Clin Oral Invest (2013) 17:1745–1750
DOI 10.1007/s00784-012-0859-1

ORIGINAL ARTICLE

Survival rate of approximal-ART restorations using a two-layer technique for glass ionomer insertion

Clarissa Calil Bonifácio · Daniela Hesse · Rachel de Oliveira Rocha · Marcelo Bönecker · Daniela Prócida Raggio · W. Evert van Amerongen

Received: 12 April 2012 / Accepted: 1 October 2012 / Published online: 11 October 2012

Abstract
Objective Good survival rates (SR) have been reported for occlusal-atraumatic restorative treatment (ART) restorations but not for approximal-ART restorations. The high-viscosity consistency of the glass ionomer cement (GIC) may lead to its incorrect adaptation into the cavity and thus to failure of the restoration. Because the use of a flowable GIC layer seemed to improve its adaptation in approximal restorations in vitro, we evaluated whether the use of an intermediate flowable GIC layer would improve the SR of approximal-ART restorations.
Methods A total of 208 children (6–7 years old) with at least one occluso-proximal carious lesion in a primary molar were selected and randomly allocated to two groups: G1, conventional technique, one-layer GIC (powder/liquid ratio 1:1); and G2, two-layer technique, consisting of a first layer of GIC with a flowable consistency (powder/liquid ratio 1:2) and a second layer of a regular consistency. Restorations were made by final-year students and evaluated after 1, 6, 12 and 18 months. Restoration survival was evaluated using Kaplan–Meier survival and logrank test. Poisson regression analyses (α=5) were used to verify the influence of factors such as insertion technique, restoration surface and operators.
Results The overall SR of the restorations after 18 months was 68 %. There was no difference in SR between the techniques, neither did the other factors influence the SR.
Conclusions Over 18 months, the use of an intermediate flowable GIC layer in approximal-ART restorations does not improve the restoration survival.
Clinical relevance This study suggests that the two-layer technique is not the answer for increasing approximal-ART restoration longevity.

Keywords Atraumatic restorative treatment (ART) · Glass ionomer cements · Primary molars · Low-viscosity glass ionomer cement

C. C. Bonifácio (✉) · W. E. van Amerongen
Department of Conservative and Preventive Dentistry,
Academic Centre for Dentistry Amsterdam (ACTA),
Gustav Mahlerlaan, 3004,
1081LA Amsterdam, The Netherlands
e-mail: C.Bonifacio@acta.nl

D. Hesse · M. Bönecker · D. P. Raggio
Department of Pediatric Dentistry, School of Dentistry,
University of São Paulo,
São Paulo, Brazil

R. de Oliveira Rocha
Department of Estomatology, School of Dentistry,
University of Santa Maria,
Santa Maria, Brazil

Introduction

The atraumatic restorative treatment (ART) was developed in the mid-1980s to prevent the extraction of decayed teeth of patients in outreach areas, where resources such as electricity and rotary dental equipment were not easily accessible [1]. Glass ionomer cements (GICs) are chosen as the most suitable filling material for ART because of their biological, physical and chemical properties [2].

The high-viscosity GICs were specially developed for ART. They have a relatively slow setting time and better physico–mechanical properties, when compared to their predecessors [2–4], resulting in higher survival rates of the restorations [5]. In a meta-analysis, van't Hof et al. [6] showed that ART restorations in single-surface (occlusal) cavities using high-viscosity GIC have higher survival rates when compared to amalgam restorations whereas the multi-surface (approximal) cavities in primary teeth still required improvements.

Several clinical trials have investigated different causative factors associated to approximal-ART restoration failures. Among these, the isolation methods, materials with different strengthened properties, influence of the operator, the post-restoration meal (time between restoration and loading) and the cavity size can be cited [7–13]. Although in some cases the survival rate had increased, this type of restorations still does not meet the ADA specifications for restoration quality [1].

The most reported failure reason for approximal-ART restorations is loss of restorations or bulk fracture [8, 14–16]. These failures might be related to the material's properties but can also result from an incorrect adaptation or cervical gap formation in approximal-ART restorations [17–19].

