

Effectiveness of ART and traditional amalgam approach in restoring single-surface cavities in posterior teeth of permanent dentitions in school children after 6.3 years

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Abstract – Objectives: The Atraumatic Restorative Treatment (ART) approach was compared with the traditional amalgam (TA) approach in order to test their appropriateness to complement a preventive and educational school oral health programme in Syria. *Methods:* Using a parallel group design, 370 and 311 grade 2 children were randomly assigned to the ART and the TA group respectively. Eight dentists placed 1117 single- and multiple-surface restorations. A modified actuarial method was used to estimate survival curves. The jackknife method was applied to calculate the standard error in the cumulative survival percentages. Results: A statistically significant difference in cumulative survival percentages between single-surface non-occlusal ART and comparable amalgam restorations was observed after 4.3, 5.3 and 6.3 years. The survival of single-surface non-occlusal ART posterior restorations  $(80.2 \pm 4.9\%)$  was statistically significantly higher than that of occlusal posterior ART restorations ( $64.8 \pm 3.9\%$ ) at evaluation year 6.3. There was no statistically significant difference observed between survival percentages of large  $(55.8 \pm 10\%)$  and that of small  $(69.2 \pm 4.6\%)$  single-surface posterior ART restorations after 6.3 years. There was an operator effect observed for singlesurface ART and comparable amalgam restorations. Secondary caries was observed in 2.3% of single-surface ART restorations and in 3.7% of singlesurface amalgam restorations during the 6.3 year observation period. Conclusions: The ART approach provided higher survival percentages for single-surface restorations than the TA approach over 6.3 years and is therefore appropriate for use in school oral health programmes. Secondary caries was only a minor reason for ART restorations to fail. An operator effect was observed for both treatment approaches.

#### J. E. Frencken<sup>1</sup>, M. A. van't Hof<sup>2</sup>, D. Taifour<sup>3</sup> and I. Al-Zaher<sup>4</sup>

<sup>1</sup>WHO Collaborating Centre for Oral Health Care Planning and Future Scenarios, Radboud University Medical Centre, College of Dental Sciences, Nijmegen, The Netherlands, <sup>2</sup>Department of Preventive and Restorative Dentistry, Radboud University Medical Centre, College of Dental Sciences, Nijmegen, the Netherlands, <sup>3</sup>School Health Department, Ministry of Education, Damascus, Syria, <sup>4</sup>WHO Regional Centre for Demonstration, Training and Research for Oral Health, Damascus, Syria

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J. E. Frencken. WHO Collaborating Centre for Oral Health Care Planning and Future Scenarios, Radboud University Medical Centre, College of Dental Sciences, PO Box 9101, 6500 HB Nijmegen, The Netherlands Tel: +31 24 361 4050 Fax: +31 24 354 0265 e-mail: j.frencken@dent.umcn.nl

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In 1991, the school health department of the Ministry of Education in Syria attempted to improve the oral health of school children by introducing a programme that was educational

and preventive oriented. The department employed a sufficiently high number of dentists, oral hygienists and auxiliary personnel to cover many primary schools in the country. Fluoride mouth rinsing programmes were introduced on a wide scale and good oral health behaviour practices were taught as part of the school's teaching programme. Evaluation of the programme after 5 years showed an inappropriately functioning traditional restorative care service (1). It was decided to look for alternative means of providing restorative care. One of the options considered was the Atraumatic Restorative Treatment (ART) approach (2).

However, at the time of discussing the inclusion of the ART approach into the oral health services (1996), sufficient information on the longevity of ART restorations was not available. Therefore, a randomized controlled clinical trial (RCT) was started in which the treatment of cavitated dentinal lesions in permanent dentitions through the ART approach with high-viscosity glass-ionomers was compared with those treated through the traditional amalgam (TA) approach. The cumulative survival percentage of singlesurface posterior restorations by the ART approach in permanent teeth after 6.3 years was 69% and it was 60% for comparable restorations by the TA approach (3). The difference was statistically significant. The present publication reports on outcomes of secondary analyses. The null hypotheses tested were that there was no difference in cumulative survival percentages of single-surface restorations placed in the posterior teeth of permanent dentitions after 6.3 years between (i) non-occlusal ART and occlusal ART restorations; (ii) non-occlusal amalgam and occlusal amalgam restorations; (iii) non-occlusal ART and amalgam restorations; (iv) occlusal ART and amalgam restorations; (v) small and large occlusal ART restorations.

