Clinical Evaluation of Multiple-Surface ART Restorations: 12 Month Follow-up

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ABSTRACT

Purpose: The purpose of this study was to evaluate the performance of multiple-surface restorations employing 2 different glass ionomer cements (GICs) and the Atraumatic Restorative Treatment (ART) approach in permanent molar teeth.
Methods: This study examined 60 restorations—36 Class I restorations involving 2 or more tooth surfaces and 24 Class II restorations—that were placed in 46 schoolchildren (9-16 years of age) by 2 dentists using the ART approach. The restorations were randomly divided into 2 groups: (a) 30 cavities were filled with high strength GIC (Ketac Molar-3M ESPE), and (b) 30 cavities were filled with resin-modified GIC (Fuji VIII-GC Corp). Two independent calibrated examiners carried out the evaluations according to ART criteria. The interexaminer kappa was 0.92. Data were submitted to chi-square, McNemar, and Fisher's tests. A difference was statistically significant if $P<.05$.
Results: In a 12-month follow-up, 59 restorations were evaluated. The success rates of the restorations were 100% and 93% for Fuji VIII and Ketac Molar, respectively. There was no statistically significant difference between GICs, cavity types, or operators.
Conclusions: Based on a 12-month follow-up evaluation, the clinical performance of the multiple-surface atraumatic restorative treatment restorations of both glass ionomer cements (high-strength and resin-modified) was considered satisfactory with a high success rate.
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KEYWORDS: ATRAUMATIC RESTORATIVE TREATMENT, GLASS IONOMER CEMENTS, RESTORATIONS

Atraumatic restorative treatment (ART) is an approach to the management of dental caries that was originally developed to provide dental treatment outside the traditional clinical setting.[1] ART combines the preventive component with the restorative procedure.[1] ART involves the removal of infected tooth tissues with hand instruments, restoration of the cavity, and sealing of adjacent pits and fissures with glass ionomer cement (GIC).[1]

Studies on use of the ART approach have shown a large variation in the survival of ART restorations.[2-9] After 1 year, the survival rates were high for single-surface restorations placed in permanent (93%-96%)[2-4,7,9] and primary (82%-95%)[4-6,8,10] dentition. On the other hand, the success rate of multiple-surface ART restorations in the same period was about 67%$_4$ in permanent and 55% to 75% in primary teeth.[4-6,8] Many reasons have been proposed to explain the high failures of the GIC restorations placed in multiple-surface cavities in primary and permanent dentition. These include, large cavity sizes, operator inexperience, inadequate caries removal, inadequate retention, blood and salivary contamination and mechanical properties of the GIC.[1,4-8,11] It is reasonable to assume that multiple-surface restoration survivals are more dependent on the material, operator, and environment compared with single-surface restoration.[12]

Based on these findings, efforts to improve the performance of these restorations have been made, resulting in the formulation of new GICs specially developed for the ART approach.[13-15] The introduction of high-strength GIC (HS GIC) was intended to extend the indication of conventional

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GICs to posterior restorations, due to their superior wear resistance, compressive and flexural strength, surface hardness and lower solubility.[13,14] As an alternative, other studies reported that the resin-modified GIC (RM GIC) luting at increased powder/liquid ratio would be an option as a filling material under circumstances where electricity is not present.[16] These studies should be viewed with caution, because if RM GIC luting is mixed with powder/liquid variations, the properties of the RM GIC will change slightly and may be disregarded, given the inaccuracy of proportioning aids.[18] A new chemically cured RM GIC, known as Fuji VIII (GC Corp), has been manufactured specifically for the ART approach as a filling material for anterior teeth and without the need of electricity and high-technology equipment.

This study's purpose was to compare the clinical performance of 2 GICs using the atraumatic restorative treatment approach. High-strength glass ionomer cement (Ketac Molar, 3M ESPE, Seefeld, Germany) was used as a control group, and resin-modified glass ionomer cement (Fuji VIII, GC Corp, Tokyo, Japan) as the test group to restore multiple-surface cavities in the permanent teeth of schoolchildren. The null hypothesis to be tested was that there is no difference in the survival of multiple-surface ART restorations with both GICs in the permanent dentition after 12 months.