Recent laboratory studies show that the insertion of a thin flowable GIC layer before the insertion of a regular high-viscosity GIC layer (two-layer technique) can improve the material adaptation within approximal cavities [20] and increase the bond strength to sound dentin [21]. To investigate whether these findings are also clinically relevant, we conducted a randomised-controlled clinical trial, in schools, using this new insertion technique. The null hypothesis tested was that there is no difference in survival rate of approximal-ART restorations made with one- or two-layer technique in primary molars.

Material and methods

Sample size calculation indicated a minimum of 81 patients per group. It was calculated based on a minimally important difference of 20 % in the success rates between treatment and control groups after 2 years, α of 5 % and a power of 80 % (using a two-tailed test).

Sampling procedure After approval for conducting the study was obtained from the local Research Ethical Committee (USP, São Paulo, Brazil), a total of 2,000 children (6–7 years old) attending public schools in the city of Barueri (State of São Paulo, Brazil) were examined. Two-hundred and eight children fulfilled the inclusion criteria and had a written consent from parents or legal guardians and were thus, included in the study. The inclusion criteria were at least one occluso-proximal carious lesion in a primary molar involving dentin with dimensions not larger than 2 mm mesio-distal, 2.5 mm bucco-lingual and occluso-cervical, cooperative behaviour, absence of fistula, abscess or pathological mobility near the selected tooth. The dimensions of the cavity were assessed with a graded periodontal probe [22].

Implementation Only one cavity per child was included in the study. If more than one cavity met the inclusion criteria, one of them was randomly chosen. The other cavitated carious lesions in the selected children were treated by dentists who work in oral health centres in the city. The operators were four final-year undergraduate dental students who were previously trained to perform ART, including the GIC mixing according to the manufacturer's protocol and to the specific technique used in this study. A training week was included to give the operators the opportunity to familiarise themselves with the local conditions and the restorative technique prior to the start of the operative phase. The operators were assisted by each other and all treatments were performed on the school premises, in field conditions without the use of dental chair or other facilities from a clinical environment. The children were assigned to one of the operators by a random list. Another random list was used to assign the insertion technique of each restoration.

Treatment procedure During treatment, no local anaesthesia was used. Infected carious dentin was removed with hand instruments and the cavities were restored with high-viscosity GIC Fuji IX (GC Europe, Leuven, BE). After cavity preparation, a metallic matrix band and a wedge were applied. All cavities were conditioned with the diluted liquid from the material (10 s), followed by rinsing with water and drying with cotton pellets. The mixing and insertion of GIC was different for each group, and for both insertion techniques, the only material used was Fuji IX. In G1, the conventional restoration group, GIC was mixed according to the manufacturer's instructions (powder/liquid ratio 1:1), and in G2, the experimental group (two-layer technique), a first layer of GIC with flowable consistency (powder/liquid ratio 1:2) was applied in the bottom of the cavity. The second layer was mixed according to the manufacturer's instructions (powder/liquid ratio 1:1) and inserted in the cavity before the final setting of the first layer [20]. After adjusting the occlusion, petroleum jelly was applied on the GIC. The presence or absence of adjacent and antagonist teeth was recorded.

Evaluation The restorations were evaluated after 2, 6, 12 and 18 months according to the ART criteria adapted for approximal restorations [17] (Table 1). A restoration was considered as a "failure" when codes 11–40 were registered. Codes 00 and 10 were considered as a "success" and codes 50–91 were assigned when the tooth was unavailable for evaluation. All evaluations were performed by two blinded and independent evaluators, who were trained and calibrated with a "gold standard" [11] regarding the evaluation criteria (Kappa inter-examiners=0.94).

Statistical analysis Statistical analysis was carried out using Stata 11.2 software (StataCorp, Texas, USA). All significant differences were detected at 95 % confidence level. The influence of insertion technique, operator, presence or absence of antagonist and adjacent tooth, tooth surface

Table 1 Evaluation criteria for approximal-ART restorations [17]

Score	Criteria
00	Restoration still present, correct
10	Restoration present, slight defect at the margin and/or wear of the surface; <0.5 mm in depth, no reparation needed
11	Restoration present, defect at the margin and/or wear of the surface; >0.5 mm in depth, repair needed
12	Restoration present; under filled >0.5 mm, no gap, repair needed
13	Restoration overfilled >0.5 mm, repair needed
20	Secondary caries, discoloration in depth, surface hard and intact, caries within dentin; repair needed
21	Secondary caries, surface defect, caries within dentine; repair needed
30	Restoration not present, bulk fracture, moving, (partly) lost; repair needed (if still possible without exposing the pulp)
40	Inflammation of the pulp (restoration still in situ, not categorised in the former categories); fistula or severe pain complaints; extraction needed
50	Tooth not present because of extraction
60	Tooth not present because of shedding
70	Tooth not present because of extraction or shedding; unable to diagnose
90	Patient not present
91	Patient transferred

involved in the restoration, mouth side and jaw (upper or lower teeth) was evaluated in each assessment using Poisson regression analysis.

