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

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The dilemma of selecting suitable proximal carious lesions in primary molars for restoration using the atraumatic restorative treatment (ART) approach

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Abstract

**Objective:** To determine the examiner’s accuracy in selecting proximal carious lesions in primary molars for restoration using the atraumatic restorative treatment (ART) approach.

**Basic research design:** Intervention study.

**Clinical setting and participants:** A total of 804 six to eight year-olds from 30 rural schools in Kenya participated in the study.

**Intervention:** Three examiners selected a total of 1,560 suitable proximal carious lesions in the primary molars after examining 6,002 children from 30 schools randomly selected out of 142 schools in two divisions. Seven operators randomly paired on a daily basis to eight assistants restored the lesions. An explanation was provided for any cavity that was not restored. Pre-and post-operative radiographs of the cavities were also taken for evaluation.

**Main outcome measures:** The examiner’s choice of suitable proximal cavities restorable using the ART approach was related to the decision made to either restore or not to restore. The radiographic findings of the selected cavities were also compared to the decision made by the examiner. The results obtained were used to determine the examiner’s accuracy in selecting suitable proximal cavities for restoration using the ART approach.

**Results:** The majority of the subjects were excluded due to absenteeism, pulpal-exposure or anxiety during the operative stage. Only 804 children received one restoration in their primary molars. The examiner’s accuracy in selecting suitable ART-restorable cavities was 79.9% based on clinical parameters. The examiners’ judgment that the cavities had not progressed into the pulp was 94.9% based on preoperative radiographic analysis and based on postoperative radiographic analysis, 91.7% that the pulp would not be involved after treatment.

**Conclusions:** A trained and diligent examiner has a very good chance of selecting proximal carious lesions restorable using the ART approach, without the threat of dental pulpal-involvement during the excavation of caries.
Introduction
Atraumatic restorative treatment (ART) technique is one of the approaches used in the management of dental caries, particularly in susceptible poor communities with very low dental restoration rate [Frencken et al., 1994], in anxious and handicapped patients. The ART approach combines the use of hand instruments in dental cavity preparation and glass ionomer cement (GIC) as the restorative material [Mjör and Valeria, 1999; Pilot, 1999; Holmgren and Frencken, 1999]. Glass ionomer cement (GIC) is the preferred restorative material for use with the technique, as it is biologically compatible with the oral tissues, chemically bonds with the tooth tissues and leaches out fluoride that has cariostatic effect [McLean, 1974]. Unfortunately, GIC has low tensile and compressive strength that makes it inapplicable in very large cavities where masticatory forces are high [Frencken et al, 2004].

The enamel and dentine in the primary dentition is very thin. Proximal dentinal lesions in the primary molars present difficulties in accessibility and visibility when treating them using only hand instruments. In addition, there is a heightened likelihood of pulpal exposure due to the thin dentine and enamel layers. Coupled with these factors is the low compressive material-strength of GIC that is likely to result in early restoration failure, particularly for the large restorations. Consequently, the choice of proximal cavities for restoration using the ART approach has to be done carefully if the longevity of the restoration is to be enhanced. Unfortunately, there is little information available on the influence of the choice of cavities on frequency of pulpal-exposure and the survival rate of the restorations placed in them using the ART approach. The purpose of the present study was to determine the examiner's accuracy of choosing suitable proximal cavities in the primary molars restorable using the ART approach.

Methods
This study formed part of a larger two-year prospective study on the survival rate of proximal ART restorations in school-children in Matungulu and Kangundo divisions in Kenya. A total of 142 public primary schools from the two divisions, with a total of 22,105 eligible children were targeted. Using random numbers, provided the school had a minimum of 50 eligible children, 30 schools with 6,002 eligible children were selected and examined for suitable proximal cavities restorable using the ART approach. Two final-year dental students and one paediatric dental specialist examined the children for the suitable proximal cavities. Only children, aged 6 to 8 years, in good general health, resident of the area of study for the past one year, having at least one proximal carious lesion in the primary molar, with a bucco-lingual opening of approximately 0.5 mm to 1.0 mm and who assented to the examination were recruited in the main study. The size of the cavity-opening was considered so as to allow for the entry of the dental hatchet tip and or the smallest excavator required to excavate dental caries. The tooth selected was without signs or symptoms of pain or mobility, and when more than one cavity existed in any of the subjects then only the one considered to be the smallest was selected for the study.