# Materials and methods

The materials and methods of the trial have been described in a previously published paper (4), the summary of which is presented. A convenience sample of grade 2 pupils was taken from 49 schools situated in the vicinity of the WHO Regional Centre in Damascus. The inclusion criteria for a child to enter the RCT was the presence of a dentinal lesion in a permanent tooth that had an opening wide enough for the smallest excavator to enter ( $\emptyset = 0.9$  mm), without suspected pulp involvement. There was no inclusion criteria set for the actual size of the cavity.

## Treatment procedure

Eight dentists in the well-equipped clinical department of the WHO Regional Centre conducted this clinical trial during October–December 1997.

The conventional treatment procedure consisted of removing caries using the drill followed by filling the cavity with Avalloy<sup>®</sup> (Cavex; Haarlem, the Netherlands), a powder/liquid non-gamma 2-triturated amalgam. In contrast to the TA cavity design, cavities were prepared without using the 'extension for prevention' concept. However, retention niches were created. Metal bands and wedges were placed for filling class II cavities. Liners were not routinely placed. Isolation and washing/drying of teeth was achieved using cotton wool rolls and through the use of suction and three-way syringe systems. This procedure was termed minimal traditional approach (TA). The ART approach consisted of opening the cavity with a dental hatchet, removing soft carious tooth tissues with an excavator and filling the cavity and the adjacent pits and fissures with a glass-ionomer. Two brands of glass-ionomers were used: Fuji IX<sup>®</sup> (GC Europe; Leuven, Belgium) and KetacMolar<sup>®</sup> (3MESPE; Seefeld, Germany), both in a hand-mix formula. The chair side assistant mixed the glass-ionomers according to the manufacturers' instructions. Conditioning the cavity and adjacent pits and fissures preceded the placement of the glass-ionomer. Moisture isolation was achieved using cotton wool rolls and cavities were washed and dried through the use of cotton wool pellets. Excess material was removed using an applier/carver instrument and the restoration was coated with a layer of petroleum jelly (2). Multiple-surface cavities were filled after placement of plastic bands and wedges. Local anaesthesia was rarely administered.

All dentists had participated previously in a related clinical trial studying the survival of ART and amalgam restorations in deciduous dentitions (5). They had ample experience in applying the ART approach. The TA procedure was known and practised by all dentists routinely.

All eligible pupils were randomly allocated to one of the treatments (ART or TA) using the class list. Parental consent was obtained in writing through the school authorities. The Ministry of Health and Ministry of Education approved the study protocol.

## Evaluation

The first evaluation of the restorations took place after 1.3 years using the criteria presented in Table 1.

Table 1. Evaluation criteria used to assess ART and amalgam restorations (5)

Code	Criteria
0	Present, satisfactory
1	Present, slight deficiency at cavity margin of less than 0.5 mm <sup>a</sup>
2	Present, deficiency at cavity margin of 0.5 mm or more <sup>a</sup>
3	Present, fracture in restoration
4	Present, fracture in tooth
5	Present, overextension of approximal margin of 0.5 mm or more <sup>a</sup>
6	Not present, most or all of restoration missing
7	Not present, other restorative treatment performed
8	Not present, tooth is not present
9	Unable to diagnose

ART, Atraumatic Restorative Treatment. <sup>a</sup>As assessed using the 0.5 mm ball-end of a metal CPI probe.

The following evaluations took place after 2.3, 3.3, 4.3 and 6.3 years. The ball end of the CPI probe (0.5 mm in diameter) was used to measure any deficiency at the restoration margin. Restorations scored code 0 and 1 were considered successful; codes 2-7 were considered failures. The evaluation not only consisted of assessing the physical condition of the restoration, but also for assessing the presence of primary and secondary caries. Caries was recorded as present if the lesion had a detectable soft wall and/or soft floor and, if present, was considered a failure. Visible debris and plaque were removed from the tooth surface with the aid of an explorer. Teeth were dried using an air syringe. The examination site was well illuminated. Both caries and restoration criteria were applied to each of the three sections (mesial-central-distal) into which the occlusal surface was divided. A large size occlusal restoration covered all three sections whereas a small size lesion covered only one section. A medium size lesion (= 2 connecting sections) was not considered as its size could vary substantially.

