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Chapter 4



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

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Summary

Aim: To evaluate the survival rate of proximal ART restorations in relation to the sizes of their cavity preparations.

Methods: In total, 804 children aged 6-8 years from a Kenyan rural population participated in the study. Trained operators and assistants restored, an equal number of proximal cavities in primary molars of the children, using only hand instruments. Fuji IX, Ketac Molar Easymix and Ketac Molar Aplicap glass ionomer cement-brands were randomly used to restore the cavities together with two tooth-isolation methods. The restorations were followed for two years.

Results: After two years, 648 restorations were available for evaluation, with a cumulative survival of 30.8%. Restorations whose sizes were 2 to 3 mm (mesio-distal, bucco-lingual and depth) or volumes between 10.0 to 19.9 mm³ had the highest number of surviving restorations, that were statistically significant (Chi-square, p=0.001).

Conclusions: In spite of the low survival rate of the proximal ART restorations, the medium-sized cavities were associated with higher survival rate of the restorations.

Introduction

From GV Black's cavity preparation concept regarding maximum intervention for prevention and mechanical retention, new concepts favouring minimal cavity preparation (MCP) approach have emerged. They are minimally invasive and focus on the preservation of the tooth tissues and the promotion of remineralization of the affected dentine below the carious lesion (1, 2). Atraumatic restorative treatment (ART) is one of the MCP techniques, and employs hand instruments in the cavity preparation and an adhesive restorative material like glass ionomer cement (GIC) (3). This technique does not need sophisticated dental equipment, piped water systems or electricity, and therefore, offers an opportunity for restorative work in children from poor communities (4). Due to the poor material strength of GIC, the technique is most suitable for small-sized cavities. Careful cavity selection is subsequently, an important consideration in facilitating adequate caries-removal using only hand instruments, and also allowing for adequate cavo-material adaptation during the placement of the restorative material (5). Caries-detection dyes can offer visual assistance in the recognition and removal of the carious material during the excavation stage, but their usefulness is debatable (6, 7). While radiographs might provide prior indication of the extent of the carious lesion, it is, however, an expensive procedure and has the inherent difficulty in accurately elucidating the true extent of the carious lesion particularly in the earlier stages of its development.

Selecting suitable cavities for the ART technique can be difficult, particularly for multi-surface cavities in the primary dentition. Due to the thin enamel and dentine layers in this dentition, larger multi-surface cavities are susceptible to pulpal-involvement with concomitant pulpal reaction-effect (8). Additionally, the multi-surface restorations made are liable to marginal failures, due to probable presence of restoration-overhangs and/or contouring/carving deficiencies (9).

ART approach can be advantageous for use in children as it is atraumatic (10). The restorations placed using the approach have reasonable survival rates for single-surface restorations of 65-96% over a period of up to three years. However, the survival rate for the multi-surface restorations of 31% -76% over the same period of time (11, 12, 13, 14) is rather low. Failures of ART restorations, diagnosed as partial or complete loss of the restoration, have been associated with incorrect indication, inadequate operator skills and poor performance during the restoration process, poor quality of the material used and secondary dental caries (15). A limited number of studies have been conducted in regard to the multi-surface ART restorations. The poor survival rates reported by the few studies available for the multiple surface restorations 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, for dentally anxious children and children with special health needs. Possibly, further research is needed in finding the best way of applying the ART approach, particularly, for multi-surface restorations. The aim of the present 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-olds, 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 the primary molars of 6 to 8 year-olds from Matungulu/Kangundo divisions, Kenya. The study received ethical approval from the

University of Nairobi and the Kenyatta National Hospital Research and Ethical Committees, and 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. A school was eligible for inclusion if it had 50 children or more of ages 6 to 8 years. The schools that fulfilled the criteria were stratified according to their division. Using random numbers, schools were selected alternately from each division, and initially 30 schools with a total of 6,002 eligible children were selected. These children were examined for the appropriate proximal cavities. The selection process was to continue if the required number of 1,200 children for inclusion in the study population was not attained after this initial selection process. This number, which was in excess of the pre-study population calculation of 382, was chosen in order to improve on the statistical power of the study as many factors were involved. Two Final-year dental students and one paediatric dentist examined the children for suitable proximal carious lesions for restoration using the ART approach. All the examiners had been trained and calibrated regarding the selection of appropriate cavities for use with the ART approach.