METHODS

SAMPLING PROCEDURE

This study was approved by the Local Ethics Committee of Baurú School of Dentistry, University of Sao Paulo, SP, Brazil (protocol no. 08/2001), according to the guidelines of the Declaration of Helsink (Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects). The schoolchildren's parents were informed of the study and were free to decide if their children would participate. The participating children were then screened clinically to assess their treatment needs. Children were included in this study only after parental or guardian consent with the respective signatures on the consent forms were given.

The inclusion criteria were the presence of dentinal lesions involving two or more surfaces in a posterior permanent tooth that had an opening wide enough for the smallest excavator to enter (Ø=0.9 mm). Exclusion criteria were pulp exposure, history of pain, presence of a swelling or fistula and cases judged to be unrestorable according to ART guidelines.[1] Patients with teeth in such conditions were advised to seek care in a basic health center.

IMPLEMENTATION

For the present study, two schools were selected on the basis of the poor oral health status of their students. Two operators, both PhD students, and one chairside assistant previously trained and calibrated on the ART approach carried out all the clinical procedures.[1] Prior to being treated, all children received instructions regarding oral health and were shown how to clean their teeth on an individual basis by trained oral health educators.

Each child had a record that included name, address, phone number, age, school registration number, medical history and dental history.

CLINICAL PROCEDURES

This study's sample consisted of 60 posterior permanent teeth divided into two groups: the control group, comprising 30 cavities filled with HS GIC (Ketac Molar); and the test group, comprising 30 cavities filled with RM GIC (Fuji VIII).

Table 1. Specifications of the GICs Tested Glass ionomer cements

Product	Manufacturer	Composition	Batch no.
Ketac Molar	3M ESPE, Seefeld, Germany	Powder: Calcium aluminum lanthan fluorosilicate glass, acrylic acid, maleic acid, copolymer, pigments Liquid: Acrylic acid, maleic acid, copolymer, tartaric acid	0108677
Fuji VIII	GC Corporation Tokyo-Japan	Powder: Fluoro-alumino-silicate glass pigment Liquid: Distilled water, polyacrylic acid, 2-HEMA, dimethacrylate, initiator	0107031

The GICs' specifications are summarized in Table 1. The teeth and GICs were chosen randomly.

The treatment was carried out inside classrooms at the selected schools using hand instruments only and portable light. Patients were positioned on a table combined with a foldable cushion and a soft headrest to achieve a proper patient-to-operator position. Cotton wool rolls were used for isolation, according to the ART approach guidelines. The tooth surface was cleaned with a wet cotton pellet for removal of debris and plaque. Cavity access was achieved using an enamel hatchet (Duflex-SS White, Petrópolis, Brazil). The next step was the removal of infected tissue with an excavator (Duflex-SS White, Petrópolis, Brazil), first at the enamel-dentin junction (EDJ) and then from the floor of the cavity. Retention niches were made on the axiobuccal and axiolingual line angles of the proximal box with a special hand instrument (Flat 0-Carisolv™, MediTeam, Sävedalen, Sweden).

The cavity was then cleaned with a small cotton pellet soaked in water and dried with a dry cotton pellet (Cremer, Blumenau, Brazil). When necessary, pulpal protection with a calcium hydroxide cement was used in deep cavities (Hydro C, Dentsply, Petrópolis, Brazil). The conditioning of the tooth structure was carried out for 10 seconds with a cotton pellet saturated with the liquid component of Ketac Molar