Kaplan–Meier survival analysis were performed on the censored data for the restoration survival. The difference between survival curves was determined with logrank tests.

Results

After 18 months, the dropout rate was 6 % and it was equally distributed among the groups. One child died, others moved from school or city, or lost the restored tooth by exfoliation or extraction. Of the 208 restored cavities, 110 (53 %) were performed with the conventional technique and 98 (47 %) were performed with the two-layer technique. The overall cumulative survival of the restorations was 68 %; for the conventional group this was 67 % and 68 % for the two-layer group. The survival curves, with censored data, are presented in Fig. 1. Logrank test indicated no significant different between the groups (p=0.8).

The Poisson regression analysis confirmed the absence of significant difference between groups. The operator, presence or absence of antagonist and adjacent tooth, surface of restoration, type of tooth (first or second molar), mouth side and jaw showed no influence on the survival rate of the

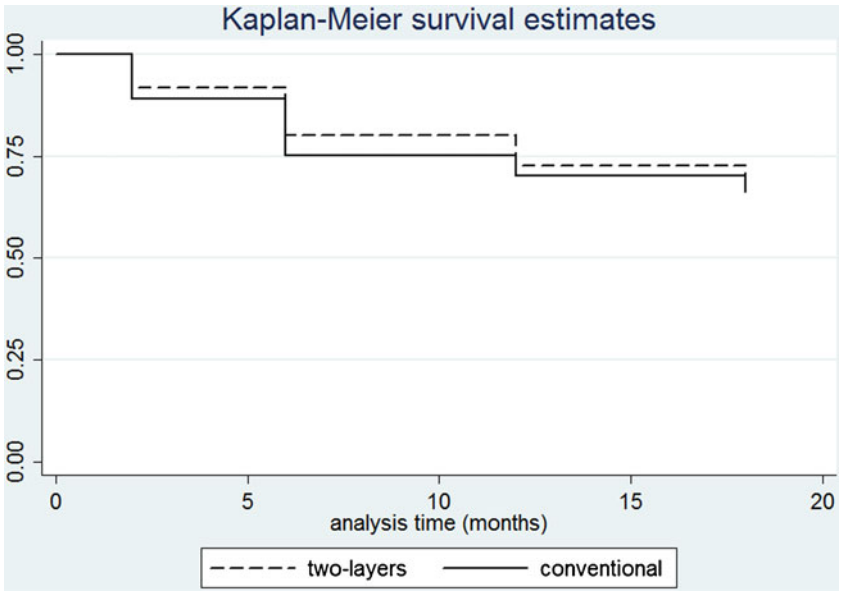

Fig. 1 Kaplan–Meier survival estimates

restorations (Table 2). The majority of failure characteristics were total or partial loss of the restoration (82 %).

Discussion

Conventional glass ionomer cements have been intensively investigated as restorative material for primary molars, and, in general, the results have been disappointing [23]. Although high-viscosity GIC produced much better results than the early conventional materials [5, 24], their consistency may contribute to incorrect cervical adaptation in class II cavities [17–19]. On the basis of promising results from recent laboratory studies [20, 21], we investigated whether inserting GIC using a two-layer technique would improve the survival rate of approximal-ART restorations in a school setting.

After 18 months, our results showed an acceptable survival rate of 68 %. The annual failure rate for permanent molars is reported to be 14 % [25] and this rate is generally higher for primary molars, reported as a weighted mean of 17 % in a meta-analysis [6]. The null hypothesis was not rejected, as the survival rates of approximal-ART restorations performed with one- or two-layer technique in primary molars were similar.