All the children selected were in good general health, assented to the examination and had at least one proximal carious lesion in the primary molar with an occlusal access of approximately 0.5 mm to 1.0 mm in the bucco-lingual direction. The size of the cavity-access was important so as to allow for easy entry into the cavity of the smallest excavator. If there were more than one cavity in a child, the smallest of them was chosen. The selected tooth had no signs or symptoms of pain or mobility. Any child who did not meet these requirements was excluded from the study.

A total of 1,560 children were initially selected based on the presence of an appropriate proximal carious lesion in their primary molars. From this number, 1,280 (82.05%) children fulfilled all the selection-criteria and were included in the study. The remaining 280 (17.9%) children lacked the required written consent from their parents to participate in the study. During the operative stage, 476 children were further excluded from the study due to being absent on the treatment day, dental anxiety or the cavity was inappropriate. Subsequently, only 804 children had each one proximal ART restoration placed in their primary molars. One cavity per child was preferred to avoid other patient dependencies, like one side being frequently used for chewing etc. Emergency treatment for any other dental complaint was provided and/or appropriate referral to the local hospital for further treatment given.

All the children in the study were from a low socioeconomic background with limited access to proper dental health care. At baseline, the male to female ratio was 1.3:1, the mean age was 7.4 (SD 0.9) years, the dmft was 4.0 (SD 2.4), and the DMFT was 0.2 (SD 0.5). In regard to the dmft/DMFT, only 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 three weeks in May 2006, three 'experienced' and four 'inexperienced' operators randomly paired on a daily basis to four 'experienced' and four 'inexperienced' assistants, made the restorations at each school. One assistant rested on each day of operation. The operators were two dentists, four final-year Dutch dental students and one community oral health officer (COHO), while the assistants were

one COHO and seven dental assistants. The operators and the assistants had been trained in their respective roles in the ART approach, based on the five-module WHO approved ART (theory and practical) training programme by Frencken *et al* (16). Within three months after training, all the operators and the assistants undertook further varied and supervised ART clinical sessions in various clinics and in the field, using similar GIC materials as those used in the study. All the restorations made during this period were documented. Prior to the commencement of the study, operators or assistants who had made or assisted in making a minimum of 50 ART restorations post-training (for operators, with at least 25 restorations being multi-surface restorations) were categorized as 'experienced'. The 'Inexperienced' operators or assistants had similarly been involved in the making between five and ten ART restorations of any class.

A bitewing radiograph of the tooth to be restored was taken before the child lay supine 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 randomly used to isolate the tooth. Other than Lidocaine (50mg/g cream) applied for two minutes to the surrounding gingiva prior to the application of the rubber dam clamp, no other local anaesthetic was used. A hatchet was used by the operator 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, the child disqualified from the study with a referral given to a local hospital for further treatment. Deep 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 measuring the cavity-size (mesio-distal, bucco-lingual and depth through the cavity centre) using the graduations on the Michigan O with William's markings periodontal probe (Figure 4.1):

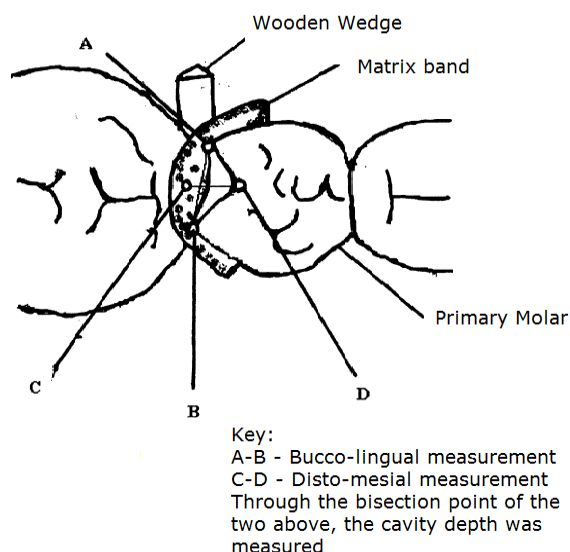


Figure 4.1: Measurement of the cavity-size.