for the control group and with the dentin conditioner for the test group (GC Corp, Tokyo, Japan). The conditioned surfaces were then washed with cotton pellets soaked in water and dried with dry cotton pellets. A Tofflemire matrix (Ultrathin, Elk Grove Village, Ill) was placed with a metal strip (TDV Dental, São Paulo, Brazil) covered with a thin layer of petroleum jelly (Sidepal, Guarulhos, Brazil) on the inner surface to avoid a chemical reaction between the GIC and the matrix. Then, matrix was established with wedges (TDV Dental, São Paulo, Brazil). The GICs were mixed according to the manufacturer's instruction and placed into the cavity using the smooth side of a spoon excavator (Duflex-SS White, Petrópolis, Brazil). Petroleum jelly was used to coat the operator's gloved finger and a slight pressure was applied on top of the entire occlusal surface for 30 seconds. This "press-finger" technique was used to condense the material into the cavity and any adjacent pits and fissures, resulting in a sealant restoration. GIC excess was removed with a spoon excavator or carver instruments (Duflex-SS White, Petrópolis, Brazil).

After initial hardening of the material, the occlusion was checked with articulating paper (AccuFilm II, Farmingdale, NY) and, if necessary, adjusted with a carver. Two layers of varnish (Copalite, Cooley & Cooley, Houston, Tex) were applied over the restoration to prevent dehydration. The patient was instructed not to eat for at least 1 hour. Local anesthesia was used only when patients reported discomfort. Table 2 details the class type of the restorations according to Black's classification.

Table 2. Distribution of Restorations According to Class Type*

	Class I		Class II	
	Involving ≥2 tooth surfaces			
	Ketac Molar	Fuji VIII	Ketac Molar	Fuji VIII
No. of restorations	17	19	13	11
Total	36		24	

** Chi–square=0.277; P=.598.*

EVALUATION

The clinical evaluation was carried out at baseline, 6 months, and 12 months by 2 independent calibrated examiners not involved in the treatment.

Initially, visible debris and plaque were removed with the aid of an explorer (Duflex-SS White, Petrópolis, Brazil). The teeth were cleaned with a small cotton pellet soaked in water and dried using a dry cotton pellet. Clinical evaluation was performed using World Health Organization periodontal probes, sharp sickle-shaped explorers, plane front-surface mirrors, and a light source. The criteria used to evaluate the ART restorations were those of a previous study and are given in Table 3.[5] The ball of the CPI probe (Ø=0.5 mm) was used to measure the size of any marginal defect and the amount of wear.

Table 3. Evaluation Criteria for ART Restorations5*

Score	Description
0	Present, in good condition
1	Present, slight marginal defect, no repair is needed
2	Present, slight wear, no repair is needed
3	Present, marginal defect >0.5 mm, repair is needed
4	Present, wear >0.05 mm, repair is needed
5	Not present, restoration partly or completely missing
6	Not present, restoration replaced by another restoration
7	Tooth is missing, exfoliated, or extracted
8	Restoration not assessed, child is not present

**Success=scores 0–2; failure=scores 3–6; excluded=scores 7–8.*

DATA ANALYSIS

Descriptive statistics was used with the chi-square test. This analysis included the computation of mean, median, and standard deviation for the continuous variables. McNemar test was used to assess statistically significant differences between evaluation periods. The Fisher test was used for comparisons between materials, operators, and cavity types. A difference was considered statistically significant if $P<.05$. Interexaminer agreement was assessed with kappa coefficient values.

RESULTS

BASELINE

A total of 46 schoolchildren, with a mean age of 11.6±1.6 years (range=9-16 years) participated in this study. The mean DMFT was 3.48 (1.77±SD), with 82% of the index related to decayed teeth.

The first operator placed 34 restorations, whereas the second placed 26. This difference was not significant (chi-square<.01; $P=.80$). The restorations were placed in first and second permanent molars. More restorations were placed in the lower (65%) than in the upper jaw (35%), with the majority in first molars (82%) compared to second molars (18%). The percentage of girls and boys was 59% and 41%, respectively. No statistically significant differences were found between the test (Fuji VIII) and control (Ketac Molar) groups regarding, age (chi-square=1.16; $P=.45$), (2) gender (chi-square=1.09; $P=.43$), (3) jaw (chi-square=0.66; $P=.59$), and (4) molar type (chi-square=0.42; $P=.75$).