To obtain the required number of appropriate proximal dental lesions, a large number of children needed to be examined. Considering that a short interval between the selection of the teeth and their restoration was needed, a decision was made to have one group to select the teeth and another to restore them. One tooth per child was also preferred so as to minimize patient-related factors as the side commonly used in chewing etc. All the
examiners and operators had been trained and pre-tested in the process of tooth-selection and restoration of the dental cavities using the ART approach. They were also calibrated by the chief investigator regarding the selection of the cavities and also carried out inter-examiner reliability (mean Kappa coefficient range of 0.80 to 0.92, n=20 to 30) and intra-examiner reliability (mean Kappa 0.78 to 0.86 on re-examination of 10% of the cavities). The parent or guardian gave a written consent for the child’s participation in the study. Approval to conduct the research was sought and obtained from the University of Nairobi and the Kenyatta National Hospital Research and Ethical Committees.

Initially, 1,560 children were selected based on the presence of the appropriate proximal cavity, out of which 1,280 (82.05%) children fulfilled all the criteria for the selection. The remaining 280 (17.9%) children were disqualified for lack of informed consent from their parents, allowing them to participate in the study. As there were many possible factors for investigation in the study, a higher figure of 1,200 subjects as the study population was agreed upon in order to improve on the statistical power of the study. This figure was higher than the pre-study sample calculation of 382. All the children in the study were from a low socioeconomic background with limited access to dental health services. The male to female ratio was 1.3:1, a mean age of 7.4 (SD 0.95) years, a mean baseline dmft of 3.96 (SD 2.38), and a DMFT of 0.15 (SD 0.52). The missing teeth component of the DMFT/dmft included only teeth expected to be in the oral cavity but missing with a history of caries or trauma. Those deciduous teeth with an oral history of natural exfoliation (age-appropriate) were excluded.

Within two months following the selection process, seven operators, who had not participated in the initial selection process, restored the selected carious lesions at each child’s school. The operators who consisted of 2 dentists, 4 final-year dental students and one community oral health officer (COHO), were randomly paired on a daily basis with 8 dental assistants (one COHO and 7 dental assistants). One assistant rested on each operative day. The operators and the assistants had been trained in the ART approach based on a five-module WHO approved ART training programme by Frencken et al contained on a compact disc [Frencken et al, 1998]. After the training each operator and assistant underwent further supervised and documented clinical practice in various clinics and in the field. Prior to the operative stage of the study, an operator who had made at least 50 ART restorations (half of them proximal restorations and the rest of any other class) was categorized as ‘experienced’, and the one who had done less than 10 but more than 5 of any class after the training was categorized as “inexperienced” in the ART approach. The assistants were similarly categorized but based on their assisting roles in placing similar number of restorations.

Using random numbers, the children were assigned to randomly paired operator and assistant. During the operative stage, the operator could make the decision to restore or reject with reasons any of the cavities that had been chosen by the examiner. The reasons for the rejection ranged from the presence and appropriateness of the cavity selected, relationship to the pulp chamber and the cooperation of the child during the treatment. A pre-and post-operative bitewing radiograph of the tooth was also taken. The radiographs were taken in a standard manner using kwik-bite (Pinnacle product Inc, USA part no. 270 US) with a ring centering film holder and a portable X-ray machine (Philips Oralix 50, 65kV 7.5mA, set at 0.3s). This procedure allowed for almost identical radiographs to be taken. Due to the busy schedule for the study and unavailability of facilities to process the radiographs in the field, the radiographs were not available to the
operators at the time of restoring the teeth. They were evaluated later by one independent examiner, who had been calibrated with a local dental radiologist (inter-examiner mean kappa, 0.88, n=50, and intra-examiner mean kappa, 1.00, on 10% of the evaluated radiographs). The radiographs were evaluated for the cavity/restoration extent within the dentine and its relationship with the pulp chamber. During the assessment of the radiographs, restorations were categorized as ‘within dentine’ when radiographically they were over one millimetre away from the pulpal lining, ‘close to the pulp’ when they were one or less millimeters from the pulpal lining and ‘involving the pulp’ when they were continuous with the pulp chamber.

All the clinical and radiographic results of the evaluations were analysed using the SPSS version 14.0 computer programme (SPSS Inc Chicago IL), and descriptive statistics used to compare the examiners’ cavity choices with the final results of the operator and the radiographic findings. When comparing the results of the study and the survival of the restorations in the cavities, Chi-square test was used with significance set at less than 5%.

