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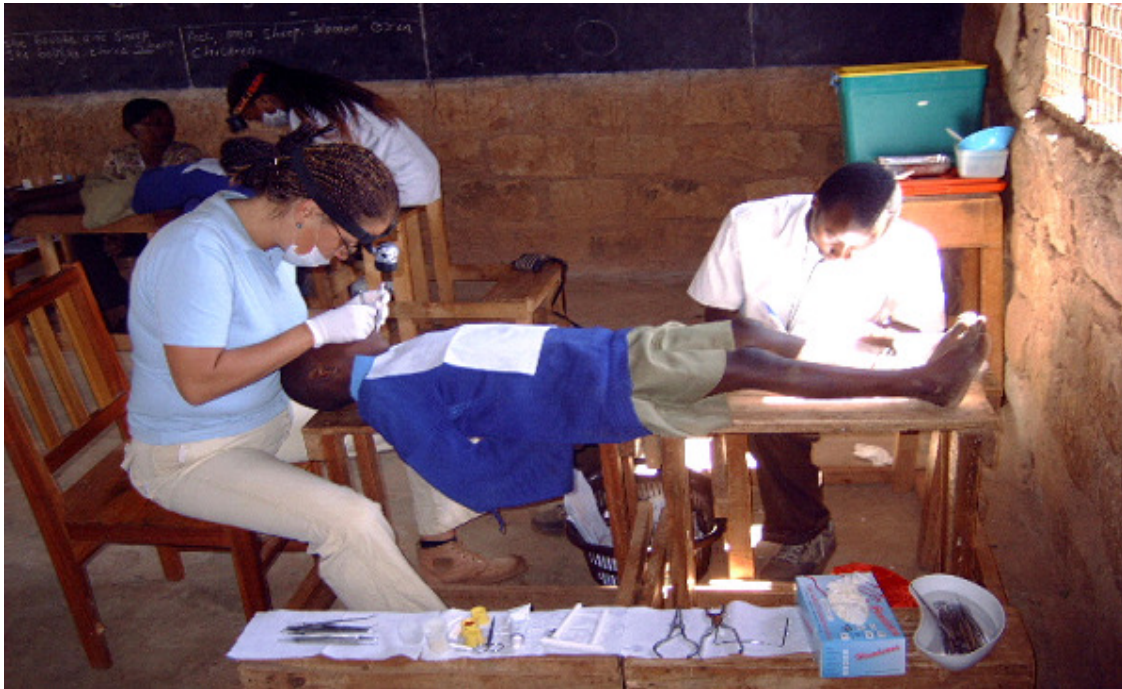
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Chapter 6



Influence of the experience of operator and assistant on the survival rate of proximal ART restorations – two-year results

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Abstract

Aim: The objective of the study was to determine the influence of the experience of the operator and the assistant on the survival rate of proximal ART-restorations after 2 years when placed using two methods of tooth-isolation and three glass ionomer cement-brands.

Study design: A clinical intervention study.

Methods: Each of the 804 children aged 6 to 8 years received one proximal restoration in their primary molars. The restorations were placed by 'experienced/inexperienced' operators randomly paired with 'experienced/inexperienced' assistants. They used atraumatic restorative treatment (ART) approach, 3 brands of glass ionomer cements (GIC) and 2 tooth-isolation methods (rubber dam and cotton rolls) to restore the cavities. Trained and calibrated evaluators evaluated the restorations, soon after placement and after two years.

Statistics: The data collected were analyzed using SPSS 14.0, to determine and relate the survival rate of the restorations to the operator and assistant with respect to the other factors such as the restorative material used and the isolation method applied.

Results: After 2 years, the survival rate of the restorations was 30.8%. In general, there were no statistical significant differences in the survival rate of the restorations made by the 'experienced' vs 'inexperienced' operators, but individually, the operator with more experience was associated with significantly higher survival rate of the restorations. The 'experienced' assistants were associated with significantly higher survival rates of the restorations. The most 'experienced' operator paired with any 'experienced' assistant and using rubber dam tooth-isolation method, was associated with a significantly higher survival rate of the restorations.

