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

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Chapter 11

General discussion, conclusions and recommendation for future research

Introduction

The present two-year prospective, longitudinal study was designed to determine factors influencing the survival rate of proximal atraumatic restorative treatment (ART) restorations in primary molars. The study population consisted of children from a low socio-economic background with high poverty levels, a high dmft and poor oral hygiene. The study area also lacked dental health facilities and therefore was basically suitable for the application of the ART. The results of this study have been compiled into eight main chapters, discussed as separate sub-studies of the main study. The last two of the eight chapters have been devoted to the effects of the proximal restorations and GIC sealants on the teeth restored. Chapters 1 and 2 have been added at the beginning, and give important information on the background of and the methodology used in the study. Set here below are important guidelines to the general discussions and interpretation of the overall results of the study and how the overall conclusions have been drawn. These general discussions have been subdivided into four sections to cover the 8 sub-studies, with each section consisting of two or more of the sub-studies, separately describing what was done in the sub-studies, the results that were obtained, the recent developments on the subjects and the conclusions drawn for each section. The four sections deal with the following in relation to the survival of proximal ART restorations:

1. cavity choices and their influence,
2. the influence of isolation methods, operator/assistant experience and the GIC material-brand,
3. the influence of the dental hygiene, residual caries and marginal cervical gaps,
4. and the effects of the restorations on the restored teeth.

1. Cavity choices and their influence on the restorations

The details for the selection of proximal cavities, their pre- and post-restorative radiographic evaluations are all contained in the sub-study described in chapter 3. There were challenges in this sub-study in obtaining a good estimate of the size of the cavity given the posterior position of the teeth and the possibility of poor visibility of the cavities. It is probable that if a properly designed and calibrated instrument was available, the accuracy of the measurements would improve. Limited facilities and resources made it difficult to accomplish this effectively and to also obtain the whole range of pre- and post-restoration radiographs, including other radiographs after two years. Availability of a fully-operational mobile dental office could have improved the situation in the field, and possibly the results of the sensitivity of cavity-selection would have been different.

The measurements of the prepared cavity were used to calculate the relative volumes of the cavities/restorations as detailed in chapter 4. Similar challenges as described in chapter 3 were also encountered in getting exact measurements of the cavities and therefore the volumes for these cavities, given their lack of definitive shapes. Besides, there were challenges in relation to the design of the study, where a split mouth study was not considered, as it was presumed that such arrangement would lead to a bias with respect to the examiner agreement during the evaluation of the restorations. The evaluator could have found it confusing by having to regard the restorations in one patient as independent units. Nonetheless, the results obtained in the sub-study should, therefore, be viewed in the light of such confounding factors.

Proximal ART restorations, not being completely surrounded by the hard tooth-tissues, are most vulnerable to failure. Cavities that are very large increase the chances of bulk

failure for the restorations placed in them (1). The very smallest restorations are associated with inadequacy in the excavation of dental caries in the enamel and dentinal surfaces, besides the irregularities created during caries excavation, material contamination due to the closeness of these cavity-bases to the gingival crevices (2) and the difficulties in the application of the restorative material to all the cavity walls (3, 4, 5, 6). All these factors can lead to early restoration failure. Although, only one technique of caries excavation was used in the present study, it is doubtful that any significant differences would have been observed if more techniques were employed. Recent studies have reported no significant differences in the survival rate of similar restorations as in the present study, when related to the technique used (7). In the sub-study described in chapter 4, probably arising from any of the reasons cited, the very large and the very small cavities exhibited poor survival rates of the proximal restorations placed in them.

In conclusion, the two sub-studies in this section indicate that the operator needs to take cognisant of the facts outline in the sub-studies, when considering restoring proximal cavities using the ART approach. A trained and skilful operator has the capability of selecting suitable cavities restorable using this approach, even when pre-operative radiographs are unavailable. Medium-sized cavities (after preparation) were more likely to hold restorations that had a higher survival rate than any other cavity-size. However, more research work involving more cavities, with both pre- and post-restorative radiographs is needed for more conclusive results.

2. Influence of isolation methods, Operator/assistant experience, and GIC material-brand on the restorations

In the sub-study in chapter 5, a description is given of the two tooth isolation-methods (rubber dam and cotton wool rolls) that were used in the study and their influence on the survival results of proximal ART restorations. The results of the sub-study showed a significant difference in the survival rate of the proximal restorations, with those restorations placed using rubber dam having higher survival rate.