The same two Syrian dentists carried out the evaluation at year 1.3 and 2.3. They were unable to participate at the third year of evaluation. Two experienced evaluators from the Netherlands replaced them. These evaluators had been calibrated with the Syrian colleagues and had participated in a related evaluation (5). One of the Syrian and one of the Dutch evaluators carried out the evaluation at year 4.3 and year 6.3. The evaluators did not participate in any way in setting up and/or implementation of the trial. The inter-evaluator consistency test was not carried out at evaluation year 2.3.

Table 2. Inter-evaluator consistency assessments in diagnosing restoration failure (yes/no) and dental caries (present/absent) over the 6.3 years of evaluation

	N <sub>rest</sub>	Restora failure	tion	Dental caries	
Year of evaluation		Карра	SE	Карра	SE
1.3 3.3, 4.3 and 6.3	88 138	0.87 0.82	0.07 0.05	0.53 0.84	0.12 0.06

The inter-evaluator consistency for assessing restoration failure and diagnosing dental caries, expressed in kappa coefficients (6), is presented in Table 2, showing a high level of reproducibility.

Two dentists, who had carried out the epidemiological survey prior to the start of the present trial, examined the children at evaluation year 6.3 for dental caries according to the criteria described by Taifour et al. (4) and for plaque at the six Ramfjord teeth according to the criteria of Greene and Vermillion (7).

#### Statistical methods

A power calculation for the 3-year comparison trial resulted in a required sample size of 524 cavities per treatment group (4). In practice 610 ART and 507 amalgam restorations were placed (4). The data were entered into a database, checked for mistakes and analysed using SPSS software (Release 6.1 version). Statistical analysis in this parallel group design aims at describing the survival curves of ART and amalgam restorations. The actuarial method was applied with the modification that restorations lost to follow-up during a period do not count in the calculations. The usual method (8) to calculate the standard error (SE) in the cumulative survival percentages is not appropriate in this situation with several restorations per child. Instead, the jackknife method (leave one patient out) (9) was applied. Handling of the longitudinal series of data resulted in survival percentages at year 5.3 (3). The difference between the survival percentages of both types of restorations was tested using the jackknife SEs of the differences. Differences between proportions were tested using the chi-squared test and difference between mean scores using the *t*-test.

#### Results

#### *Caries and plaque scores*

A total of 108 children of the ART group and 84 children of the TA group were examined at evaluation year 6.3. They were on average

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13.8 years old. The mean DMFT and DMFS scores of the children in the ART group were 5.5 (SD = 3.0) and 8.2 (SD = 5.4) respectively. The mean DMFT and DMFS scores of the children in the TA group were 6.0 (SD = 3.3) and 9.4 (SD = 6.4). There was no statistically significant difference in caries scores between the children of the two groups (P > 0.05). The mean plaque score for the children in the ART and TA group were 1.3 (SD = 0.58) and 1.2 (SD = 0.52) respectively.

# Survival of single-surface occlusal and non-occlusal posterior restorations

The number of ART restorations placed at baseline in occlusal and single-surfaces non-occlusal in posterior teeth was 355 and 132, respectively, whereas the number of occlusal and single-surface non-occlusal amalgam restorations in posterior teeth was 295 and 108 respectively. The modified actuarial cumulative survival percentages and jackknife SE for occlusal and single-surface nonocclusal posterior ART and comparable amalgam restorations over the evaluation years are presented in Fig. 1. The cumulative survival percentages and SE for occlusal ART and amalgam restorations at evaluation vear 6.3 were 64.8% (SE = 3.9%) and 58.4% (SE = 4.1%) respectively. This difference statistically not significant (P = 0.26)was (Fig. 1a). The cumulative survival percentages and SE for single-surface non-occlusal ART and



*Fig.* 1. The modified actuarial cumulative survival percentages and jackknife standard errors (SE) for occlusal ART and comparable amalgam restorations (a) and for single-surface non-occlusal ART and comparable amalgam restorations (b) by year of evaluation. Difference between single-surface non-occlusal ART and comparable amalgam restorations: a, P = 0.009; b, P = 0.018; c, P = 0.019.

comparable amalgam restorations at evaluation year 6.3 were 80.2% (SE = 4.9%) and 62.8% (SE = 5.6%) respectively. This difference was statistically significant (P = 0.019) as was the difference at evaluation year 4.3 (P = 0.009) and at evaluation year 5.3 (P = 0.018) (Fig. 1b). The survival percentages of single-surface non-occlusal posterior ART restorations were statistically significant higher than those of occlusal ART restorations at evaluation year 6.3 (P = 0.014). There was no statistically significant difference between occlusal and single-surface non-occlusal amalgam restorations at evaluation year 6.3 (P = 0.53).

