Survival of ART and Amalgam Restorations in Permanent Teeth of Children after 6.3 Years

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ABSTRACT

The null hypothesis tested was that there is no difference in the survival percentages of all restorations placed through the Atraumatic Restorative Treatment (ART) approach, with high-viscosity glass ionomer, and those produced through the traditional approach, with amalgam (TA), in the permanent dentitions of children after 6.3 years. Using a parallel group design, we randomly assigned a total of 370 children, aged 6 to 9 years, to the ART group and 311 children, also aged 6 to 9 years, to the TA group. Eight dentists placed a total of 1117 single- and multiple-surface restorations. The cumulative survival percentages for ART glass-ionomer restorations were statistically significantly higher than those of amalgam restorations at all time intervals except the first ($p \leq 0.044$). After 6.3 years, the cumulative survival percentages of ART and amalgam restorations were 66.1% (SE = 3.1%) and 57.0% (SE = 3.3%), respectively. We concluded that the restorations produced with the ART approach, with high-viscosity glass ionomer, survived longer than those produced with the traditional approach, with amalgam, in the permanent teeth of young children.

KEY WORDS: restorations, atraumatic restorative treatment, amalgam, glass ionomer, survival.

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INTRODUCTION

In 1991, the school health department in the Ministry of Education in Syria attempted to improve the oral health of schoolchildren by introducing a program that was educational and preventive in orientation. Evaluation of the program after 5 yrs showed that the restorative care service was not functioning correctly (Taifour, 2002).

Because the difficulties encountered by the school health department in implementing the traditional restorative care concept at the schools were caused by its high cost and dependency on electricity, it was decided to look for alternative means of providing restorative care. One of the options considered was the Atraumatic Restorative Treatment (ART) approach. This approach uses only hand instruments in combination with an adhesive restorative material, usually an auto-cured glass ionomer, and can be applied on school premises (Frencken *et al.*, 1996).

However, at the time when the inclusion of the ART approach into the oral health services was discussed (1996), only one study had been published on the effectiveness of the ART approach in comparison with the traditional approach in permanent teeth (Phantumvanit *et al.*, 1996). Because of the lack of information on the longevity of ART restorations, the Regional WHO Centre in Damascus started a comparative randomized controlled clinical trial. The null hypothesis was that there is no difference in the survival percentages between restorations produced through the ART approach, with high-viscosity glass ionomer, and those produced through the traditional approach, with amalgam, after 6.3 years. This is the first trial comparing the two approaches over a period of more than 6 yrs.

MATERIALS & METHODS

Sampling Procedure

The study protocol was approved by both the Ministry of Health and the Ministry of Education. Parental consent was obtained in writing through the school authorities.

A convenience sample of grade 2 children who ranged from 6 to 9 yrs of age was taken from 49 schools situated in the vicinity of the WHO Regional Centre in Damascus. Each child was diagnosed for dental caries by three calibrated examiners. The prevalence of dental caries in the children examined was 57.6%. The mean DMFS and DMFT scores were 1.6 and 1.4, respectively.

The inclusion criteria for a child to enter the RCT were the presence of a dentinal lesion in a permanent tooth, without suspected pulp involvement, that had an opening wide enough for the smallest excavator to enter (Ø = 0.9 mm). There were no inclusion criteria set for the actual size of the cavity.

Implementation

Eight dentists, aided by a chair-side assistant, conducted this RCT in the well-equipped clinical department of the WHO Regional Centre during October-December, 1997. Prior to being treated, all children attended group oral health education sessions and were taught individually, by experienced oral health

Table 1. Evaluation Criteria for the Assessment of Atraumatic Restorative Treatment and Traditional Approach Restorations

Code	Criterion
0	Present, satisfactory
1	Present, slight deficiency at cavity margin of less than 0.5 mm*
2	Present, deficiency at cavity margin of 0.5 mm or more*
3	Present, fracture in restoration
4	Present, fracture in tooth
5	Present, overextention of approximal margin of 0.5 mm or more*
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
C	Caries present

* As assessed by use of the 0.5-mm ball-end of a metal CPI probe.

educators, how best to clean their teeth with fluoridated toothpaste. Teeth that had caries involving the pulp, but not included in the study, were extracted as part of the care routinely provided at the Centre.