Local anesthesia was required only in 4 treatments. In 12 deep cavities, a thin layer of calcium hydroxide was applied over the deep spots.

Only 10% of the children indicated they had experienced a slight pain or discomfort during the treatment. Postoperative discomfort was reported by 6% of the children. Ninety percent of the patients were willing to undergo ART restorations again should a need arise.

FOLLOW–UP

At the 6- and 12-month follow-ups, the overall success rate of the treatment was 98% and 97%, respectively. The suc-

cess rates of the restorations were 100% and 97% for Fuji VIII and Ketac Molar, respectively, at the 6-month follow-up. There was no statistically significant difference between baseline and 6 months (McNemar: chi-square=.00; *P*=1.00. No significant differences were found in the same period between materials (Fisher test; *P*=1.00), cavity types (Fisher test; *P*=1.00) and operators (Fisher test; *P*=1.00).

At the 12-month follow-up, the success rates of the restorations were 100% and 93% for Fuji VIII and Ketac Molar, respectively. There was no statistically significant difference between baseline and 12 months (McNemar test: chi-square=0.50; P=.48). No significant differences were found between materials (Fisher test; *P* =.24), cavity types (Fisher test; *P*=1.00) and operators (Fisher test; *P*=1.00). Table 4 summarizes the status of the ART restorations at the baseline, 6-month and 12-month evaluation periods, according to the Class type.

Results of the duplicate examinations on restoration status showed very good interexaminer reproducibility, with kappa values of 1.00 and 0.92 in the evaluations after 6 and 12 months, respectively.

addition of retention niches combined with the use of GICs more suited for stress-bearing situation.

The creation of retention niches and the meticulous care with removing carious dentine from EDJ may provide more adequate mechanical retention by increasing the surface area for chemical adhesion of the GICs. On the other hand, it is important to emphasize that mechanical interlocking of those materials could avoid displacement of GIC restorations and increase the strength of the multiple-surface ART restorations. These suggestions are relevant because the high quality of the tooth/GIC interface provides tooth surfaces capable of developing durable adhesive bonds to GIC.[20] This study's results were similar, regardless of the GIC tested. As the present study is the first in which multiple-surface ART restorations with retention niches were tested, there are not references in the literature concerning the influence of retention niches in these restorations.

Comparing the performance of the two GICs marketed specifically for use with the ART approach, the survival of the multiple-surface ART restorations was not significantly different statistically after 12 months. Thus, the null hypothesis was accepted. Even though Fuji VIII had been developed for anterior restorations, whereas Ketac Molar is indicated for anterior and posterior restorations, Fuji VIII was tested as a material for posterior restoration because it is the only RM GIC developed specifically for this approach. On other hand, a recent study reported that, after 6 months, RM GIC (Vitremer, 3M ESPE, Seefeld, Germany) exhibited better clinical performance than HS GIC (Ketac Molar, 3M ESPE), except for marginal discoloration.[21] Since the ART approach can be performed without electricity and is suited for communities in which resources are scarce, the inclusion of the light curing for polymerizing RM GIC (Vitremer, 3M ESPE) in this approach could be questioned.

Table 4. Status of the multiple-surface ART restorations after 6 and 12 months (expressed in numbers)

	Class I: Involving ≥2 tooth surfaces						***Class II***					
	Ketac Molar*			**Fuji VIII**			**Ketac Molar**			**Fuji VIII**		
	Baseline	6 mos	12 mos	Baseline	6 mos	12 mos	Baseline	6 mos	12 mos	Baseline	6 mos	12 mos
Score	**(N=17)**	**(N=16)**	**(N=16)**	**(N=19)**	**(N=19)**	**(N=19)**	**(N=13)**	**(N=13)**	**(N=13)**	**(N=11)**	**(N=11)**	**(N=11)**
0	17	16	15	19	19	19	13	12	9	11	11	10
1	--	--	--	--	--	--	--	--	3	--	--	1
2	--	--	--	--	--	--	--	--	--	--	--	--
3	--	--	1	--	--	--	--	--	--	--	--	--
6	--	--	--	--	--	--	--	1	1	--	--	--

**** Control group: 1 restoration was not evaluated at the 6-month follow-up (score 8=excluded).***
McNemar test: Chi-square=0.00; P=1.00 at the 6-month follow-up.
McNemar test: Chi-square=0.50; P=.48 at the 12-month follow-up.