# Survival of small and large occlusal restorations

A total of 222 small and 70 large ART restorations, and 116 small and 108 large amalgam restorations were available for analyses at baseline. The modified actuarial cumulative survival percentages and jackknife SE for small and large occlusal ART restorations at evaluation year 6.3 were 69.2% (SE = 4.6%) and 55.8% (SE = 10.0%) respectively. This difference was not statistically signifi-

(P = 0.23).The cumulative cant survival percentages and SE for small and large occlusal amalgam restorations at evaluation year 6.3 were 63.4% (SE = 7.7%) and 52.4% (SE = 6.6%) respectively. This difference was not statistically significant (P = 0.28). There was no statistically significant difference between the survival percentages of small ART and those of small amalgam restorations (P = 0.52) and between the survival percentages of large ART and those of large amalgam restorations in occlusal surfaces (P = 0.77).

#### **Operator** effect

The modified actuarial cumulative survival percentages and jackknife SE for single-surface ART and comparable amalgam restorations by operator at evaluation year 6.3 are presented in Tables 3 and 4 respectively. The cumulative survival percentages and SE for single-surface posterior ART restorations ranged from 85.0% (SE = 6.2%) for operator 6 to 35.3% (SE = 14.5%) for operator 7 after 6.3 years. This difference was statistically significant (P = 0.001). The cumulative survival

Table 3. Cumulative survival (%) and standard error (SE), calculated using the jackknife method, of single-surface posterior ART/glass-ionomer restorations over the 6.3-year study period by operator.  $N_{\text{total}}$  = total number of restorations at entry of interval

	Operator								
Interval	1	2	3	4	5	6	7	8	
(years)	$Surv \pm SE$	Surv $\pm$ SE	$Surv \pm SE$	$Surv \pm SE$	$Surv \pm SE$	$Surv \pm SE$	Surv $\pm$ SE	Surv $\pm$ SE	N <sub>total</sub>
0.0-1.3 1.3-2.3 2.3-3.3 3.3-4.3 4.3-5.3	$90.0 \pm 5.5 \\90.0 \pm 5.5 \\90.0 \pm 5.5 \\75.0 \pm 9.7 \\75.0$	$96.6 \pm 2.5 \\94.5 \pm 3.2 \\92.5 \pm 3.8 \\83.0 \pm 5.7 \\79.5 \pm 6.7 \\76.1 \pm 8.4$	$92.3 \pm 5.5 \\83.9 \pm 9.6 \\83.9 \pm 9.6 \\83.9 \pm 9.6 \\65.3 \pm 20.1 \\55.9 \pm 20.8 \\$	$94.1 \pm 3.4 90.1 \pm 5.2 88.0 \pm 6.9 85.5 \pm 7.1 85.5 \pm 7.1 78.1 \pm 10.2 85.5 \pm 7.1 \\85.5 \pm 7.1 \\85.$	$93.4 \pm 3.0 90.6 \pm 3.5 87.7 \pm 3.9 86.0 \pm 4.0 83.2 \pm 4.8 68.8 \pm 7.0 $	$95.7 \pm 2.5$ $93.8 \pm 3.1$ $93.8 \pm 3.1$ $88.8 \pm 4.7$ $85.0 \pm 6.2$ $85.0 \pm 6.2$	$79.2 \pm 5.8 \\69.3 \pm 6.2 \\64.7 \pm 6.5 \\64.7 \pm 6.5 \\53.0 \pm 13.9 \\25.2 \pm 14.5 \\$	$97.2 \pm 1.6$ $88.2 \pm 3.8$ $79.9 \pm 4.3$ $76.1 \pm 4.6$ $73.7 \pm 5.2$ $66.8 \pm 5.7$	487 397 348 288 161

\*P = 0.001.