Results
After the examination of the 6,002 children targeted for in the study, the results were as given in Table 3.1. Each of the 804 children selected from the 1,280 children who met all the criteria for inclusion in the study, received one proximal restoration in their primary molar using the ART approach. Of the 476 cavities excluded from the study during the operative stage, 99 experienced pulpal exposure, 37 were inappropriate (very large) and 30 lacked the reasons for their disqualification. The children with these cavities were from schools where radiographs were either not taken or were of poor quality for inclusion in the study. The remaining 310 cavities were for children who were absent on the day of the operation, children with anxiety or pre-operatively had lost the tooth or the tooth had been restored elsewhere or the child had been transferred from the school prior to the start of the operative stage of the study (Table 3.2). After adjusting for the discrepancies mentioned, the possible number of cavities that were available to the operator during the operative stage were 970 cavities. Out of this number, the examiner made incorrect choice of 166 cavities: pulpal exposure (99), inappropriate cavity-size (37), no explanation given (30), as shown in Table 3.2. The probability of the examiner making the appropriate cavity selection suitable for restoration based on clinical parameters was then 804 out of 970 cavities or 82.9%.
Table 3.1: The selection process and the proximal cavities restored in the study using the ART approach.

<table>
<thead>
<tr>
<th>Findings during the selection stage</th>
<th>The number of children from the 30 schools</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of children examined</td>
<td>6,002</td>
</tr>
<tr>
<td>Children had unsuitable cavities</td>
<td>2,809</td>
</tr>
<tr>
<td>Children who had no dental cavities</td>
<td>720</td>
</tr>
<tr>
<td>Children who were absent on the day of the examination</td>
<td>870</td>
</tr>
<tr>
<td>Children with inappropriate age</td>
<td>43</td>
</tr>
<tr>
<td>Children selected on the basis of having a suitable proximal dental cavity</td>
<td>1,560</td>
</tr>
<tr>
<td>Children who fulfilled all the criteria of inclusion into the study</td>
<td>1,280</td>
</tr>
<tr>
<td>Children with suitable proximal cavity, but were absent or were anxious, or the tooth experienced pulpal exposure during the restoration stage</td>
<td>476</td>
</tr>
<tr>
<td>Children who had one proximal restoration placed in their primary molar during the operative stage</td>
<td>804</td>
</tr>
</tbody>
</table>

Table 3.2: Analysis of the 476 children excluded from the study.

<table>
<thead>
<tr>
<th>Reason for failure to restore</th>
<th>Number of children</th>
<th>Percentage of the total number of children who met the study requirements</th>
<th>Percentage of the total number of children who had been excluded from the study</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Not treatment related</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Absent at time of restoring</td>
<td>192</td>
<td>15</td>
<td>40.3</td>
</tr>
<tr>
<td>Anxiety and fear</td>
<td>25</td>
<td>2.0</td>
<td>5.3</td>
</tr>
<tr>
<td>Already filled before day of restoration</td>
<td>1</td>
<td>0.08</td>
<td>0.2</td>
</tr>
<tr>
<td>Age problem (child not within 6 to 8 years)</td>
<td>47</td>
<td>3.7</td>
<td>9.9</td>
</tr>
<tr>
<td>Children already transferred from the school</td>
<td>3</td>
<td>0.2</td>
<td>0.6</td>
</tr>
<tr>
<td>Already exfoliated/mobile at day of restoration</td>
<td>42</td>
<td>3.3</td>
<td>8.8</td>
</tr>
<tr>
<td><strong>Treatment related</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pulpal exposure during preparation</td>
<td>99</td>
<td>7.7</td>
<td>20.8</td>
</tr>
<tr>
<td>Inappropriate cavity size (error of selection mainly very large cavity)</td>
<td>37</td>
<td>2.9</td>
<td>7.8</td>
</tr>
<tr>
<td>No explanation given</td>
<td>30</td>
<td>2.3</td>
<td>6.3</td>
</tr>
<tr>
<td><strong>Total number of children excluded from study</strong></td>
<td><strong>476</strong></td>
<td><strong>37.19</strong></td>
<td><strong>100.0</strong></td>
</tr>
</tbody>
</table>
Out of the 804 cavities restored in the study, only 648 (80.6%) cavities had pre-operative radiographs of good quality for the study and of this number 507 (78.2%) had both pre-and post-operative radiographs (Table 3.3). The remaining 141 radiographs lacked the corresponding post-operative radiographs. The missing radiographs were a result of spoilt radiographs, missing due to truancy by the child or lack of electricity power during the restoration process. The 648 cavities whose pre-operative radiographs were evaluated for the relationship of the pulpal-walls of the dental cavities to their pulpal-chambers had 514 (79.3%) cavities with pulpal-walls within sound dentine, 101 (15.6%) cavities had pulpal-walls close to the pulpal chamber and 33 (5.1%) cavities had pulpal-walls involving the pulp chamber. The most desirable cavities for restoration should have their pulpal-walls not involving the pulp chamber. According to the present results, the probability of the examiner having chosen the preferred cavities based on the pre-operative radiographic evaluations was therefore 94.9%.