Fuji IX (GC, Europe), Ketac Molar Easymix (KME, 3M ESPE, Germany) and Ketac Molar Aplicap (KMA, 3M ESPE, Germany) glass ionomer cements were randomly used to restore

the cavities. The cavity and the adjacent occlusal fissures were initially conditioned for 15 seconds with the diluted part of the liquid material (Fuji IX), and the manufacturer's conditioner (Ketac Molar brands). The restoration was adjusted for occlusion aided by an articulating paper (Bausch Articulating paper, Nashua, NH03060, USA) before applying petroleum jelly over it to protect it from contamination. A post-operative bitewing radiograph of the restored tooth was taken, and the child advised not to eat within the next one hour. Post-placement clinical evaluation of the restoration was done within two hours.

Clinical and radiographic follow-ups: Four Final-year and two postgraduate Dutch dental students, trained and calibrated, evaluated the restorations, soon after placement (within two hours) and after two year respectively. They evaluated them using the ART evaluation criteria (Table 4.1). Pre- and post-operative radiographs were also evaluated by the chief investigator using the criteria given in Table 4.2.

Table 4.1: Evaluation-criteria for the proximal restorations.

Score	Condition of the Restoration	Comments
0	Present, good	Successful
1	Present, marginal defects but ≤ 0.5 mm in depth.	Successful
2	Present, defect > 0.5 mm depth.	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, wear over the restoration of ≤ 0.5 mm at the deepest point.	Successful
7	Present wear over the restorations of >0.5 mm at the deepest point	Failed
8	Un-diagnosable	Censored

Table 4.2: Evaluation-criteria for the pre- and post-operative bitewing radiographs.

Code	Pre-operation evaluation	Post-operation evaluation
0	Cavity pulpal wall wholly within dentine	Sound restoration
1	Cavity pulpal wall involves pulp	Residual caries present
2	Cavity pulpal wall close to the pulp	Marginal gaps present & secondary caries
3		Pulpal involvement
4		Restoration party/totally absent

Reliability: The chief investigator initially calibrated with an experienced dentist to establish a 'gold' standard (Kappa coefficient of 0.92, n=20) (17). The chief investigator then calibrated all the evaluators with the results ranging from Kappa 0.78 to 0.95 for restorations (mean n = 22). The mean inter-evaluators Kappa coefficient was 0.84 to 86 (n= 42) for restorations. The daily intra-evaluator reliability on 10% of the restorations

ranged from Kappa 0.80 to 1.0. Consensus between the evaluators was reached for doubtful cases. The mean inter-examiner agreement between the chief investigator and the local dental radiologist regarding the assessment of the radiographs was Kappa 0.88 (n=50) and the intra-examiner value of kappa 1.00 (re-examination of 10% of the cases).

Statistical analysis: SPSS version 14.0 computer programme was used to analyze the data and the survival rate of the restorations was related to the cavity sizes, the dental arch where the restoration was placed, the radiographic findings, the operator experience and the material used. Descriptive statistics, Kaplan-Meier survival, Cox Proportional Hazard model and multiple-logistic regression tests were used to test the results with the probability of less than 0.05 considered statistically significant.

Results

Survival of restorations and clinical findings: Out of the 804 cavities restored, 794 (98.8%) could be evaluated in this study at the beginning because of the presence of all the relevant data. Of these restorations, 54.6% and 45.4% were disto-occlusal and mesio-occlusal type and 69.7% and 30.3% were in the mandible and maxilla respectively. Most of the cavities had sizes of 2.1 to 3 millimetres in disto-mesial (67.6%) and bucco-lingual direction (45.3%), and of 3.1 to 4 millimetres for the depth (48.1% (see Table 4.3).

Table: 4.3: Cavity-size and their volume groupings.