Table 4. Cumulative survival (%) and standard error (SE), calculated using the jackknife procedure, of single-surface amalgam restorations over the 6.3-year study period by operator.  $N_{\text{total}} =$  number of restorations at entry of interval

Interval (years)	Operator								
	1	2	3	4	5	6	7	8	
	$Surv \pm SE$	$Surv \pm SE$	$Surv \pm SE$	$Surv \pm SE$	$Surv \pm SE$	$Surv \pm SE$	$Surv \pm SE$	$Surv \pm SE$	$N_{\rm total}$
0.0–1.3	$84.8 \pm 6.6$	$87.3 \pm 5.4$	91.3 ± 6.2	$100 \pm 0.0$	98.7 ± 1.3	$90.5 \pm 4.3$	$95.0 \pm 5.3$	90.1 ± 2.7	403
1.3-2.3	$81.5 \pm 7.1$	$79.0 \pm 6.5$	$81.7 \pm 9.0$	$94.7 \pm 5.6$	$91.5 \pm 3.2$	$84.7 \pm 5.7$	$77.2 \pm 9.6$	$74.4 \pm 4.6$	323
2.3–3.3	$81.5 \pm 7.1$	$76.8 \pm 6.8$	$76.9 \pm 10.3$	$94.7 \pm 5.6$	$90.0 \pm 4.0$	$82.7 \pm 5.6$	$64.3 \pm 16.3$	$70.7 \pm 4.6$	267
3.3-4.3	$69.8 \pm 9.0$	$74.1 \pm 7.4$	$76.9 \pm 10.3$	$94.7^* \pm 5.6$	$83.2 \pm 5.0$	$66.1 \pm 7.5$	$64.3 \pm 16.3$	$54.0^* \pm 6.5$	218
4.3–5.3	$69.8 \pm 9.0$	$74.1 \pm 7.4$	$64.1 \pm 17.5$	$78.9 \pm 20.3$	$80.4 \pm 5.7$	$66.1 \pm 7.5$	$64.3 \pm 16.3$	$49.1 \pm 6.3$	113
5.3–6.3	$69.8 \pm 9.0$	$67.9 \pm 11.2$	$51.3 \pm 16.7$	$63.2 \pm 22.9$	$74.9^{**} \pm 6.5$	$57.5 \pm 7.6$	$64.3 \pm 16.3$	$41.8^{**} \pm 7.3$	108

\*P = 0.0001; \*\*P = 0.001.

percentages and SE for single-surface amalgam restorations ranged from 74.9% (SE = 6.5%) for operator 5 to 41.8% (SE = 7.3%) for operator 8 after 6.3 years. There was an operator effect observed for single-surface amalgam restorations between operators 4 and 8 at evaluation year 4.3 (P = 0.0001) and between operators 5 and 8 at evaluation year 6.3 (P = 0.001). Single-surface ART restorations of operators 6 and 8 had higher survival rates than their comparable amalgam restorations after 6.3 years (P < 0.01). Tables 3 and 4 show that operator 7 performed significantly worse in ART and operator 8 in TA than their colleagues after 6.3 years.

## Failure characteristics

A total of 487 ART and 403 amalgam single-surface posterior restorations were available for longitudinal analyses. In total 225 restorations failed, 106 restorations in the ART group and 119 restorations in the TA group. Eleven (2.3%) single-surface ART restorations failed because of dentine lesion development only compared with 15 (3.7%) of singlesurface amalgam restorations during the 6.3 year observation period for which the difference was not statistically significant (P = 0.28). Statistically significant more single-surface amalgam (39; 9.7%) than comparable ART restorations (25; 5.1%) failed because of mechanical defects (P = 0.01). The majority of single-surface restorations failed because of a combination of dentine lesion development and mechanical defects; 48 ART and 44 amalgams. Rerestoration was recorded for 22 ART and 21 amalgam restorations over the 6.3year evaluation period.

# Discussion

All possible efforts were exercised to trace the participating children at the evaluation periods. However, a large number of children had left the primary school for an intermediate school during evaluation interval 4.3–6.3 years, and some had left the city. This resulted in a substantial dropout from the original sample during the last two evaluation intervals.

The decision to opt for a parallel group ensures that the number of restorations placed per treatment modality would differ. However, the difference in number of restorations placed per treatment group turned out to be larger than anticipated ( $N_{\text{ART}} = 610$ ,  $N_{\text{TA}} = 507$ ). The rea-

son for this was due to the fact that the electricity supply failed during a number of days. On those days, the principal investigator decided that all children, who had been bussed to the WHO Centre for treatment, would be treated using the ART approach. We do not think that this decision has biased the outcome of the study.

The actual size of the single-surface restorations was not measured. In the present study the restoration size was determined based on the number of sections in which it appeared. To be certain that the analyses would be carried out on data of two distinctly different restoration sizes, only small and large single-surface restorations were identified. The medium size restorations were excluded as its determination needed to be based on two connecting sections, which could lead to restoration sizes of extreme differences. A restoration could be large (appearing in two full sections) or small (appearing in a small part in both sections). Under such circumstances it is better to refrain from using potentially unreliable measurements.