Table 3.3: Results of the radiographic evaluations.

<table>
<thead>
<tr>
<th>Cavity category</th>
<th>Pre-operative radiographic results</th>
<th>Post-operative radiographic results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Radiographs without corresponding post-operation radiographs</td>
<td>Radiographs with corresponding post-operation radiographs</td>
</tr>
<tr>
<td>Pulpal cavity surface within sound dentine</td>
<td>103</td>
<td>411 (81.1%)</td>
</tr>
<tr>
<td>Pulpal cavity surface close to the pulp cavity involves the pulp</td>
<td>31</td>
<td>70 (13.8%)</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>26 (5.1%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>141</td>
<td><strong>507 (100%)</strong></td>
</tr>
</tbody>
</table>

It should be noted that the 33 cavities (i.e. 7+26 cavities as shown in the pre-operative radiographic results column in Table 3.3) had pulpal involvement, yet they had been restored by the operator. These incorrect choices of cavities made here were added to the incorrect choices made of 166 cavities clinically seen during the treatment phase (Table 3.2). The examiner had, therefore, made a total of 199 in appropriate cavity-choices out of the possible 970 cavities available for selection. A further 35 (68 - 33) cavities were detected on the post-operative radiographs as also involving the dental pulp, as a result of the caries excavation process. Of the 141 cavities that did not have corresponding post-operative radiographs, only 31 cavities had their pulpal-walls in close proximity with the pulp and seven involved the pulp, and all these cavities had been restored, as shown in Table 3.3 column 2 (subsection 1). The 166 cavities excluded during the operative stage could not be fully assessed radiographically, as they all lacked the two pairs of radiographs. The cavities that had pulpal involvement (post-operatively) were followed at all evaluation moments, and in one case the child had the tooth extracted after complaining of pain. The other cases either exfoliated naturally or were
lost due to drop-outs.

The results of the radiographic evaluation of the 507 cavities that had satisfactory corresponding pre-and post-operative bitewing X-rays are also shown in Table 3.3 column 2 (sub-section 2). It was apparent that after the excavation of the cavities, 348 (68.6%) cavities had their pulpal-walls ending within sound dentine (from 411 pre-operatively), 91 (17.9%) cavities had their pulpal-walls close to the pulp (70 pre-operatively) and 68 (13.4%) involved the pulp chamber (26 pre-operatively). Of the 411 cavities with pulpal-walls in sound dentine(pre-operatively), 60 cavities ended up being very close to the pulp chamber and three were involving the pulp chamber, after instrumentation (post-operatively). Of the 70 cavities that were close to the pulp chamber (pre-operatively), 39 cavities involved the pulp chamber after instrumentation (post-operatively). These results were categorized as follows: S (true positive) – cavities diagnosed by the examiner as having their pulpal-walls in dentine and radiographically confirmed so, T (false positive) - cavities diagnosed by examiner with their pulpal-walls within dentine but which were not, V (true negative) - cavities diagnosed by the examiner as involving the pulp and radiographically confirmed so and W (false negative) - cavities diagnosed by the examiner as involving the pulp but which were not. Using these symbols, the examiner’s diagnosis of a cavity not involving the pulp was:

\[
\begin{align*}
S+V & \text{ for accuracy, } S & \text{ for sensitivity and } V & \text{ for specificity [Andreasen et al, 1987]} \\
S+V+T+W & S+W & V+T
\end{align*}
\]

In the present study, S was 348 plus 91, T was 39 plus 3, V was 26 and W was zero. The results obtained from these calculations, and which were based on the outcomes of the initial clinical findings and the pre- and post-radiographic findings of the available radiographs, gave an accuracy of 91.7%, a sensitivity of 100% and a specificity of 40%. The negative predictive value (V/ (V+W) was 100%, indicating that all cavities said to involve the pulp did involve the pulp when diagnosed radiographically.