Rubber dam tooth-isolation method might not be the most popular method for routine use with ART approach. Rubber dam is a rather expensive method for combination with the ART approach, that has been considered as a "low-tech low-cost" dental caries management technique. Furthermore, a controversy still exists as to which method between rubber dam and cotton rolls provides the best working environment. Whereas some studies have supported the use of rubber dam for tooth isolation to be best, others have not (8, 9). Other studies have reported lack of any difference between the two isolation methods (9). What is generally accepted is the fact that adequate tooth-isolation improves visibility of the cavity and lessens material contamination, offering an easier opportunity to the operator to adequately clean the dental cavity (6, 11).

Chapter 6 details the training and the criteria for the categorization of the operators and the assistants into 'experienced' and 'inexperienced'. The 'experience or inexperience' in the context of the present study related only to the experience with ART approach, as all operators and assistants had adequate clinical experience in their various roles in managing dental caries. Higher education was not a criterion for the categorization. The results of the sub-study showed the experience of the operator and the assistant was an important influencing-factor on the survival rate of the proximal ART restorations (12). One operator with the longest experience with the ART approach had placed restorations that had a significantly higher survival results than those placed by the other 6

operators. Perhaps the cut-off threshold for the operator's 'experience' in the sub-study was inadequate, given the closeness of the survival results for the 6 operators. Future studies should explore and redefine the requirements for an operator or assistant to be considered 'experienced'. Perhaps, longer periods and or more restorations could be required for an operator to be 'experienced'.

Past studies have reported the importance of training and self-diligence for the operator when higher survival rates for the ART restorations are to be attained (13, 14). On the contrary, the survival rate of the sealants adjacent to the restoration did not show any corresponding association with the operator's experience as demonstrated in this chapter, or the material and isolation method that were used. The use of rubber dam isolation method was associated with higher survival rate of the restorations, and so was the material mixing times that were closest to those recommended by the manufacturer. The importance of adequate mixing and handling of the restorative material by the assistants and operators are vital factors in enhancing the physical strength and retention strength of the restorations (chapter 6, 15).

In chapter 7, three high-viscosity GIC material-brands - Fuji IX, Ketac Molar Easymix (KME) and Ketac Molar Aplicap (KMA) - used in this study are discussed in relation to the mixing-times, room temperatures and tooth isolation-methods, the next meal taken by the child and the survival rate of the restorations. The results of the sub-study showed no significant differences in the survival rates of the restorations placed using KME, KMA and Fuji IX, but KME and Fuji IX had the lowest and highest survival rates for their respective restorations. The next meal taken that was of a 'hard' consistency had a significant negative effect on the survival rate of the restorations. The ambient temperature at the time of placing the restoration did not affect the survival rate of the restorations. However, more information relating to the next meal needs to be documented, as the limited documentation done in this sub-study might not be conclusive. More details of what was eaten over, for example, a period of a month or more would have been realistic, and probably could have given an idea on the type of diet of the children. Either the next meal taken was a representative of the daily food consumed by the child or it might have been a one-on meal that might not have been representative of the diet of the child. Also the use of the materials in a wider environment with wider variations in ambient temperatures could help improve on these results. Other factors as individual habits etc could also have compounded the results of the study. Future studies should probably take cognizant of such factors.

The GIC materials used in the study (16), owe their strength to the manufacturer's formula and other handling conditions. Unlike hand-mixed materials, mechanical mixing produces a good consistency mixture with predictable results (15, 17). Both hand- and mechanically-mixed materials were used in the present study. Some studies have reported lack of any significant differences in the survival rates of Ketac Molar Applicap and Fuji IX materials (18, 19, 20), as was in the case in the present study. Higher or lower temperatures, known to increase the speed of a reaction of the GIC, can bring about differences in the survival of the restorations placed in the teeth. Longer mixing and placement times leads to the material being placed in the cavity when the setting process is in its advanced stages, leading to reduced adaptation and bonding of the material to the cavity-wall (21). In the present study, there were daily variations in the ambient temperatures, and generally the materials that were mixed around the manufacturer's recommended temperatures had higher retention rates.

In conclusion, this section demonstrates that the experienced operators/assistants and the use of rubber dam tooth-isolation enhanced the survival rate of proximal ART in this study. The GIC material-brand did not have any effect, but the next meal of 'hard' consistency had a negative influence on the survival rate of these restorations.

