have any signs or symptoms of pain or mobility. Any child who did not meet these requirements was excluded from the study.

A total of 1560 children were initially selected based on the presence of the appropriate proximal cavity in their primary molar. From this number, 82.05% (n = 1280) of the children fulfilled all the selection-criteria and were recruited into the study. About 17.9% (n = 280) of them were excluded for lack of the required written consents from their parents allowing them to participate in the study. During the operative stage, 476 children were further excluded from the study on the basis of either being absent on the day of treatment, were anxious or the cavity was found to be inappropriate. Subsequently, only 804 children had each one proximal ART restoration made in their primary molars. One cavity per child was preferred to avoid other patient dependencies, like one side being frequently used for chewing etc. Those other cavities that were present but not selected

were either given emergency treatment in the field but not as part of the study and/or referred for management at the local hospital.

All the children in the study came from a low socio-economic background with limited access to proper dental health care. The male to female ratio was 1.3 : 1, the baseline mean age was 7.4 ± 0.9 years, the dmft was 4.0 ± 2.4, and the DMFT was 0.2 ± 0.5. For the dmft/DMFT of the study population, only the teeth with a history of premature loss (not a result of natural exfoliation for the primary dentition or un-erupted teeth for the permanent dentition) were included.

Clinical procedure

Over a period of 3 weeks in May 2006, three 'experienced' and four 'inexperienced' operators randomly paired on a daily basis with four 'experienced' and four 'inexperienced' assistants, made the restorations at each school. The operators included two dentists, four final-year dental students and one community oral health officer (COHO). The assistants were composed of one COHO and seven dental assistants. The operators and the assistants had been trained in their various roles relating to the ART approach. The 1-week training course was a WHO approved ART theory and practical training based on a five-module programme on a compact cassette by Frencken JE, Holmgren C and Milkx F, 1998–2000. After the training each operator made and each assistant helped to make further ART restorations in various clinics and in the field. Prior to the operative stage of the study, any operator who had made 50 ART restorations (half being class II and the rest of any other class) was classified as 'experienced', and any operator who had done less than ten but more than five of any class after the training was classified as 'inexperienced' in the ART technique. The assistants who had helped the operators to make similar numbers of ART restorations were also similarly classified.

The child was made to lie, in a supine position on a table, facing towards a natural light-source with the operator sitting at the head of the table. A battery-powered headlamp augmented the visibility within the oral cavity. Cotton rolls and rubber dam were used randomly to isolate the tooth. No local anaesthesia was used, other than a topical anaesthetic (Lidocaine 50 mg/g cream) applied for 2 min on the surrounding gingiva prior to the application of the rubber dam clamp, for cases where rubber dam isolation method was used. The operator used a hatchet to gain access into the cavity and a spoon excavator to remove the infected dentine, aided by a caries-detector dye. Wet and dry cotton pellets were used to rinse and dry the cavity. If pulpal exposure occurred during the excavation of caries the tooth was dressed and the child disqualified from the study with a referral to the local hospital for further treatment. Deep, un-exposed cavities had their bases covered with calcium hydroxide (Caulk, Dycal) to protect the pulp[3].

A pre-contoured matrix band (Union Broach Moyco) and a wooden-wedge retainer (Sycomore Interdental wedges No. 823, Hawe Neos Dental, Switzerland) were applied around the tooth before taking measurements for the cavity-size (mesio-distal, bucco-lingual and depth through the cavity centre) using the graduations on the Michigan O with Williams markings periodontal probe (Fig. 1).

The cavity and the adjacent occlusal fissures were conditioned for 15 s with the diluted part of the liquid material [Fuji IX (GC Europe), and the manufacturer's conditioner (Ketac Molar (3M ESPE) brands]. Fuji IX, Ketac Molar Easymix (KME) and Ketac Molar Aplicap (KMA) GICs were randomly used to restore the cavities. After adjusting for the occlusion with the help of articulating paper (Bausch Articulating paper; Nashua, NH 03060, USA), petroleum jelly was applied over the restoration to protect it from contamination. The child was advised not to eat within the next 1 h. The restoration was clinically evaluated within 2 h, post-placement.