A comparison of the cavity-choices made by the operator with the survival rate of the restorations after two years indicated that restorations in cavities that were 'within dentine' had the highest survival rate. The difference between the survival rate of these restorations and the combine survival rate for the restorations in the cavities whose pulpal-walls were less than one millimetre from the pulp chamber or involving the pulp was significantly higher (Chi-square 27.596, 2df, p<0.0001). In general, there was no statistical significant difference in the choice made by the ‘experienced’ or ‘inexperienced’ operators in relation to the survival rate of the restorations (Chi-square, 5.011. 9df, p=0.833). However, one operator who had longer experience with the ART approach even before this study, had placed restorations whose survival rates were higher and statistically significant (Ch-square, 30.78, 5df, p<0.0001) when related to those placed by the other operators. This operator had also the least number of restorations involving the pulp chamber.

**Discussion**
The selection of the cavities to be restored was based exclusively on the clinical assessment by the examiner, and even at the time of restoring them, the operator had not seen the radiographs taken, which were evaluated later after restoring the cavities. The present study took place in a poor rural area in Kenya, with moderately high caries
prevalence. The area largely lacked basic dental health facilities, electricity and piped water to the majority of the population [Frencken et al, 1996], and it would be an appropriate site for the application of the ART technique [Frencken and Holmgren, 1999] if the facilities were available.

In the present study, the selection of suitable carious proximal lesions for restoration using the ART technique was simple, and dependent on visual estimation of the size of the lesion. After the initial selection by the examiners, the operators were only required to restore or reject them on the basis of the criteria that had been set. All the examiners and the operators had general experience in treating dental patients. For the operators in the present study, it was assumed that a relatively simple technique as the ART approach would not form an unacceptable risk for the patient in case the operator had only little experience with the ART technique as such. Although only 507 (78.2%) of the radiographs were available for analysis of pre-and post-operative status of the cavities, the results may not be conclusive. However, they do provide some idea on the challenges faced when selecting these proximal cavities. The operator’s decision, pre-and post-operative radiographs were used to determine the examiner’s accuracy to choose good cavities. The criterion of a cavity being close to the pulp was to be able to establish the possibility of such cases being able to be restored or not and also what proportion end up involving the pulp chamber after the excavation stage. Unfortunately, not all the radiographs were available due to the numerous technical difficulties experienced in the field.

From the study, majority of the eligible children excluded at all levels of the selection was essentially due to absenteeism, besides the initial lack of informed consent. This phenomenon could be attributed to the prohibitively long distances travelled by the majority of the children to school and the hunger experienced due to the general food scarcity as observed in the area. The high poverty levels seen in the community could imply that the majority of the parents were possibly having low-education level and spending most of their time fending for the family needs as not to be bothered with their children maintaining regular school-attendance. Unfortunately, this could only be speculated, as it could not be established in the present study.

With the cavity selection accuracy of 94.9% (pre-operatively) and 91.7% (post-operatively) for the examiner having chosen acceptable ART-restorable proximal cavities, it is indicative that a trained examiner has the capability of making reasonably good cavity-choices (not involving the pulp chamber) for the technique unaided by radiographs. A good cavity-choice is likely to lead to a restoration with enhanced survival rate. Obviously, some cavities were lost after instrumentation either as a result of diagnostic errors or poor instrumentation technique that might have led to pulpal exposures, hence reducing the number of correct cavity choice [Kidd, 2004]. This could be a possible reason for the reduction in the correct cavity choices made by the examiner. Probably if the pre-operative radiographs were available to both the examiner and the operator before restoring the cavities, the situation could have been different. It is apparent from the analysis of the radiographs that the number of cavities involving the pulp increased after restoring the cavities, possibly a result of operator errors, unnecessary excessive removal of dentine during the instrumentation stage or other diagnostic errors.

ART remains an operator-dependent process, with the operator making decisions based
on clinical experience and skills in choosing the cavities for restoration, removal of
carious material within the cavities, correct manipulation and application of the materials
used and the tooth-isolation technique applied during the placement of the restoration.
While there are many radiographic (when available) and biological factors that could
influence the correct diagnosis of a suitable cavity for the ART restoration, the present
study did indicate that the accuracy of the examiner in selecting the appropriate cavities
(without bite-wing radiographs), for the ART technique was very good.

Conclusions
It is possible that even without the benefit of a bitewing dental-radiograph, a trained,
skilled and diligent examiner is capable of making a good choice of ART- restorable
proximal carious lesion in primary molars.

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