3. Influence of oral hygiene, residual caries and marginal cervical gaps on the restorations

The sub-study described in chapter 8, the child's level of oral hygiene was measured using plaque index. The post restoration bite-wing radiographs taken in the study were assessed for the presence of residual caries and marginal cervical gaps. For the results of this sub-study, the survival rate of the restorations was significantly affected in the negative by the marginal gaps and not with oral hygiene and residual caries. The presence of marginal cervical gaps and a combination of the marginal cervical gaps and residual caries reduced the survival rate of proximal restorations.

In view of the oral hygiene education that was provided to the study population during the study period, the compliance with oral hygiene habits appear to have been very low before and during the study period. Probably, this was the result of the social problems in the face of dental diseases and lack of the needed facilities to manage the diseases. Plaque has been reported to be associated with dental caries (22), and if this happened in cases with restorations then it is likely to lead to failure of the restorations. Additionally, other studies have reported that poor oral hygiene does affect the survival of dental restorations (23). Future studies should explore the effects on the survival rate of these restorations of the children's and parent's attitude wards keeping a good oral hygiene. The residual caries factor remains a very sensitive issue. As to whether all the caries has to be removed from the dental cavity or not, remains a matter for scientific resolution. A study in Tanzania reported no influence of the residual caries or gaps on the survival rate of proximal ART restorations, but the two combined variables (residual caries and cervical gaps) having a considerable influence on the survival rate of proximal ART restorations (24), just as the results of the present study showed. Some studies have reported that residual caries can be inactivated with a restoration offering a hermetic cavo-material seal (25, 26). There is a need for further studies on residual caries and the age of the child receiving such restorations, although other previous studies have refuted the influence of this factor on the survival rate of these restorations. On the contrary, other studies have closely associated the presence of residual caries and gaps in relation to the restorations, to the operator experience (27). The present sub-study reported that children below 7 years of age had more residual caries than those above the age, but this was not clearly associated with the experience of the operator. Further studies could elicit the reasons for such discrepancy, and whether it could be related to the disruption by the child, its anxiety or even the anxiety of the operator. Nonetheless, while the improvement of oral hygiene could marginally enhance the survival rate of the proximal ART restorations, marginal cervical gaps should absolutely be avoided if the survival rate of these restorations is to improve.

4. Effects of the restorations on the restored teeth

The sub-study described in chapter 9, concerning the GIC sealants placed together with the proximal ART restorations, the results of the sub-study showed the cumulative survival of the sealants was 10.9%. Additionally, very few of the teeth that received the sealants had caries on the surface that had been sealed.

Routinely, a sealant is placed on the remaining pits and fissures of a tooth receiving a restoration when using the ART approach, basically as a caries preventive measure (28). Since few of the restored teeth in the present study had new caries on the sealed surface, it could be presumed that the sealant offered some protection from dental caries. However, this sub-study had its own setbacks. It would have been good to measure the surface area and describe the type and approximate depth of the pits and fisures present on the remaining surfaces of the restored teeth. The comparison of the sealants amongst the teeth sealed would have been better rather than the blanket method that was used in the sub-study. Nonetheless, this was not done due to the study design that had not included these aspects and the resources that would have been required to accomplish this. Previous studies on GIC sealants have reported their caries reduction effects on the teeth sealed (25, 29, 30, 31). Probably the same effects had taken place in the present study.

The sub-study described in chapter 10 had 128 participants who had lost their proximal ART restorations during the two years of follow-up. The hardness of the dentine of the cavities that had lost their restorations was scored on a 3 point scale: 1 = hard, 2 = medium, 3 = soft (32). A colour-match scale defining the dentine colours of cream-white, light brown, brown and dark brown was used to compare the dentine of the cavities and relate to the three-point scale. The results were that the presence of the restoration led to hypermineralization of the dentine below it, and the longer the retention of the restoration the higher the hypermineralization.

It is possible therefore, that the presence of GIC restoration enhanced hypermineralization of the dentinal surfaces of affected tooth, as was the case in the sub-study. Other studies have reported similar effect (33). This phenomenon provided protection against new or progressing carious processes (34). As proximal ART restorations appear to have a low survival rate, it is probably important to know what could be done after such a loss. The conclusions drawn from this sub-study were that there was reduced incidence of caries on the tooth surfaces that received sealants. Additionally, the summary of sub-study in chapter 9 was that in some cases where the restoration was prematurely lost, there is possibly no need to re-restore it due to hypermineralization that takes place. However, more studies are needed, preferably, comparative studies that can relate the filled and the unfilled, the sealed and unsealed teeth.