Post-restoration follow-ups

Nine final-year dental students, trained and calibrated, clinically evaluated the restorations over the 1-year period. Four students evaluated the restorations soon after placement (within 2 h), at 1 week and 1 month, two students at the 5 months and three students

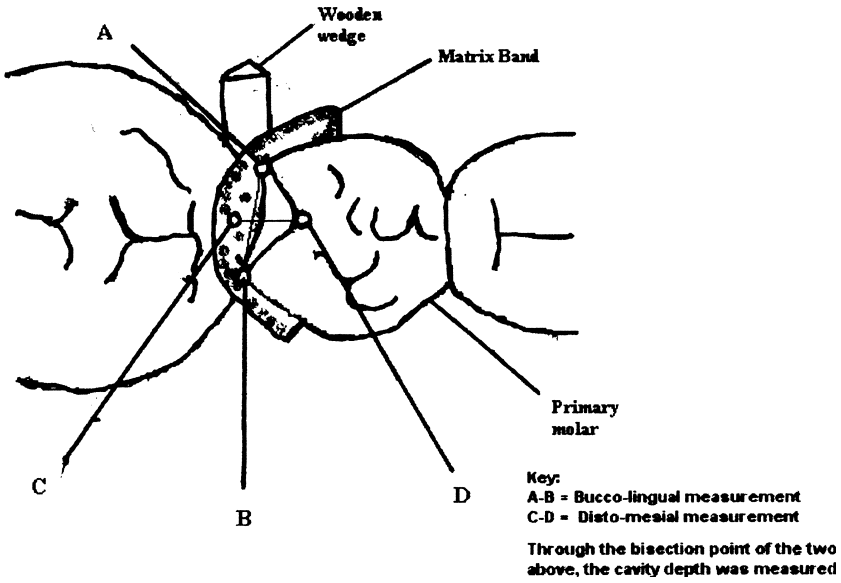

Fig. 1. Measurement of the cavity-size.

at the 1-year evaluation moments. They calibrated with the previous group, with each other and with the chief investigator. Blinded to the operator, assistant, material and isolation method used, they evaluated the fillings with the help of the Michigan O with Williams markings probe using the criteria given in Table 1. For doubtful cases, consensus between the examiners was reached.

Reliability and statistical analysis

A 'gold standard' for the evaluations had been initially established between the chief investigator and an experienced dentist using 15 ART restorations in extracted teeth and five actual restorations in the oral cavity (kappa coefficient of 0.92, $n = 20$). The mean weekly calibrations between the examiners and the chief investigator ranged from kappa 0.80–1.00 ($n = 35$), the daily inter-examiner range was kappa 0.82–0.86 ($n = 40$–75) and the daily mean intra-examiner consistency had a range of kappa 0.86–0.98 (10% of the children examined).

SPSS (SPSS Inc., Chicago, IL) version 14.0 computer program was used to analyse the data. The survival rate of the restorations was related to the cavity sizes and also to possible confounding factors as the dental arch in which the restoration was placed, operator experience, the material used and the tooth-isolation method used. This was done with the aid of descriptive statistics, Kaplan–Meier survival, Cox Proportional Hazard model and Logistic-regression tests. The probability of less than 0.05 was considered statistically significant.

Table 1. Evaluation-criteria for fillings.

Score	Condition of the Restoration	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 at the deepest point	Failed
8	Un-diagnosable	Censored
9	Presence of secondary caries in relation to restoration	Failed

Results

Clinical findings, survival of restorations and the cavity-size

Out of the 804 cavities restored, 98.8% (n = 794) could be evaluated in this study because of the presence of all the relevant data. Of these restorations, 54.6% and 45.4% were disto-occlusal and mesio-occlusal type of proximal restorations, respectively and 69.7% and 30.3% were in the mandible and maxilla, respectively. After the preparation, most of the cavities had sizes between 2 and 3 millimetres for disto-mesial and bucco-lingual direction and between 3 and 4 millimetres for the depth (see Table 2).

As the cavity prepared did not have a definite geometrical shape, the calculation of the cavity/restoration volume presented a problem. A decision to calculate a relative-volume rather than an absolute-volume could be made using the measurements obtained, and calculated as the product of disto-mesial, bucco-lingual, and depth lengths, with the results categorised as shown in Table 3. The mean volume was 20.4 mm^3 (SD = 14.8). Most cavity/restoration volumes belonged to category 2 (355 or 44.7%) with the lowest in category 4 (66 or 8.3%).

Because of absenteeism and drop-out, 768 and 695 restorations were evaluated soon after placement and after 1 year, and 94.4% and 44.8% had respectively survived (see Fig. 2). The cumulative survival of the restorations over the 1-year period of follow-up was as shown in Fig. 2. The cumulative survival of the restorations did not show any statistical significant differences with respect to the arch in which they were placed or the type of proximal cavity chosen (Chi-square, $P > 0.5$). Nevertheless, when the survival rate of the restorations was related to the cavity size (volume), the restorations with volumes 10–19.9 mm^3 (21%) had higher survival rates, that were statistically significant after 1 year compared to those with volumes 30.0–39.9 (6.5%) and those over 40 mm^3 (5.3%) combined (Chi-square, $P = 0.002$, Cox Proportional Hazard model test, $P = 0.005$). The smallest cavities of volumes 0–9.9 had restoration survival close to that of volumes 30.0–39.9.