The use of a GIC liner in approximal cavities was first described by McLean and Gasser in 1985 [26]. These authors used either resin composite or amalgam as final restoration, in what is often called "open sandwich" restoration. Because the cervical area of approximal cavities is often difficult to isolate from saliva and gingival fluid, it is more sensitive to secondary caries formation [23]. In an area of such high risk, the use of an intermediate adhesive layer and/or a fluoride releasing material, such as the GIC, is indicated. With high-viscosity GIC, the cervical adaptation was reported to be sub-optimal [17–19]. Laboratory studies testing a flowable GIC layer as a liner suggested that material adaptation to the enamel and bond strength to sound dentin were both increased, and microleakage was reduced [20, 21]. However, these improved laboratory findings did not culminate with any clinical improvement in the survival rate of the restorations when a flowable GIC layer was used.

Irrespective of the insertion technique, the main reason for failure was restoration fracture or loss (n=38). As some material was observed in the bottom of the cavity, most of the restorations failures (90 %) were caused by restoration fractures. We therefore speculate a reason for not finding better success rates for the two-layer group, while the adaptation to tooth structures may have been improved by the two-layer technique, the fracture resistance of the material may have worsened since the reduced powder content of the first layer results in fewer glass particles in the set material. Fonseca et al. [27] reported no difference in the diametral tensile strength of conventional GIC when the powder/liquid ratio was reduced by 50 %; however, Darvell showed that the validity of the diametral strength methodology for brittle materials is low [28].

One possible reason for the absence of difference between the insertion techniques is that the operators, besides being final-year students, were well trained for the restorative technique. We found no operator effect, and for both groups, a reasonable survival rate was observed. Individual differences are expected between the different operators. To prevent that a more sensitive and laborious method would accentuate differences in individual skills, the operators received a comprehensive training not only in ART but also in handling and insertion the GIC for the two-layer technique. This training may have improved their skills in performing approximal-ART restorations in general, making the insertion technique irrelevant. With that, we discourage the use of the two-layer technique. Besides that, the two-layer technique needs additional clinical time, potential problems of isolation and layers adhesion between the two layers and additional material.

Although previous studies have investigated the survival rate of approximal-ART restorations using composite resin [7], different cavity preparation methods [8, 15] and isolation methods [13, 29], none of them significantly reduced the failure rate. Mickenautsch et al. [30] showed in a systematic review that approximal-ART restorations made with high-viscosity GIC or amalgam were equally successful.

Table 2 Variables and corresponding prevalence ratio (PR), calculated with 95 % confidence interval (95 % CI) and p values

Variable	PR	95 % CI	p value[a]
Insertion technique: 2 layers	1.00		0.866
Insertion technique: 1 layer	1.03	0.70 to 1.54	
Operators influence: operator 1	1.00		0.160
Operators influence: operator 2	1.37	0.89 to 2.12	
Operators influence: operator 3	0.52	0.20 to 1.36	
Operators influence: operator 4	1.13	0.60 to 2.11	
Antagonist tooth: absent	1.00		0.578
Antagonist tooth: present	1.19	0.64 to 2.24	
Adjacent tooth: absent	1.00		0.570
Adjacent tooth: present	0.86	0.52 to 1.43	
Surface of restoration: distal	1.00		0.828
Surface of restoration: mesial	1.05	0.65 to 1.70	
Type of tooth: 1st molar	1.00		0.408
Type of tooth: 2nd molar	0.78	0.44 to 1.39	
Mouth side: right	1.00		0.596
Mouth side: left	0.90	0.61 to 1.33	
Jaw: upper	1.00		0.552
Jaw: lower	0.89	0.60 to 1.32	

[a] Calculated by Wald test

Nevertheless, they could also be classificated as equally unsuccessful, as their survival rates were both very low.

Our study suggests that the two-layer technique does not increase approximal-ART restoration longevity. Several authors have reported that the failure of ART restorations may not be attributed to a specific variable but to a combination of factors such as cavity selection and preparation, salivary contamination, restorative material and knowledge and clinical skills of the operator [12–14, 17, 31, 32]. Despite the improved mechanical properties of the high-viscosity GIC, they are difficult to manipulate and to insert into the cavity. The strength of the restorative material or its adaptation into the cavity seems to make no difference when the operators are well trained to use the technique and to manipulate the material [7, 15]. To minimise the cumulative effect of all causes of failure in approximal-ART restorations, we therefore recommend that particular attention should focus on operators' training and on developing alternative self-curing restorative materials with enhanced mechanical properties.