The survival percentages were analysed at restoration level. This assumes independence of the survival percentages of children. The jackknife method was applied to deal with the dependency of restoration outcomes and resulted in higher SE values than those calculated through the commonly used Greenwood method (8).

There is only one other study that has reported survival results of (non)- and occlusal ART restorations in permanent teeth (10). In this Thai study, non-occlusal posterior ART restorations (85%) had a higher survival rate than occlusal posterior ART restorations (62%) after 3 years. This finding and the magnitude of the survival percentages are in line with the ones observed in the present study but only after 6.3 years. The fact that the Thai study was the first major ART study in which the approach was tested using a less durable medium-viscosity glass-ionomer than in the present study could explain the difference in magnitude of single-surface non- and occlusal ART restorations observed between the two studies. The present study showed that the survival percentages of single-surface non-occlusal posterior ART restorations were significantly higher than for comparable amalgam restorations after 4.3, 5.3 and 6.3 years. Although it is known that non-occlusal glassionomer restorations survive long (11), we observed significant lower survival results for non-occlusal amalgam than for comparable ART glass-ionomer restorations. A reason for this difference is not apparent. However, the present study showed that the survival of all types of ART restorations was statistically significant higher than that of comparable amalgam restorations at all evaluation years but the first (3).

Different to the 6 year study from China (12), we did not observe a statistically significant difference between the survival percentages of large and small occlusal ART restorations. However, the definition we used for determining the size of the cavity differed from the one used in the China study and that could be the reason for the difference in survival results observed.

The survival results of restorations produced by both ART and TA approaches varied widely by operator. The variation resulted in an operator effect for single-surface ART and amalgam restorations. The cumulative survival percentage of single-surface ART restorations of the worst performing operator was about 50% less than the best performing operator after 6.3 years. This difference in performance started at evaluation year 1.3, indicating that the application of the ART approach must have been difficult for this operator. The operator who placed more single-surface amalgam restorations than any of the others scored the lowest survival result after 6.3 years. The survival of single-surface posterior ART restorations of this particular dentist was significantly higher than that of operators' single-surface amalgam restorations whereas placing amalgam restorations has been practised for many more years than placing ART restorations. It is difficult to provide a reason for the operator effect observed for amalgam restorations, other than poor workmanship. An operator effect has been cited in a number of ART studies (13-15) but other ART studies have not reported an operator effect (10, 12). Although all operators (dentists and dental therapists) in the studies referred to above had followed a training course on ART, the operator effect seems to indicate that in order to perform quality ART restorations, the operating dental personnel requires skill, diligence and comprehension (16). An ART training course of a couple of days may be too short for some qualified dentists and dental therapists.

Similar to the 6-year study from Tanzania (17) and that from China (12), the percentage of secondary caries alongside single-surface posterior ART restorations after 6.3 years was very low. Despite the fact that some infected dentine may have been left behind in the cavity, and that the children in the study group were considered to be at high risk for dentine lesion development (mean DMFT score = 5.5), secondary caries, whether residual or primary in origin, does not seem to have affected the survival of ART restorations seriously after 6.3 years as has often been suggested. A significant decrease in micro-organisms has been reported after manual cavity preparation using the ART approach (18, 19). Even partial removal of infected dentine did not cause secondary caries development (18), instead remineralization of the affected dentine occurred under incompletely removed infected dentine (20, 21). The latter observation is supported by numerous studies (22). The predominant reasons for ART restorations to fail in the present study were unacceptable defects at the margin and rerestoration. Excessive wear was hardly observed. This pattern of reasons for failure differed from the 6-year ART studies in China (12) and Tanzania (17) where loss of restoration and replacement (China) and loss of material and poor marginal integrity/restoration fracture (Tanzania) were the main reasons for failure. Based on the reported reasons for failure in the present and the two studies referred to above, glass-ionomers with improved physical properties, such as fracture toughness, need to be manufactured in order to increase the survival of ART restorations.

We conclude that the survival of single-surface non-occlusal ART restorations was statistically significantly higher than that for comparable amalgam restorations after 4.3, 5.3 and 6.3 years and higher than for occlusal ART restorations after 6.3 years. Dentine lesion development alongside single-surface ART and amalgam restorations were rarely observed during the 6.3-year observation period. An operator effect was present for both single-surface ART and amalgam restorations. The ART approach is appropriate for use in school oral health programmes.

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