Conclusions: The combination of the 'experienced' operator and assistant using rubber dam tooth-isolation method had the best chance of survival for proximal ART restorations, irrespective of the material-brand used.

Introduction

Correct diagnosis and use of appropriate management techniques, can lead to improvement in the prevention and treatment of dental caries [Smales *et al*, 1991]. One of the techniques used in the management of dental caries is the atraumatic restorative treatment (ART) approach. It was developed in the early 1980's for use in communities without access to sophisticated dental health care, but has since expanded to include cases where the use of traditional restorative methods is impossible to apply, for patients suffering from dental anxiety and those with special health care needs. The ART technique employs hand instruments in dental-cavity preparation and an adhesive restorative material such as glass ionomer cement. As glass ionomer cement (GIC) has low tensile and compressive strength, careful selection of the cavities to be restored is important, and possibly small to medium-sized cavities may be appropriate for use with the technique in order to avoid early loss of the restoration. The use of hand instruments in the preparation of the dental cavity can lead to hand-fatigue, insufficient caries removal [Frencken *et al*, 1996(a)] and consequently a restoration with shorter survival expectation. Additionally, incorrect matrix band application (class II cavities), poor cavity-conditioning, poor manipulation of the restorative material and insufficient cavo-material adaptation can also lead to poor survival results of the ART restoration [Mjör and Gordan, 1999, Abramowitz, 1966]. All these are operator/assistant-dependent factors.

Dentists, dental students and ancillary dental personnel (dental therapists and community oral health workers) with reasonable clinical background knowledge are often used as operators for the ART approach. They form a group of dental personnel that has received a certain amount of training in the management of dental diseases and can be able to undertake a number of dental operative interventions dependent on the training skills given. It is possible for each of these operators to make good ART restorations after receiving the appropriate training.

Previous studies have reported good survival rates of single-surface ART restorations made by experienced operators [Frencken *et al*, 2004, Rahimtoola and van Amerongen, 2002, Taifour *et al*, 2003, Yu *et al*, 2004]. The few results reported on the survival rates of multi-surface ART restorations have been unsatisfactorily low [Yu *et al*, 2004, Lo *et al*, 2007, van den Dungen *et al*, 2004, van Gemert-Schriks *et al*, 2007, van der Hoef and van Amerongen, 2007]. Failures of ART restorations have been associated with the inexperience of the operator, incomplete removal of the dental caries, inadequate isolation of the cavity to be restored and other patient-dependent factors [Yu *et al*, 2004]. If the restorative material mixture is poorly done, there are deficiencies in the proportionation of the material or long material-handling time can negatively affect the integrity of the restorations. The physico-chemical properties of GIC are dependent on the manufacturer's brand and their variations can also lead to variations in the integrity of the restorations [Nomoto R, McCabe JF]. Whether these factors have any effects on the survival rates of the multi-surface ART restorations, particularly, in regard to the influence of the experiences of the operator or the assistant is still unclear.

The aim of the present 2-year longitudinal study was to determine what influence the experience of the operator and the assistant have on the quality and longevity of proximal restorations made in primary molars using the ART approach, 3 GIC brands and 2 methods of tooth-isolation.

Materials and Methods

Subjects: The present study formed part of a two-year clinical trial to investigate the survival rate of proximal ART restorations in the primary molars. It was carried out in Matungulu and Kangundo rural divisions, Machakos district, Kenya. To be included in the study, each child had to be healthy, aged 6 to 8 years, cooperative with at least one ART conservable proximal carious lesion in a primary molar with no signs or symptoms of pain or mobility. The cavity-entrance was approximately 0.5 to 1.00 mm in the bucco-lingual direction, so as to allow for the entry of the smallest size of excavator. 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. A total of 1,560 cavities in a similar number of children from the 30 public schools in the study area met the cavity-selection criteria.

After receiving a written explanation about the study, each child's parent/guardian voluntarily gave a written consent for the child's participation. The children had the restorations placed in their primary molars within 2 months of their selection.