Total	794	794	794	794
Cavity-sizes	Disto-mesial (millimetres)	Bucco-lingual (millimetres)	Depth (millimetres)	Cavity/restoration volume (mm ³)
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

Since the cavity prepared/restoration placed did not have a definite geometrical shape, calculation of its volume presented a problem. A relative-volume rather than an absolute-volume was made using the product of disto-mesial, bucco-lingual and depth lengths. The results were categorized as shown in Table 4.4. The table also shows the restorative material that was used and the cumulative survival after 2 years of the restorations placed in the cavities. The mean volume of the all the restorations that were placed during the operative stage was 20.4 mm³ (SD = 14.8), and most cavity/restoration volumes belonged to category 2 with the lowest volumes being in category 4. After 2 years, most of the surviving restorations were in category 2 and the least in category 5 (Table 4.4).

Table 4.4: The restoration-volumes and their two-year cumulative survival in relation to the GIC materials used.

Cavity volumes and number of restorations evaluated at two years		Number of restorations per each volume group and the material used (in bracket as % of the group at two years)			Cumulative survival at 2 years (in bracket as % for each group)
Volume category	Number of cavities/ restorations & their valid %	Fuji IX	Ketac Molar Easymix	Ketac Molar Aplicap	
1 (0- 0.9 mm ³)	125 (19.3)	12 (9.6)	9 (7.2)	7 (5.6)	28 (22.4%)
2 (10 – 19.9 mm ³)	319 (49.2)	46 (14.4)	42 (13.2)	35 (11.0)	123 (38.6 %)
3 (20 – 29.9 mm ³)	121 (18.7)	14(11.6)	11 (9.1)	8 (6.6)	33 (27.3%)
4 (30 – 39.9 mm ³)	49 (7.6)	4 (8.2)	4 (8.2)	3 (6.1)	11 (22.4%)
5 (over 40 mm ³)	34 (5.2)	3 (8.8)	2 (5.9)	0 (0.0)	5 (14.7%)
Total	648 (100%)	79 (12.2%)	68 (10.5%)	53 (8.1%)	200 (30.8%)

Due to absenteeism and drop-out, only 648 restorations could be evaluated after two years, and 94.4% and 30.8% had respectively survived soon after placement and after two years (see Figure 4.2). Two teeth with pulpal involvement were referred for extraction during the period, after the child complained of pains.

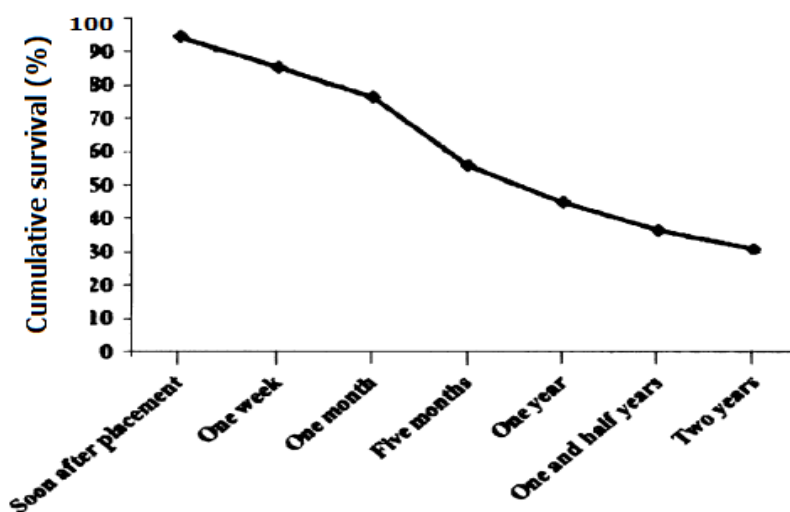


Figure 4.2: The percentage cumulative survival of the fillings.