Treatment Procedure

The conventional treatment procedure consisted of the removal of carious tissues with a rotary instrument, after which the cavity was filled with Avalloy® (Cavex, Haarlem, the Netherlands), a powder/liquid non-gamma 2 triturated amalgam. Cavities were prepared with the creation of retention niches, but without the "extension for prevention" concept. Metal bands and wedges were placed when class II cavities were filled. Isolation and washing/drying of teeth were achieved with the use of cotton wool rolls and through the use of suction and three-way syringe systems. This procedure was termed the "traditional approach" (TA). The ART approach consisted of the opening of the cavity with a dental hatchet, the removal of soft carious tooth tissues with an excavator, and the filling of the cavity and the adjacent pits and fissures with a glass-ionomer cement. Two brands of glass-ionomer cements were used: Fuji IX® (GC Europe, Leuven, Belgium) and Ketac Molar® (3M ESPE, Seefeld, Germany), both in a hand-mixed formula. The chair-side assistant mixed the glass-ionomer cements according to the manufacturers' instructions. Conditioning of the cavity and adjacent pits and fissures, with cotton wool pellets, preceded the placement of the glass ionomer. Moisture isolation was achieved with the use of cotton wool rolls, and cavities were washed and dried with cotton wool pellets. Excess material was removed by means of an applier/carver instrument, and the restoration was coated with a layer of petroleum jelly (Frencken *et al.*, 1996). Multiple-surface cavities were filled after the placement of plastic bands and wedges. Local anesthesia was rarely administered.

All dentists had previously participated in a related clinical trial studying the survival of ART and TA restorations in deciduous dentitions (Taifour *et al.*, 2002). They had ample experience in applying the ART approach. The TA procedure was known and routinely practiced by all dentists.

All eligible children were randomly assigned by the principal investigator (DT) to one of the two treatments (ART or TA) with the use of a gender-stratified class list. In the case of ART, Fuji IX® was allocated in the first part (34%) and Ketac Molar® in the second part (64%) of the implementation period.

Table 2. Inter-evaluator Consistency Assessments in Diagnosing Restoration Failure (yes/no) and Dental Caries (present/absent) over the 6.3 Years of Evaluation

Year of Evaluation	N_{rest}	Restoration Failure Kappa	Restoration Failure SE*	Dental Caries Kappa	Dental Caries SE
1.3	88	0.87	0.07	0.53	0.12
3.3, 4.3, and 6.3	138	0.82	0.05	0.84	0.06

* SE = standard error

Evaluation

The evaluation of the restorations took place after 1.3, 2.3, 3.3, 4.3, and 6.3 yrs, according to defined criteria (Table 1). The 5.3-year evaluation was not performed because of the war in neighboring Iraq. The ball end of the CPI probe (0.5 mm in diameter) was used to measure the deficiency at the restoration margin. Restorations scored code 0 and 1 were considered successful; codes 2-7 were considered failures. A caries lesion was recorded as present if the lesion had a detectable soft wall and/or soft floor and was considered a failure for the survival analysis. Visible debris and plaque were removed from the tooth surface with the aid of an explorer. Teeth were dried by means of an air syringe. The examination sites were well-illuminated. Both caries and restoration criteria were applied to each of the three sections into which the occlusal surface was arbitrarily divided.