Clinical procedure: Using random numbers, each child was allocated to an operator, assistant, a glass ionomer material and an isolation method. Natural light augmented by a battery-powered headlamp illuminated the oral cavity. Three 'experienced' and four 'inexperienced' operators randomly paired daily with four 'experienced' and four 'inexperienced' assistants made the restorations. The 'experienced' operators were two Kenyan dentists and one Community Oral health worker (COHO), and the 'inexperienced' operators were all final-year Dutch dental students. Prior to the commencement of the study, one 'experienced' operator (COHO) had dropped out of the study due to personal reasons. The 'experienced' assistants were composed of one COHO and three dental assistants, while the four 'inexperienced' assistants were all dental assistants. The 7 operators who remained, were daily paired with the eight assistants in such a manner that one assistant rested on each given day.

Training and experience: The operators and the assistants underwent a one-week WHO approved ART theory and practical training, in their respective roles as operators or assistants, based on the five-module training programme by Frencken *et al* [Frencken *et al*, 1999]. After the training and within 3 months, the operators and the assistants undertook further varied but supervised and documented clinical sessions in clinics and in the field to improve on their experiences with the ART approach. Prior to the commencement of the study, operators/assistants who, after training, had made/assisted in making a minimum of 50 ART restorations, with at least 25 of them being proximal restorations (operators only), were classified as 'experienced'. Similarly, 'inexperienced' operators/assistants had each made or assisted in making any 5 to 10 ART restorations after the training. Among the 'experienced' operators, one operator (COHO) had previously placed over 100 ART restorations (not as part of the present study). All the other two 'experienced' operators had done less than 60 ART restorations. The 'experienced' assistants had been working as general dental assistants for 4 or more years, while the 'inexperienced' assistants had just completed their training as dental assistants. The assistants were in charge of the proportionation (hand-mixed material), the mixing and handing over to the operator of the materials, and the documentation of the mixing and restoration times. All the operators and the assistants were pre-tested in their respective roles in the ART approach prior to the commencement of the study.

Choice of the teeth for ART: This depended on the presence of an appropriate proximal carious lesion restorable using the ART approach. The operator restored the tooth without discrimination as to whether it was a first or second primary molar, from the upper or lower dental arch or from the right or left side of the arch.

Restorative materials: Fuji IX (GC Europe), Ketac Molar Easymix (KME) and Ketac Molar Aplicap (KMA) (3M ESPE AG products) GIC materials were randomly used to restore the cavities and seal the adjacent fissures.

Cavity preparation and ART placement: Each operator used a hatchet to widen the cavity access and remove enamel overhangs, and the spoon excavator to remove the soft dentine aided by a caries detector-dye (private label based on acid red, by ACTA, the Netherlands). Wet and dry cotton pellets were used to rinse and dry the cavities. A matrix band (Union Broach Moyco) was applied to the prepared tooth and retained interdentally with a wooden wedge (Sycomore Interdental wedges No. 823, Hawe Neos Dental, Switzerland). Deep cavities had a thin layer of calcium hydroxide (Caulk, Dycal) applied as a base to protect the pulp prior to restoring them. The surfaces were first pre-treated for fifteen seconds using the diluted part of the liquid material for Fuji IX and the manufacturer's conditioner for the two brands of Ketac Molar cements. The assistant mixed Fuji IX and KME manually and KMA mechanically for 10 seconds (Duomat 2 amalgamator, Germany), in accordance with the manufacturer's instructions. The assistants also recorded the time taken to hand-mix the material. Petroleum jelly was applied over the finished restoration to protect it from contamination during the setting period.

Evaluations: The 4 final-year undergraduate Dutch dental students and 2 post-graduate paediatric dentistry Dutch students respectively evaluated the restorations, soon after placement (within 2 hours) and after two years. They had previously been trained and calibrated in the technique. They used the clinical evaluation criteria for the ART restorations as given below to evaluate the restorations. The restorations categorized as 0, 1, 6 had survived, 2, 3, 7, 9 had failed and 4, 5, 8 were censored.