DISCUSSION

In this study, 59 of the 60 restorations were evaluated at the 12-month follow-up. The drop-out-rate was very low (2%; patient moved to another city) compared with previous ART studies that showed 9%[2] and 33%[4] over the same evaluation period. According to Chadwick et al,[19] the main reason that patients could not be evaluated was that the child moved to other parts of the city, rural areas or other cities. It is worth mentioning that the evaluation of approximately 30% of the patients was difficult due to the schoolchildren's irregular school attendance. The low lost-to-follow-up rate was possible by particular attention given to the patient's chart. This action was made with visits to the new school or patient's homes.

After 12 months, the success rates for multiple-surface ART restorations using HS GIC and RM GIC were very promising and the earlier trend observed after 6 months had continued.[15] The success rate was probably due to the

In the present study, all restorations were recorded as successful for RM GIC (Fuji VIII) and 2 out of 29 HS GIC (Ketac Molar) restorations were recorded as failures. One restoration was replaced by another material, and the other presented with a marginal defect. The child's mother reported that replacement of the restoration occurred 4

months after the treatment because the son felt pain, so that endodontic treatment was required. The pulpal involvement occurred probably because it is not possible to predict the lesion depth with precision in the ART approach. This tooth had deep carious lesions as well as an absence of signs or symptoms of pulp degeneration and spontaneous pain. Also, the tooth was judged only by clinical criteria, since no X ray was used, therefore an accurate diagnosis was difficult. Despite the fact that endodontic treatment had been required in this case, the remaining 11 teeth with deep carious lesions, in which calcium hydroxide cement was also applicated, responded favorably to maintain pulp vitality. The other restoration recorded as a failure presented a marginal defect higher than 0.5 mm. In such a case, one occlusal site did not present enough bulk. This problem probably contributed to the marginal defect of the restoration, but caries adjacent to the restoration was not observed.

Other important aspect to be considered in the success rate of ART restorations, especially multiple-surface, is the presence of the assistant. In this manner, the operator could spend more time on saliva control after conditioning, while the assistant was mixing the GICs. This assumption agrees with other researchers who have reported difficulty in controlling cavity contamination from saliva or blood in cavities with margins close to the cervical area, thereby having a detrimental effect on bonding of the GICs.[5,16]

In the present study, similar success rates were achieved by both operators. Some ART studies have reported an operator effect on the success rate of the treatment.[2,3,7,16] In those studies, the outcomes revealed that less-experienced operators obtained worse results compared with experienced ones.[2,3,7,16] Frencken et al[22] emphasized that the operators in the early ART studies had not been specifically trained in this approach, while those of the later studies had attended a structured ART training course. This study's findings corroborate this statement, since the operators received adequate training in the ART approach.

It was particularly encouraging to find that over 90% of the children were willing to receive ART restorations again should a need arise. This very high acceptance of the ART approach by patients is undoubtedly attributable to the non-use of rotary instruments and local anesthetic was required only in 4 of 60 treatments. These factors may explain why the treatment was so acceptable and are in agreement with previous studies.[2,3,5,23]

Although the early 12-month findings are promising, more studies of longer duration are needed to confirm these results.

CONCLUSIONS

Based on this study's results, the following conclusions can be made:

1. The atraumatic restorative treatment (ART) approach was highly appropriate, effective, and acceptable for multiple-surface restorations at the 12-month follow-up.
2. The high survival of multiple-surface ART restorations was independent of the glass ionomer cements tested.

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