The same two Syrian dentists carried out the evaluation at years 1.3 and 2.3. They were unable to participate in the third year of evaluation and were replaced by two experienced evaluators from the Netherlands. The Dutch evaluators had been calibrated with their Syrian colleagues and had participated in a related evaluation (Taifour *et al.*, 2002). One of the Syrian and one of the Dutch evaluators carried out the evaluations at years 4.3 and 6.3. The evaluators were not involved in the planning and treatment provision of the trial. The inter-evaluator consistency test was not carried out at evaluation year 2.3. The quality of the inter-evaluator consistency for assessing restoration failure and diagnosing dental caries, expressed in kappa coefficient values (Landis and Koch, 1977), was calculated (Table 2).

Statistical Methods

A power calculation for the three-year comparison preceded the sampling procedure (Taifour *et al.*, 2003). The principal investigator, who was not an operator, recorded the data on a case report form; they were later entered into a database at the College of Dental Sciences in Nijmegen. There, the data were checked for errors, and a biostatistician (Mv'tH) analyzed them with SPSS software (Release 6.1 version). The actuarial method was applied for estimation of the survival percentages of the ART and TA restorations over time, with the modification that restorations lost to follow-up during a period did not count in the calculations. The usual method (Greenwood, 1926), used to calculate the standard error (SE) in the cumulative survival percentages, was not appropriate in this situation, with several restorations *per* child. Instead, we applied the Jackknife method (where one patient is left out) (Efron, 1982), to deal with the dependency of the data and to calculate the standard errors for the survival percentages. The

Table 3. Cumulative Survival (%) and Standard Errors (SE), Calculated by the Jackknife Method, of All Restorations Produced through the ART/Glass-ionomer and Traditional/Amalgam Approaches over the 6.3-year Study Period

	ART/Glass-ionomer Approach				Traditional/Amalgam Approach				
Interval (yr)	N_{child} at Entry[c]	N_{rest} at Entry	N_{Fail}	Survival ± SE[a] (%)	N_{child} at Entry	N_{rest} at Entry	N_{Fail}	Survival ± SE[a]	p-value[b]
0.0-1.3	330	539	44	91.8 ± 1.3	267	436	40	90.8 ± 1.5	0.60
1.3-2.3	273	431	25	86.5 ± 1.8	215	346	44	79.3 ± 2.2	0.012
2.3-3.3	242	377	18	82.4 ± 2.0	180	279	12	75.9 ± 2.4	0.037
3.3-4.3	208	309	17	77.8 ± 2.1	149	227	29	66.2 ± 2.9	0.002
4.3-5.3	109	173	8	74.2 ± 2.6	78	115	5	63.3 ± 3.1	0.007
5.3-6.3	105	165	18	66.1 ± 3.1	75	110	11	57.0 ± 3.3	0.044

[a] Survival percentage is calculated as the preceding survival rate multiplied by the survival rate in the corresponding period (actuarial method).
[b] p-value for the difference between all ART/glass-ionomer and traditional/amalgam restorations.
[c] N_{rest} = Number of restorations at entry of interval. N_{Fail} = Number of failed restorations at end of interval. N_{child} = Number of children at entry of interval.

difference between the survival percentages of both types of restorations over 6.3 yrs was tested *via* the Jackknife SEs of the differences. Statistical significance was set at $\alpha = 0.05$.

RESULTS

Disposition of Restorations

In total, 681 children, 325 boys and 356 girls, with a mean age of 7.5 yrs (range, 6-9 yrs), participated in the trial. The ART group consisted of 370 children and the TA group of 311 children. The eight operators placed a total of 1117 restorations, of which 610 were made according to the ART approach and 507 were made using the TA approach.

Eighty-four children with 142 restorations were never evaluated (non-participation). There was no statistically significant difference ($p > 0.05$) between non-participating and participating children for the background variables age, gender, treatment procedure, restorative material, and operator.