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

Reproducibility: Cohen's Kappa Coefficient ([Cohen, 1960] was used to determine the repeatability of the evaluators. Initially, the chief investigator and an experienced dentist established a 'gold' standard by examining several ART restorations (Kappa 0.92, n=20). The chief investigator then trained and calibrated all the evaluators on a weekly basis during the evaluation period.

Statistical analysis: The data collected were entered into the computer and analyzed using SPSS version 14.0 programme (SPSS Inc, Chicago, USA). Using descriptive statistics, the survival rate of the restorations were related to the operator/assistant experience, and with relation to the method of tooth-isolation, the material used and the position of the restored tooth in the arch. The results were tested using Pearson Chi-square, Kaplan-Meier survival (KM), Log-rank, Cox Proportional Hazard (Cox PH) and multiple logistic tests with significance pegged at 95% confidence level.

Results

Subjects: Out of the original number of children selected, 280 had no parental consent, 25 children were anxious, 99 cavities experienced pulpal exposure during the operative stage and 365 cavities were inappropriate for the study or the children had transferred from the area before the operative stage of the study. After excluding these children, only 804 proximal cavities in a similar number of children were restored at site during the month of May, 2006. The mean baseline age of the children was 7.4 (SD±0.9) years, the male/female ratio was 1.3:1, and the mean DMFT/dmft was 0.2 (SD±0.5) and 4.0 (SD±2.4) respectively.

At the end of two years, out of the initial 804 children in the study, only 648 children were still available for evaluation, 5.3% (n = 43) of the children had dropped-out, 15.5% (n = 44) were absent and 8.6% (n = 69) had transferred to schools outside the study area. Of the 648 restorations evaluated, 13.4% (n = 87) had developed secondary caries and 45.3% (n = 294) had exfoliated.

Restorations placed: In total 244 (30.4 %) and 560 (69.6%) restorations were placed respectively in the maxillary and mandibular arches, out of which 439 (54.6%) were disto-occlusal and 365 (45.4%) mesio-occlusal restorations. There was an almost equal distribution of the restorations between the 'experienced' and 'inexperienced' operators and assistants. A total of 404 (50.2%) and 397 (49.4%) restorations were placed.

Reproducibility of assessment: The chief investigator recorded a mean Kappa of 0.84, n=63 with the first group and Kappa 0.86, n= 52 with the second group. The mean inter-evaluator consistency with each group was Kappa 0.82 (n=48) for the first group and 0.92 (n=52) for the second group. The daily intra-examiner agreements on 10% of the restorations evaluated ranged from Kappa 0.80 to 1.0 for both groups.

Survival rate of the restorations: The cumulative survival rate of the restorations dropped from 94.4% soon after placement to 30.8% after 2 years. At the initial evaluation moment, 38 (4.7%) children missed the evaluation due to truancy. There were no significant differences in the survival rates of the restorations in relation to the operator and the method of tooth-isolation, the type of restorations placed, the teeth in which they were placed and the position of the teeth in the jaw (Cox PH model, p > 0.05).

Survival rate of the restorations and the operator experience: After 2 years, there were differences in the survival rate of the restorations amongst the operators (Log-rank, Chi-square 43.95, 6 df, p < 0.0001). However, there were generally no statistical significant differences between the 'inexperienced' operators and the 'experienced' operators (Log-rank, Chi-square 92.04, 1 df, p = 0.15), although the 'inexperienced' operator-group had an overall higher survival rate than the 'experienced' operator-group

(Figure 6.1 for the Kaplan-Meier survival plot). One 'experienced' operator (COHO) was associated with a significantly higher two-year survival rate of the restorations than the other two 'experienced' operators (Chi-square, $p < 0.05$). There were statistical significant differences amongst the survival rates of the restorations placed by the 'experienced' operator (COHO) with the highest survival rate and those placed by all the other operators (Chi-square, $p < 0.05$). Between this 'experienced' operator (the COHO) and the 'inexperienced' operator (one of the Dutch dental students) with the best survival results of the restorations, the two-year survival rate of the restorations they placed showed statistical significant differences, in favour of the COHO (Kaplan-Meier, Chi-square 35.26, 1 df, $p = 0.002$).