There were no significant statistical differences in the survival rate of the restorations, after two years, when related to the dental arch (Cox Proportional Hazard model, Est. = 0.08, S.E. = 0.11, Chi-square = 0.55, $p = 0.46$) or the type of proximal cavity in which the restoration was placed (Chi-square = 9.87, 9 df, $p = 0.36$). However, when the survival rate of the restorations was related to the cavity size (volume), those restorations with volumes 10 to 19.9 mm³, had significantly higher survival rate when related to any of the other restoration volumes (Chi-square, $p < 0.05$). The smallest cavities with volumes 0 to 9.9 had equal survival rate as those of the restorations with volumes in category 30.0 to 39.9 mm³.

Survival of the restorations in relationship to the cavity size and the operator/assistant experiences: When the survival rate of the restorations was related to their sizes and the operator-experience, no significant statistical difference was detected in the survival rate of the restorations. However, those restorations made by 'experienced' operator with longer experience with the ART approach, had a higher survival rate than those by the 'inexperienced' operators (Log-rank Chi-square = 2.04, 1 df, $p = 0.15$). The 'experienced' assistants, and not the 'inexperienced' assistants paired with any operator were associated with higher survival rate of the restorations. The highest survival rate after two years for both operator-experiences was for volumes in category 2 and 3 (Table 4.4).

Survival of restorations in relationship to the radiographic findings of the cavities: Only 507 cavities (63.1%) with both pre-and post-restoration radiographs were of good quality for the study and analyzed as shown in Table 4.5.

Table 4.5: Pre-and post-operative radiographic-evaluation results of the cavities.

Pre-operative cavity evaluations			
Description	Number of cavities	Percentage of all cavities in the study	Valid percentage for those evaluated radiographically
Cavity within sound dentine	411	51.1	81.1
Cavity involving the pulp	26	3.2	5.1
Cavity close to the pulp	70	8.7	13.8
Total	507	63.1	100.0
Post-operative restoration evaluations			
Good restoration	348	43.3	68.7
Presence of residual caries	55	6.8	10.8
Presence of marginal gaps	65	8.1	12.8
Restoration involves dental pulp	32	4.0	6.3
Absence of restoration	7	0.9	1.4
Total	507	63.1	100.0

The pre-operative radiographic analysis of the 507 cavities showed 411 (81.1%) lesions had their pulpal-walls within sound dentine, 70 (13.9%) close to the pulp and 26 (5.1%) involving the pulp. After two years, those cavities with pulpal-walls entirely within sound dentine had significantly higher survival rate than those close to or involving the pulp (Chi-square = 27.60, 2 df, $p < 0.0001$). The post-restorative radiographic evaluations showed 68.6% of the restorations ended within sound dentine (pulpal-wise), 10.8% had

residual caries under them, 2.8% had marginal gaps, 6.3% involved the pulp and 1.4% had lost their restorations. Irrespective of the general decline in the restoration-survival rate, the restorations with marginal gaps had the lowest survival rate after two years, but the difference was not significant statistically (Chi-square = 0.39, 4 df, $p = 0.98$). In regard to the operator-experience and the post-restoration radiographic results, all the operators placed restorations that had higher survival results when the cavity/restoration's pulpal wall ended entirely within the dentine and lower when the cavity/restoration involved the pulp. The differences were not statistically significant (Chi-square = 5.01, 9 df, $p = 0.83$).

Survival of restorations in relationship to the cavity-size and GIC used: When the two-year cumulative survival of the restorations was related to the cavity-size and the materials used, Fuji IX GIC had the highest number of surviving restorations for cavities in category 2 followed by category 3 followed by KMA for cavities in category 2 followed by category 3 and KME had the lowest with cavities in category 2 followed by category 3 (Table 4.4). While there were no significant statistical difference in the survival rate of the restorations when related to the type of GIC material and the cavity-volume (Chi-square, $p=0.41$), there were however significant statistical difference in the restoration survival rates when restorations for all materials in category 2 were related to those in categories 1, 4 and 5 (Chi-square, $p < 0.05$).

Survival of restorations in relationship to the cavity-size and tooth-isolation method used: In general, irrespective of the size of the cavity restored, the survival rate of the restorations was significantly higher when rubber dam isolation method was applied (Chi-square, $p < 0.05$). This high survival rate of the restorations in relation to the use of rubber dam was maintained for all the GIC material brands used and for all operator/assistant experience.