Longitudinal Assessment Series

We used data from a total of 597 children, including 287 boys and 310 girls, to estimate survival percentages. The ART group consisted of 330 children and the TA group of 267 children. The total number of restorations eligible for evaluation was 975, including 539 ART restorations (of which 185 were made with Fuji IX and 354 restorations were made with Ketac Molar) and 436 amalgam restorations. These restorations consisted of 890 single surfaces and 85 multiple surfaces. The percentages of children with 1, 2, and 3 or more restorations were 58, 27, and 15, respectively. The mean number of restorations placed *per* child was 1.6 (SD = 0.9).

Handling of Longitudinal Data

Each of the 975 restorations was associated with the longitudinal evaluation series of its corresponding 7 (sub-) surfaces, which translates into 6825 different sequences of evaluation scores over the 6.3 yrs. These longitudinal series were clearly interpretable in 96.7% of the cases (no errors, censored, or a distinct moment of failure). In 2.0% of the longitudinal series, no distinct moment of failure could be specified (multi-interpretable), owing to missed observation occasions. In 1.3% of the cases, an error was encountered (*i.e.*, regression of the restoration quality was detected). This situation could be corrected in 0.4% of the cases (almost uniquely interpretable) if a failed restoration was followed up by a recording that the restoration was sound at least two times. In the other 0.9% of the cases, the true failure could not be determined on the basis of the longitudinal series. An intelligent decision was made as to which evaluation year the failure was allocated. This process led to unique survival percentages at evaluation year 5.3.

Comparison of Treatment Approaches

All Types of Restorations

The modified actuarial cumulative survival percentages and standard errors (SE) for all types of restorations for both treatment approaches over the 6.3 yrs were calculated (Table 3). Higher survival percentages were observed for ART than for TA restorations at all intervals (Table 3). The differences in the survival percentages between the two groups were statistically significant at all intervals except for the first. The 6.3-year cumulative survival percentages of ART restorations with Fuji IX and Ketac Molar were 61.8% (SE = 6.0%) and 68.5% (SE = 3.6%), respectively, and this difference between the survival percentages of restorations made with the two brands of glass ionomer was not significantly significant ($p = 0.34$).

Single-surface Restorations

The modified actuarial cumulative survival percentages and standard errors (SE) for single-surface restorations for both treatment approaches over the 6.3 yrs were calulated (Table 4). Higher survival percentages were observed for ART than for TA restorations at all intervals (Table 4). The difference between the survival percentages was statistically significant at all intervals except for the first and the third.

DISCUSSION

All possible efforts were exercised to trace the participating children at the evaluation periods. Nevertheless, a large number of children had left the primary school for an intermediate school during evaluation intervals from 4.3 to 6.3 yrs, and some had left the city. This resulted in a substantial reduction in the number of restorations evaluated during the last two evaluation intervals.

The decision to opt for a parallel group design ensured that the number of restorations placed *per* treatment modality would differ. However, the difference in numbers of restorations

Table 4. Cumulative Survival (%) and Standard Error (SE), Calculated by the Jackknife Method, of Single-surface ART/Glass-ionomer and Traditional/Amalgam Restorations over the 6.3-year Study Period

	ART/Glass-ionomer Approach				Traditional/Amalgam Approach				
Interval (yrs)	N_{child} at Entry[c]	N_{rest} at Entry	N_{Fail}	Survival ± SE[a] (%)	N_{child} at Entry	N_{rest} at Entry	N_{Fail}	Survival ± SE[a] (%)	p-value[b]
0.0-1.3	302	487	33	93.2 ± 1.3	254	403	33	91.8 ± 1.4	0.46
1.3-2.3	254	397	22	88.1 ± 1.7	205	323	34	82.1 ± 2.1	0.026
2.3-3.3	224	348	14	84.5 ± 2.0	175	267	9	79.4 ± 2.2	0.086
3.3-4.3	193	288	14	80.4 ± 2.1	145	218	27	69.5 ± 2.9	0.003
4.3-5.3	102	161	8	76.4 ± 2.7	78	113	5	66.5 ± 3.0	0.014
5.3-6.3	98	153	15	68.9 ± 3.3	75	108	11	59.7 ± 3.3	0.048