Survival of the restorations in relationship to the cavity size and the operator/assistant experience

The survival of the restorations after 1 year and their sizes were related to the operator and the assistant experiences. The restorations made by 'experienced' operators had higher survival rate than those by the 'inexperienced' operators, but the difference was not significant statistically (Cox Proportional Hazard test, $P = 0.30$, Kaplan–Meier survival of 332 days and 329 for 'experienced' and 'inexperienced' operators, respectively). The highest survival rate was for the restoration-volumes in category 1 and 2 irrespective of the experience of the operator. It was also found that the highest survival of the restorations was for those placed with the aid of the 'experienced' assistants.

Table 2. Cavity-size and volume groupings.

Cavity-sizes	Disto-mesial (mm)	Bucco-lingual (mm)	Depth (mm)	Cavity/restoration volume (mm^3)
Total	794	794	794	794
0–2.0	94 (11.8)	20 (2.5)	3 (0.4)	
2.1–3.0	537 (67.6)	360 (45.3)	124 (15.6)	
3.1–4.0	131 (16.5	301 (37.9)	382 (48.1)	
4.1–5.0	21 (2.6)	72 (9.0)	225 (28.3)	
5.1–6.0	11 (1.4)	41 (5.2)	60 (7.5)	
Mean size	2.14	2.70	3.28	19.0
Mode	2.0	2.0	3.0	12.0
Std deviation	0.72	0.89	0.84	14.5
Minimum size	1.0	1.0	1.0	1.0
Maximum size	6.0	5.0	5.0	180.0

Values given in parentheses are in percentages.

Table 3. The restoration-volumes and their one-year cumulative survival in relation to the material used.

Cavity volumes and as percentage of the total number			No. restorations and the volume-category for each material after 1 year (percentage of the fillings evaluated)		
Volume category	No. cavities/ restorations	Valid percentage	Fuji IX (%)	Ketac Molar Easymix (%)	Ketac Molar Aplicap (%)
1 (0–0.9 mm^2)	150	18.9	27 (3.4)	12 (1.5)	18 (2.3)
2 (10–19.9 mm^2)	355	44.7	62 (7.8)	51 (6.4)	53 (6.7)
3 (20–29.9 mm^2)	154	19.4	21 (2.6)	20 (2.5)	14 (1.8)
4 (30–39.99 mm^2)	66	8.3	21 (2.6)	9 (1.1)	13 (1.6)
5 (over 40 mm^2)	69	8.7	17 (2.1)	7 (0.9)	11 (1.4)
Total	794	100			

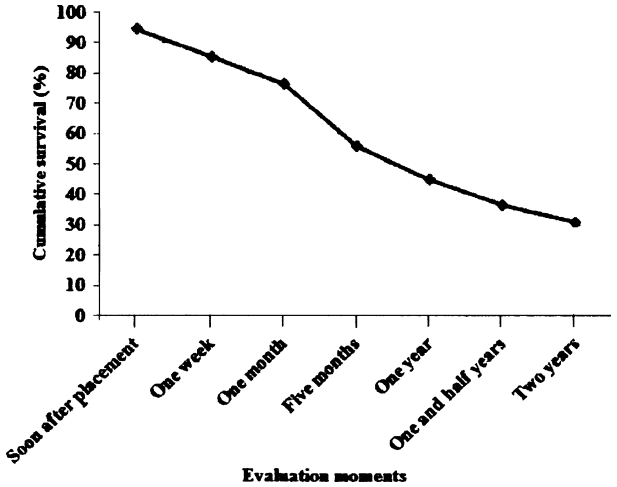

Fig. 2. The percentage cumulative survival of the fillings in the first year of study.

Survival of restorations in relationship to the cavity-size and GIC used

At 1 year, the cumulative number of restorations that had survived was related to the cavity-size and the materials used (see Table 3). The restorations made out of Fuji IX GIC had the highest survival results for cavities in category 2 followed by category 1. KME followed with restorations in cavities in category 2 followed by category 3 and KMA restorations had the lowest with cavities in category 2 followed by category 1 (Table 3).

More restorations made out of the three materials were still present after 1 year for the cavities in category 2 and the number was lowest for cavities in categories 4 and 5 (see Table 3). The Kaplan–Meier test for the mean survival rate of the restorations as related to the material used was 328.7 days, with a mean of 335.4 days for Fuji IX, 324.6 days for KME and 327 days for KMA for restorations in the category 2. There were no statistical significant differences between the three materials when related to the cavity volumes (Chi-square, $P = 0.43$) at this time.