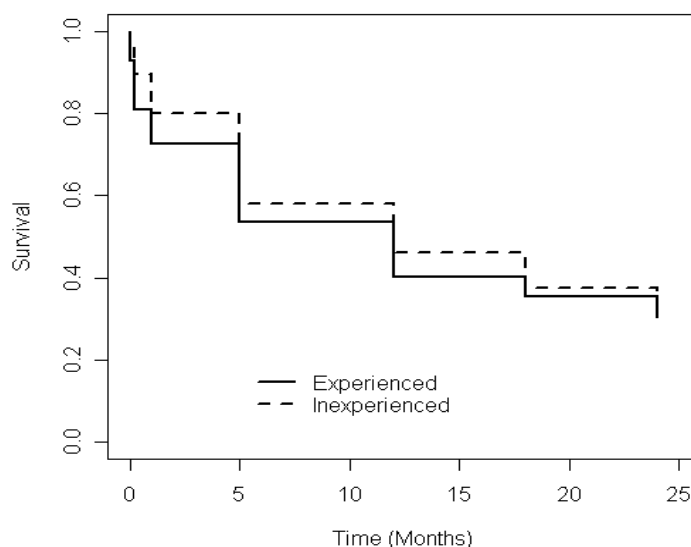


Figure 6.1: Kaplan-Meier survival probabilities of the proximal ART restorations in relation to an operator's experience.

During the three-week operative stage of the study, 34.3% ($n = 276$), (37.2% ($n = 276$) and 28.5% ($n = 229$) of the restorations were placed by the operators in the first, second and third week respectively. When the survival rates of the restorations were related to the operative week, the highest survival rates were observed during the third operative week (Figure 6.2 for Kaplan-Meier survival plot). The difference in the survival rates of the restorations after two years as related to the first and third operative weeks was statistically significant (Cox PH, Est 0.44, SE 0.12, Chi-square 13.05, $p = 0.0003$). The difference amongst the survival rates of the restorations placed by the operators was observed to be least during the third operative-week.

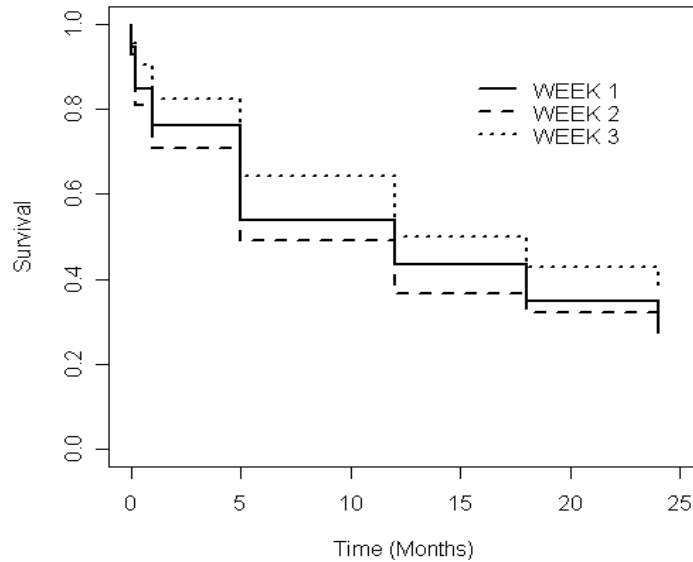


Figure 6.2: Kaplan-Meier survival plots for proximal ART restorations in relation to the operative week of placing the restorations.

The 'experienced' assistants were associated with a significantly higher survival rate of the restorations when related to the 'inexperienced' assistants (Log-rank, Chi-square 12.41, 1 df, $p = 0.0004$) as shown in Figure 6.3. The risk in the survival rate of the restorations as related to the assistant experience was lowest for the restorations made in the third operative week as compared to the first operative week (Cox PH, Est 0.48, SE 0.12, Chi-square, 16.03, $p < 0.0001$). When the survival rate of the restorations were related to the 'experienced' assistants and the operative-weeks, there were almost no changes between the restorations placed during the first week and those placed in the third week. On the contrary, the 'inexperienced' assistants showed significant statistical difference for the restorations placed with their assistance during the first operative week when compared to those placed during the third operative week (Cox ph, est 0.31 se 0.13, chi-square 5.88, $p = 0.02$). The difference in the survival rate of the restorations in relation to the assistant experience were minimal during the third operative week.