A multiple regression model analysis was used to test for the effects on the survival rate of the restorations of the various risk factors that were considered in the study. These factors included the cavity chosen, the operator/assistant, the method of tooth-isolation and the GIC materials used. There was a significant intercept of the survival rate of the restorations with these factors (Est. -1.05, SE 0.29, 1df, Chi-square 13.09, $p = 0.0003$), with the cavity-size having a significant influence on the survival rate of the restorations (Est. 0.02, SE 0.01, 1df, Chi-square 7.70, $p = 0.006$). The other factors that had also significant influence were the operator/assistant experience and the tooth-isolation method ($p < 0.05$).

Discussion

In the present study, the examiner selected the proximal cavities for ART approach, primarily on the basis of a visual examination. A simplified method using a Michigan O with William's markings periodontal probe was used to measure the cavity-sizes and to clinically evaluate the restorations using the criteria for evaluating ART restorations. The evaluation of the bitewing radiographs taken was also done to determine the different choices of cavities restored by the operator. Unfortunately, the available radiographs were fewer than expected. The discrepancy arose from some children not showing up for the post-operative radiographs, lack of electricity in some schools, malfunction of the X-ray machine or unsatisfactory radiographs after processing, thus excluding all these.

The experience of the operator and the GIC materials used in the present study did not have any statistical significance on the survival rate of these restorations after two years. The two-year cumulative survival rate of the restorations from the clinical assessment, of 30.8% was slightly higher than the 30% obtained by Roeleveld using Fuji IX (18) and lower than the 83.1% obtained by Nazan, using Fuji IX (19) for comparable period of time. However, the two other cases did not have cavity sizes as part of the study (20). In the present study, cavities with mean sizes of between 2 to 3 mm (restoration volumes of 10 – 19.9 mm³) had the highest survival rate. Further, the radiographs that were evaluated seem to suggest that the restorations would be those that had their pulpal walls detected radiographically to end entirely within sound dentine. The smallest restorations did not have the highest survival rate, as has previously been reported. Probably, factors as inadequate visibility, removal of caries and deficiencies in material application could have contributed to the poor survival results (15, 20). The largest restorations had poor survival rates possibly arising from bulk failure or pulpal effect. Consequently, very small and too large cavities appear to be inappropriate for this technique.

Unfortunately, the radiographic results were fewer than anticipated and their results should be treated with caution. Nonetheless, the 507 radiographic evaluations in the present study were based on cavities/restorations for which both radiographs were of good quality for evaluation. Primary molars have thin enamel and dentine layers, making them more susceptible to pulpal exposure during instrumentation. This could explain why there were higher pulpal involvements seen in the post-operative radiographic evaluation compared to the pre-operative radiographic results. The survival rate of the restorations with residual caries underneath them marginally declined over the two-year period, suggesting that the operator probably achieved a good cavo-material seal. Nonetheless, restorations that had marginal gaps showed significantly poor survival rate, so were the small cavities, deep carious lesions and the very large cavities.

Just like the results of some previous researches, after Two years the restorations made by 'experienced' operators had higher survival rate than those made by the 'inexperienced' operators (15). Both the 'experienced' and 'inexperienced' operators had higher survival rate for restorations with volumes 10 mm³ to 10.9 mm³, with the poorest survival rate for cavities/restorations involving the pulp.

The three GIC materials used in the present study had restorations with optimum survival in cavities of volume 10-19.9 mm³ and generally decreased with increasing size. In general, there were no significant statistical differences with the survival rate of the restorations when related to the material used. KME had the poorest survival for cavities over 40mm³ when compared to the other two GIC's. Nonetheless, in all cases evaluated, the use of rubber dam isolation method provided a higher survival rate of the proximal restorations for all materials and for all operators and assistants.

Conclusions

The general survival rate of the proximal ART restorations in the present study was low, but in relation to the cavity-size, medium-sized proximal cavities had the best chance of survival for these restorations.

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