[a] Survival percentage is calculated as the preceding survival rate multiplied by the survival rate in the corresponding period (actuarial method).
[b] p-value for the difference between single-surface ART/glass-ionomer and traditional/amalgam restorations.
[c] N_{rest} = Number of restorations at entry of interval. N_{Fail} = Number of failed restorations at end of interval. N_{child} = Number of children at entry of interval.

placed *per* treatment group turned out to be larger than anticipated (N_{ART} = 539, N_{TA} = 436). The reason for this was due to the fact that the electricity supply failed on several days. On those days, the principal investigator decided that all of the children, who had been transported to the WHO Centre for treatment, would be treated by the ART approach. We do not think that this decision biased the outcome of the study.

The survival percentages were analyzed at the restoration level. This assumed independence of the survival percentages of children. We applied the Jackknife method to deal with the dependency of restoration outcomes within each child; this resulted in higher SE values than those calculated through the commonly used Greenwood (1926) method.

The criteria used in the present study have been applied in most other ART studies in the permanent dentition (Frencken and Holmgren, 2004). Usually, the USPHS criteria are used for the assessment of restoration survival. Studies have shown no significant difference in survival outcomes of ART restorations that were evaluated according to both sets of criteria (Holmgren *et al.*, 2000). Further, it has been suggested that the ART criteria are more stringent than the USPHS criteria (Lo *et al.*, 2001). Thus, we may reasonably assume that the results of the present study are comparable with those from non-ART studies.

The percentage of restorations that survived after the end of each evaluation period was higher for the ART approach than for the amalgam approach group. Despite the fact that many restorations were lost to follow-up during the last two intervals, thus decreasing the power of the trial, the differences in the percentages of survival of restorations between the two treatment approaches were statistically significant at all intervals but the first. The null hypothesis was rejected: There *is* a difference in the percentage of restorations that survived produced through the ART approach, with high-viscosity glass ionomer, and those produced through the traditional approach, with amalgam, after 6.3 yrs. Survival percentages for ART restorations were higher than those for amalgam restorations after 6.3 yrs. This was also found to be true with the subset of single-surface restorations that showed higher survival percentages for ART than for amalgam restorations after 6.3 yrs.

The present study is the first in which ART restorations with high-viscosity glass ionomer were compared with traditionally produced restorations. The majority of the restorations were placed in single surfaces. There is one other study (in Tanzania) in which the ART approach was compared with the traditional approach, with amalgam in single surfaces in permanent dentitions, after 6 years (Mandari *et al.*, 2003). The latter study reported no significant difference between the two approaches, but amalgam restorations performed better than ART restorations. The ART restorations in the Tanzanian study were placed by one dental therapist, who used a medium-viscosity glass-ionomer cement. Whether these two aspects contributed to the difference in final outcome between the Tanzanian and the present study is uncertain.

The cumulative survival percentage (68.9%) of single-surface ART restorations after 6.3 yrs in the present study is equal to that (68.6%) reported from Tanzania (Mandari *et al.*, 2003).

In recent years, few studies have reported on the placement of single-surface amalgam restorations by multiple dentists. The median survival of one-surface amalgam restorations, placed by 22 general practitioners, has been reported to be 7.1 yrs (Mjör *et al.*, 1997), whereas the median survival time for Class I amalgam restorations, placed by 73 dentists, has been reported to be 7.4 yrs (Burke *et al.*, 1999). These results are in line with the 6.3-year cumulative survival percentage of single-surface amalgam restorations of 59.7% placed by eight dentists in the present study.

We conclude that the restorations produced with the ART approach, with high-viscosity glass ionomer, survived longer than those produced with the traditional approach, with amalgam, in the permanent teeth of young children. We recommend the ART approach as a complement to the preventive activities in the Syrian school oral health programs.

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