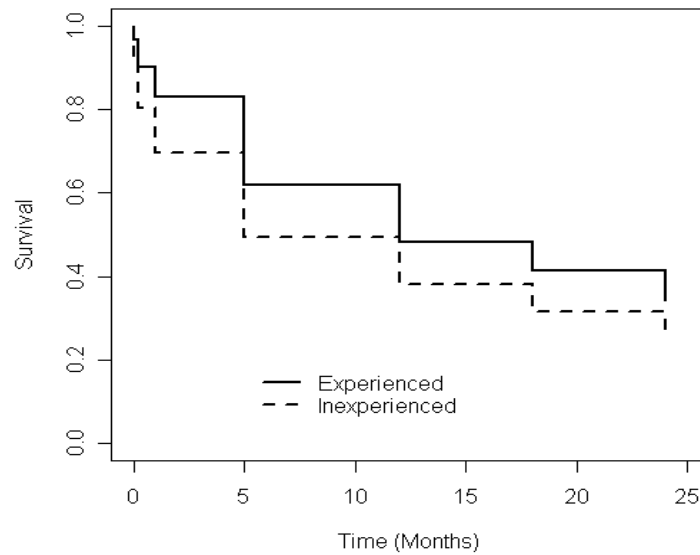


Figure 6.3: Survival probabilities of ART proximal restorations in relation to the assistant-experience.

Survival of the restorations versus material usage: The mixing times of the materials by the assistants were categorized as: 1=0- 29s, 2=30-59s and 3= 60s and over. The majority of the mixing times were in category 1 and 2, and only negligible numbers were in category 3. The mixing times were then related to the survival rate of the restorations and the assistant-experience. The survival rates were higher during the third week and also the mixing time was more or less similar amongst the assistants during the third week. There were no statistical significant difference between the survival rate of the restorations when related to the mixing times (Cox PH model, Est = - 0.112, SE= 0.607, Ch-square= 0.034, p= 0.853). With the passage of time, the mixing times for the 'inexperienced' assistants improved for most of them to fall back into category 1.

Survival of the restorations and the operator/assistant combinations: After the two-year evaluation moment, the interaction between the operator and assistant experiences was statistically significant as related to the survival rate of the restorations they placed (Log-rank Chi-square test, Chi-square 15.82, 3 df, p= 0.001) . There were also statistical significant differences in the survival rate of the restorations as the operator interacted with the 'experienced' assistants, particularly in relation to the mixing times of lower than 30 seconds (Cox PH, p= 0.02, the third operative week (Cox PH, p= 0.002) and the rubber dam isolation method (Cox PH, p= 0.01). The 'experienced' operators paired with the 'experienced' assistants were associated with significantly higher survival rates of the restorations when related to any other combinations, while the poorest results were for the 'inexperienced' operator-assistant combinations. A multiple logistic model to establish the best model of dichotomized survival rate of the restorations was done. The factors considered were the type of cavity, the position of the restored teeth in the dental arch, the method of tooth-isolation, the material used and the experience of the operator and the assistant. The results showed a significant intercept amongst these factors (Est - 1.05, 1 df, SE 0.29, Chi-square 13.09, p = 0.0003). The significant factors that gave the best model for predicting the survival rate

of the restorations were the isolation method (rubber dam being better) (Est -0.17, 1 df, SE 0.08, Chi-square 3.87, $p = 0.04$), the operative week (Est 0.24, 1 df, SE 0.11, Chi-square 4.94, $p = 0.26$), the assistant experience (Est 0.20, 1 df, SE 0.09, Chi-square 5.69, $p = 0.02$).