Survival of the restorations in relationship to the cavity size and the method of isolation used

The 1-year survival rate of the restorations was related to the cavity-size and the method of isolation used. The survival rate of the restorations were higher when placed using the rubber dam than the cotton roll isolation methods (Kaplan–Meier test, $P = 0.53$). The highest survival rates of the restorations were for cavity-sizes in category 2 followed by categories 1 and 3 for both isolation-methods. After 1 year, the isolation method used at the time of material placement did not have any influence on the survival rate of the restorations for various cavity sizes (Chi-square, $P > 0.05$).

A multi-logistic model test with backward selection for the best model of dichotomised survival for the restorations was carried out to test the risk factors. The results after 1 year showed that the best model for predicting the survival of the restorations were dependent only on the cavity volume ($P = 0.006$) and the experience of the assistant ($P = 0.02$).

Discussion

In this study, the examiner selected the proximal cavities for ART approach, primarily on the basis of a visual examination. At, the beginning, 1.2% ($n = 10$) of the cavities

were not properly documented and were, therefore, left out of the analysis. Two teeth that showed signs and symptoms of pulpal involvement were referred for extraction during the period. The cumulative survival rate of the restorations, after 1 year of follow-up, was 44.8%. This was slightly higher than the 30% by Roeleveld using Fuji IX[16] and lower than the 83.1% by Nazan, using Fuji IX[17], over a comparable period of time. Nevertheless, in these two studies, determination of the cavity-sizes was not part of the study.

The size of the cavity has been reported to affect the survival rate of its restorations[18]. In this study, cavities with mean sizes between 2 and 3 mm (restoration-volumes 10–19.9 mm^3) had the highest survival rate. The smallest restorations did not have the highest survival rates, as reported in other studies, probably a result of inadequate visibility, removal of caries and deficiencies in material application[15,18]. The largest restorations had relatively poor survival rates and this might have been because of bulk failure or pulpal effect. Consequently, very small and too large cavities did not show good survival results with this technique.

The experience of the operator, the GIC material used and the tooth-isolation method applied did not have any significant statistical influence on the survival rate of these restorations in relation to their cavity-sizes. Nonetheless, after 1 year, the restorations made by 'experienced' operators had higher survival rate than those made by the 'inexperienced' operators[15], though not statistically significant (Log-rank Chi-square, $p = 0.16$, Kaplan–Meier survival of 332.4 and 328.8 days, respectively for 'experienced' and 'inexperienced' operators). All the operators had their highest survival rate of restorations for cavity-volumes of 10–10.9 mm^3, and the results were significant statistically when the 'experienced' assistants (not 'inexperienced' assistants) were paired with the operators.

The three high viscous GICs used in this study were of high powder/liquid ratio that makes them have good compressive strength on setting. Similar materials to those used in this study have previously proven in other ART studies to give rise to good survival rates for their restorations, particularly for the single-surface ART restorations[19]. The three GIC materials used in this study had proximal restorations with optimum cumulative survival for cavities of volume 10–19.9 mm^3 and decreased with increasing size. KME had the poorest survival for cavities over 40 mm^3 when compared with the other two GIC's. Probably, the very smallest cavities and the very largest ones, as found in this study, had effect on either the cavo-material adherence and or on their restoration's susceptibility to fracture and hence early failure.

Adequate tooth-isolation during the placement of the restorative material has been associated with superior restoration quality[20]. Although the rubber dam isolation-method would be presumed to offer better tooth-isolation than cotton rolls, up to 1-year of follow-up in this study, there were no statistically significant differences between the survival results of the restorations made using the two isolation methods. Nevertheless, the restorations made under rubber dam had a slightly higher survival rate than those made using cotton rolls. Probably, the rubber dam isolation method could have facilitated a better cavo-material adhesion than did the cotton rolls[20].

Pre- and post-operative radiographs would have offered additional information on the status of the cavities and their restorations. While the procedure had been included in the study, there were some technical problems encountered in the field, in terms of power supply, machine break-down, failure by the child to have the radiograph taken and unsatisfactory radiographs after processing, Consequently, this part of the study was excluded from this analysis. Only a few radiographs were of good quality and available for the analysis, making it difficult to draw any definitive conclusive results in relationship to this study.

Conclusions

While the survival rates of proximal ART restorations were still very low after 1 year, the medium-sized proximal cavities had the best survival results of the restorations placed in them using the ART technique.

What this paper adds
- A good cavity selection can enhance the survival rate of proximal ART restorations in primary molars.

Why this paper is important for paediatric dentists
- The paper reports on the possible difficulties the operator faces in making a good cavity-choice for improved survival rate of proximal ART restorations in primary molars.

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