The standing question is whether it is possible to improve the success rate of approximal-ART restorations performed under field conditions to the point that they would be as successful as the ones performed under ideal conditions in private practices [33, 34]. Although an 18-month assessment showed that the two-layer technique using a flowable GIC under another GIC layer did not improve the survival of approximal-ART restoration, the results of ongoing studies may provide more insight into the most researched minimal intervention technique [35, 36] and the appropriate material for approximal restorations.

Acknowledgments We would like to thank the school children, their parents and the staff at the schools and the health service of Barueri for their kind assistance in performing this study. We are very grateful to Malou Schoenmakers, Nicole Sluitman, Kristel Filius and Marieke Herman for their dedication during the operative phase. The contribution of Camila Guglielmi in the process from the set up until the evaluation is much appreciated. We thank Dr. Fausto Mendes for his statistics assistance. We would like to express our gratitude to GC Europe for kindly donating the materials used in this study. This study was partially supported by Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq) #472882/2010-4.

Conflict of interest The authors declare that they have no conflict of interest.

References

1. Frencken JE (2009) Evolution of the ART approach: highlights and achievements. J Appl Oral Sci 17:78–83
2. Molina GF, Cabral RJ, Frencken JE (2009) The ART approach: clinical aspects reviewed. J Appl Oral Sci 17:89–98
3. van Duinen RN, Kleverlaan CJ, de Gee AJ, Werner A, Feilzer AJ (2005) Early and long-term wear of 'fast-set' conventional glass-ionomer cements. Dent Mater 21:716–720
4. Bonifacio CC, Kleverlaan CJ, Raggio DP, Werner A, de Carvalho RC, van Amerongen WE (2009) Physical–mechanical properties of glass ionomer cements indicated for atraumatic restorative treatment. Aust Dent J 54:233–237
5. Frencken JE, Van't Hof MA, Van Amerongen WE, Holmgren CJ (2004) Effectiveness of single-surface ART restorations in the permanent dentition: a meta-analysis. J Dent Res 83:120–123
6. van't Hof MA, Frencken JE, van Palenstein Helderman WH, Holmgren CJ (2006) The atraumatic restorative treatment (ART) approach for managing dental caries: a meta-analysis. Int Dent J 56:345–351
7. Ersin NK, Candan U, Aykut A, Oncag O, Eronat C, Kose T (2006) A clinical evaluation of resin-based composite and glass ionomer cement restorations placed in primary teeth using the ART approach: results at 24 months. J Am Dent Assoc 137:1529–1536
8. Eden E, Topaloglu-Ak A, Frencken JE, van't Hof M (2006) Survival of self-etch adhesive class II composite restorations using ART and conventional cavity preparations in primary molars. Am J Dent 19:359–363
9. Topaloglu-Ak A, Eden E, Frencken JE (2009) Managing dental caries in children in Turkey—a discussion paper. BMC Oral Health 9:32
10. Kemoli AM, van Amerongen WE (2009) Influence of the cavity-size on the survival rate of proximal ART restorations in primary molars. Int J Paediatr Dent 19:423–430
11. Kemoli AM, van Amerongen WE, Opinya G (2009) Influence of the experience of operator and assistant on the survival rate of proximal ART restorations: two-year results. Eur Arch Paediatr Dent 10:227–232
12. Kemoli AM, Opinya GN, van Amerongen WE, Mwalili SM (2011) Two-year survival rates of proximal atraumatic restorative treatment restorations in relation to glass ionomer cements and postrestoration meals consumed. Pediatr Dent 33:246–251
13. Carvalho TS, Sampaio FC, Diniz A, Bonecker M, Van Amerongen WE (2010) Two years survival rate of class II ART restorations in primary molars using two ways to avoid saliva contamination. Int J Paediatr Dent 20:419–425
14. van Gemert-Schriks MC, van Amerongen WE, ten Cate JM, Aartman IH (2007) Three-year survival of single- and two-surface ART restorations in a high-caries child population. Clin Oral Investig 11:337–343
15. Topaloglu-Ak A, Eden E, Frencken JE, Oncag O (2009) Two years survival rate of class II composite resin restorations prepared by ART with and without a chemomechanical caries removal gel in primary molars. Clin Oral Investig 13:325–332
16. da Franca C, Colares V, Van Amerongen E (2011) Two-year evaluation of the atraumatic restorative treatment approach in primary molars class I and II restorations. Int J Paediatr Dent 21:249–253
17. Roeleveld AC, van Amerongen WE, Mandari GJ (2006) Influence of residual caries and cervical gaps on the survival rate of class II glass ionomer restorations. Eur Arch Paediatr Dent 7:85–91
18. Mhaville RJ, van Amerongen WE, Mandari GJ (2006) Residual caries and marginal integrity in relation to class II glass ionomer restorations in primary molars. Eur Arch Paediatr Dent 7:81–84
19. Kemoli AM, Amerongen WE (2011) Effects of oral hygiene, residual caries and cervical marginal-gaps on the survival of proximal atraumatic restorative treatment approach restorations. Contemp Clin Dent 2:318–323
20. Bonifacio CC, van Amerongen WE, Meschini TG, Raggio DP, Bonecker M (2010) Flowable glass ionomer cement as a liner: improving marginal adaptation of atraumatic restorative treatment restorations. J Dent Child (Chic) 77:12–16
21. Lenzi TL BC, van Amerongen WE, Bönecker M, Nogueira FN, Raggio DP (2012) Flowable glass ionomer cement layer bonding