Discussions

The clinical evaluations of the restorations were done using the ART evaluation criteria [Frencken *et al*, 2001, Lo and Holmgren, 2001]. These criteria have previously been applied and the results found plausible when compared to the USPHS criteria [Ryge and Snyder, 1973]. The cumulative survival rate of the restorations after two years was 30.8%. The initial failure of 5.6% of the restorations could have resulted from insufficient caries removal, poor moisture control, cavity conditioning, material manipulation [Frencken and Holmgren, 1999] or patient related factors [van Amerongen, 1996 Fritz *et al*, 1998].

'Experienced' and 'inexperienced' operators and assistants were used to restore proximal cavities in primary molars. The level of experience was arbitrarily determined on the basis of the number of restorations that each operator and assistant had been involved in making. Operator-effect on the survival rate of ART restorations has previously been reported, with the experienced operators associated with higher survival results [Frencken *et al*, 2004, Rahimtoola and van Amerongen, 2002, Taifour *et al*, 2003, van den Dungen *et al*, 2004]. In the present study, the operator with the most 'experience' (the COHO) had significantly higher survival rate of the restorations (Chi-square, $p < 0.05$) [Abramowitz, 1966, Lopez *et al*, 2005]. It was possible that the arbitrary categorization of the operator-experiences might have set the level of 'experience' much lower than the actual threshold required. Probably that could explain why the survival rates of the restorations made by the two 'experienced' operators were closely matching those by the 'inexperienced' operators, a situation that tended to depress the combined 'experienced' operator-group' effects on the survival rate of the restorations. The fact that the most 'experienced' operator (COHO) had restorations with a higher survival rate than all the other operators could be a pointer to the importance of the experience [Frencken *et al*, 1996(b), Frencken, 1999, Fritz *et al*, 1998, Mickenautsch *et al*, 2003, Mjör *et al*]. There are other studies that have reported to the contrary on the relationship of the operator experience when using this technique [Hawthorne and Smales, 1997].

As the difference between the survival rates of the restorations in relation to the operators and assistants were least for the restorations made in the third operative-week, this strongly indicates the probable gain in experience for those operators and assistants with least experience at the beginning of the operative-stage. [Frencken *et al*, 1996(b), Frencken and Holmgren, 1999, Mickenautsch and Grossman, 2006, Mickenautsch and Rudolph, 2002)].

The mixing of the material, being a preserve for the assistants, was used to determine the assistants' skills of performance. Quality mixture of the restorative material, an assistant-dependent factor, enhances the survival rate of the restorations [Frencken *et al*, 1996(b)]. The 'experienced' assistants were generally associated with higher survival rate of the restorations after the two years. Probably, they were able to accurately proportionate and quickly manipulate the material [Frencken and Holmgren, 1999], while simultaneously helping the operator to allay any anxiety in the child [Frencken *et al*,

1996(a)]. By so doing, they probably helped the operator to concentrate on the critical areas of the restoration process.

The invariability of the mixing times of the 'experienced' assistants and the reduction of the mixing times for the 'inexperienced' assistants with time to mostly category 1 (for less than 30 seconds) during the second and third operative-week could be the result of gain in skills. As KMA glass ionomer was mechanically mixed, the assistant factor was confined to the time taken to deliver the material to the operator. It is probable that the 'experienced' assistants were able to do this with greater speed than the 'inexperienced' assistant.

In the present study, the highest survival rates for the restorations were obtained when the most 'experienced' operator (the COHO) was paired with any 'experienced' assistants. All the operators had higher survival rates of the restorations they placed while using rubber dam and when assisted by 'experienced' assistants. Further, the poorest survival results for the survival rate of the restorations were obtained with the combination of the 'inexperienced' operators and 'inexperienced' assistants. This therefore, suggests that the experience of the operator and that of the assistant were crucial factors in enhancing the survival rate of the restorations. The brand of GIC did not show any significant effect on the survival rate of the restorations in relation to the operator or assistant.

Conclusions

Although the proportion of satisfactory results for the survival rate of proximal ART restorations dropped over the 2 years, the combination of 'experienced' operators and assistants had the best chance of high survival rate of the proximal ART restorations.

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