Overall results of the study

The two-year cumulative survival was 30.8% for the proximal restorations and 10.9% for the sealants adjacent to the restorations. The test-retest correlation coefficients in this study were generally higher than 0.80, indicating high reliability of the results obtained. Even with the variations in the follow-up period of study, the results of the study were almost similar to results from studies by Carvalho et al of 32% using rubber dam isolation method, but higher than the 18% in the same study using cotton rolls isolation method (35), and also higher than the 12.2% found by van Gemert-Schriks et al (36), yet it was lower than the 49% in another study by Zanata et al (37) and the 82% by Farag et al (36 (38). It was possible that the survival rate of these restorations could have been much higher through further moderation of the influencing factors as described in this study. Medium-sized proximal cavities/restorations, rubber dam tooth-isolation method, experienced operator and assistant and the next meal consumed by the

recipient have all got significant influence in achieving higher survival rate of the proximal ART restorations. Much more sub-studies would have been accomplished in this research work, if the expected higher participants did participate. However, due to the socio-economic factors and the limitation in resources, everything that needed to be done could not be done.

Conclusions

The objective of this thesis was to investigate possible correlations between the survival rate of proximal ART restorations in the primary molars and a number of possible factors influencing the survival of the proximal ART restorations. The null hypothesis was that there is no relationship between the survival rate of proximal ART restorations and the cavity-choice, the experience of the operator, the experience of the assistant, the method of tooth-isolation, the GIC brand used and its manipulation, the ambient temperature at the time of placing the restoration, the residual caries/restoration gaps, the next meal taken and the oral health status of the child. The results of this study have shown significant association with some of them and not others. Based on these outcomes, it can be concluded that the optimal conditions for proximal ART restorations with higher survival rate can be obtained under the following conditions:

1. through training of personnel and sustained improvement in their experience with the technique, improvement of their skills in making decisions on appropriate cavities to restore and re-restore, routine use of rubber dam tooth-isolation method and continuous provision of regular oral hygiene and diet counselling to the patients.
2. through continuous research on alternative modes of improving the survival and even other closely related cheaper alternative treatment modes that have better outcomes.

General comments

The use of the ART approach for the management of proximal carious lesions is still a possibility, and can play a major role in poor communities lacking essential dental facilities. The fact that the results of the present study were low, this does not imply that the technique need not be used in these indications. Since a number of these restorations had survived, the sealants could have offered protection to these vulnerable surfaces of the teeth. There was also the hypermineralization of dentinal surface of the cavities that had lost their restorations, unique characteristics relating to this treatment and which could have offered additional advantages to the use of this technique. These advantages could be utilized in a community lacking access to dental health care, given also the cost-effectiveness of the ART approach when compared to the conventional approach (39), 40). Further, some other studies have even reported good performance of these proximal GIC restorations even after 6 years of follow-up (41).

Direction for future research

The present study has demonstrated a strong link of this technique in managing dental caries, to the experience of the operator in making the correct clinical diagnosis of the carious process (selection of carious lesions), intervening earlier in the process (effects of the cavity size), the improvement in tooth-isolation method during the placement of the restorative material in the cavity, the handling conditions of the material and the dissemination of relevant dental health information relating to diet and oral hygiene of the target group. These factors are dependent on the acquisition by the dental operator of the relevant knowledge, practical skills and experience in the practice of ART approach as stated in chapter 6.

GIC materials will probably continue to yield the greatest challenges in future dental practice, particularly in their use in conjunction with multi-surface ART approach. Probably with continuous research efforts to overcome the challenges relating to the material strength and the handling conditions, ART will become more acceptable to the community of dental practitioners (42) and to the general public, who probably still view it as a low class treatment mode. Obviously solving the challenges will also depend on the close collaboration amongst the material developers, the technique and the dental personnel as the end-users. The dissemination of preventive oral health education to the general population and the children, with greater emphasis on regular oral health care as an important adjunct to this technique need not be over-emphasized to both the policy makers and the users of the technique.

Nonetheless, there is still a need for further research in the application of this technique, particularly with a focus on some of the aspects considered in this thesis that require further refinement in the methodology. Such studies should run for longer period of time and include the use of more GIC brands, operators and assistants with longer experience with the ART approach, further comparison of the tooth-isolation methods, and documentation of the diet of the participants over a relatively longer but specific time-span and the use of aggressive oral hygiene measures. It should also be possible to compare the results of such studies between permanent and primary dentition, and also compare the technique used in this study with other techniques like the Hall's technique which is similarly simple and affordable technique, that uses GIC and preformed metal crowns. The comparative study may be able to distinctly bring out any advantages or disadvantages for either technique in managing proximal carious lesions in the child-population.

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