to sound and caries affected primary dentin. Journal of Dental Child (Chicago) (in press)
22. Farag A, van der Sanden WJ, Abdelwahab H, Frencken JE (2011) Survival of ART restorations assessed using selected FDI and modified ART restoration criteria. Clin Oral Investig 15:409–415
23. Tyas MJ (2006) Clinical evaluation of glass-ionomer cement restorations. J Appl Oral Sci 14:10–13
24. Rutar J, McAllan L, tyas MJ (2002) Three-year clinical performance of glass ionomer cement in primary molars. Int J Paediatr Dent 12:146–147
25. de Amorim RG, Leal SC, Frencken JE (2012) Survival of atraumatic restorative treatment (ART) sealants and restorations: a meta-analysis. Clin Oral Investig 16:429–441
26. McLean JW, Gasser O (1985) Glass-cermet cements. Quintessence Int 16:333–343
27. Fonseca RB, Branco CA, Quagliatto PS, Goncalves Lde S, Soares CJ, Carlo HL, Correr-Sobrinho L (2010) Influence of powder/liquid ratio on the radiodensity and diametral tensile strength of glass ionomer cements. J Appl Oral Sci 18:577–584
28. Darvell BW (1990) Uniaxial compression tests and the validity of indirect tensile-strength. J Mater Sci 25:757–780
29. Kemoli AM, van Amerongen WE, Opinya GN (2010) Short communication: Influence of different isolation methods on the survival of proximal ART restorations in primary molars after two years. Eur Arch Paediatr Dent 11:136–139
30. Mickenautsch S, Yengopal V, Banerjee A (2010) Atraumatic restorative treatment versus amalgam restoration longevity: a systematic review. Clin Oral Investig 14:233–240
31. Smales RJ, Yip HK (2002) The atraumatic restorative treatment (ART) approach for the management of dental caries. Quintessence Int 33:427–432
32. van den Dungen GM, Huddleston Slater AE, van Amerongen WE (2004) ART or conventional restorations? A final evaluation of proximal restorations in deciduous molars. Ned Tijdschr Tandheelkd 111:345–349
33. Scholtanus JD, Huysmans MC (2007) Clinical failure of class-II restorations of a highly viscous glass-ionomer material over a 6-year period: a retrospective study. J Dent 35:156–162
34. Friedl K, Hiller KA, Friedl KH (2011) Clinical performance of a new glass ionomer based restoration system: a retrospective cohort study. Dent Mater 27:1031–1037
35. Holmgren CJ, Frencken JE (2009) Conclusions from the symposium: two decades of ART: success through research. J Appl Oral Sci 17:134–136
36. Frencken JE, Leal SC, Navarro MF (2012) Twenty-five-year atraumatic restorative treatment (ART) approach: a comprehensive overview. Clin Oral Investig 16(5):1337–1346