

Clinical Evaluation of Atraumatic Restorations in Primary Molars: A Comparison Between 2 Glass Ionomer Cements

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ABSTRACT

Dental caries continues to be a highly prevalent disease among Brazilian preschoolers, especially those with low socioeconomic status. The purpose of this randomized, controlled trial was to evaluate in vivo 245 simplified restorations in deciduous molars using glass ionomer cements (Vidrion R and Ketac-Molar). Dental restorations were evaluated at 6- and 12-month follow-ups. The teeth restored with Vidrion R (SS White) on a single tooth surface were successful in 87% of the cases evaluated at 6 months and in 63% at 12 months. The teeth restored with Ketac-Molar on one surface achieved a success rate of 95% at 6 months and 82% at 12 months. No recurrent caries or pulpal infection was evident. Logistic regression analysis demonstrated that teeth with cavities restricted to the occlusal surface on sclerotic dentin showed the best adhesion to the restorative material. The restorations with Ketac-Molar had a better clinical performance than those with Vidrion R. (J Dent Child 2006;73:91-97)

KEYWORDS: ATRAUMATIC RESTORATIVE TREATMENT, PRIMARY TEETH,
GLASS IONOMER CEMENT, DENTAL CARIES

Tooth decay is still a public health problem among preschool children of poor background in Brazil.^{1,2} A restorative technique, referred to in the literature as atraumatic technique,³ was chosen to treat carious deciduous molars in preschoolers in the city of Aracaju, Brazil. This technique uses fewer instruments and is less invasive, quicker to perform, and inexpensive compared to the conventional procedure, favoring the psychological management of treatment in childhood, eliminating pain, and contributing to the re-establishment of health.⁴ In this technique, the decayed tissue is removed manually and the cavity is filled with adhesive material. The material of choice is glass ionomer cement (GIC), owing to its biocompatibility properties, chemical adherence to the dental tissues, and coefficient of thermal expansion similar to that of the tooth and supposed fluoride release.

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The main indications for the use of glass ionomer cement are in pediatric dentistry, in view of the simultaneous wear and tear of the material and the physiological wear of deciduous teeth.⁵

Atraumatic restorations for deciduous teeth have not been well evaluated, in spite of the fact that some reviews have shown good clinical results. Since this technique has the potential for being particularly useful with small children, further research is required in this area.⁶

The purpose of the present study was to evaluate the atraumatic restorative technique for the treatment of caries in deciduous molars. Two glass ionomer cements were used to restore cavities in children from 4 to 6 years of age in the city of Aracaju, Brazil. Restorations were evaluated after 6 and 12 months.

METHODOLOGY

This was a clinical, randomized, double-blind, controlled trial. The evaluations were performed at 6- and 12-month intervals.

STUDY POPULATION

The sample consisted of 245 primary carious molars in dentin, affecting 110 patients 4 to 6 years old. The inclusion criteria for this study were:

1. no current systemic diseases;
2. no current use of medications;
3. no history of spontaneous toothache; and
4. at least one tooth presenting with a carious lesion in dentin.

The selected tooth to be treated should not have any physiological or pathological mobility, and its antagonist should be present.

The dropouts were:

1. patients not found at the 6- or 12-month recall evaluation;
2. those whose restored teeth had exfoliated; and
3. those whose restorations were lost and replaced in another health center.

Ethical approval was obtained from the Ethics Committee of the University of Pernambuco, Recife, Brazil.

DEFINITION OF THE INTERVENTION GROUPS

The experimental groups and the control groups were established according to the tooth surface to be treated and the brand of restorative cement used and were selected by random and double-blinded methods as follows:

1. group 1—cavity placed in 1 surface (occlusal) and restored with the Vidrion R GIC (SS White, Senador Alencar, Rio de Janeiro, Brazil; 43 teeth);
2. group 2—cavity placed in 2 surfaces (occlusal-proximal or occlusal-lingual) and restored with Vidrion R GIC (72 teeth);
3. group 3—cavity placed in 1 surface (occlusal) and restored with the Ketac-Molar GIC (3M ESPE, Seefeld, Germany; 45 teeth);
4. group 4—cavity placed in 2 surfaces (occlusal-proximal or occlusal-lingual) and restored with the Ketac-Molar GIC (75 teeth);
5. group 5—cavity placed in 3 or 4 surfaces (proximal-occlusal-buccal or proximal-occlusal-lingual) and restored with the Vidrion R GIC (4 teeth);
6. group 6—cavity placed in 3 or 4 surfaces (proximal-occlusal-buccal or proximal-occlusal-lingual) and restored with the Ketac-Molar GIC (6 teeth).

All the procedures were performed by the same operator, with the help of a dental assistant (DA), and the materials were manipulated according to the manufacturer's instructions.

The atraumatic technique was performed without local anesthesia and the field was kept dry by the use of a saliva ejector and cotton rolls. Sharp excavators were used to remove the soft decayed tissue. To avoid pulpal exposure in deep cavities, the remaining dentin was left.

After the teeth were conditioned using Ketac-Molar GIC or Vidrion R conditioner, they were washed and dried.

In case of restorations involving 2 tooth surfaces, a previously cut-out and slightly curved 0.5-mm steel matrix was

used, adapted to the proximal surface of the tooth and held in place with a wooden wedge.

The cement was inserted into the cavity by pressing with a petroleum jelly-coated gloved finger to prevent the formation of bubbles and improve the cement's adaptation to the cavity walls.

Excess material was removed with a Hollenback carver. The occlusion was checked with blue paper, and the restorations were subsequently protected from moisture and dehydration with a layer of colorless nail polish.^{1,7} The patient was advised not to chew solids for 1 hour after the restoration was placed.

RANDOMIZATION AND RESTORATIVE TECHNIQUE

The selection of children consisted of a convenience sample who presented to the clinic. The procedure was randomized as follows:

1. After entering the clinic, the child randomly drew a slip of paper marked with letters A or B, which stood for materials to be applied to the tooth.
2. This slip of paper was returned to the jar.
3. The clinical procedure was registered in the clinical record, which was blinded for the dentist until the end of the study.

To double blind the study, the dental assistant received a bottle of GIC already labeled with the letter A and another bottle labeled with the letter B from an independent person not involved in this study.

Since the manipulation of the GICs was made by this same dental assistant (who did not know which GIC was letter A or B) and since they looked and felt the same for the operator, neither the operator nor the patient could distinguish which glass ionomer was being used.

FOLLOW-UP ASSESSMENTS

Six- and 12-month evaluations were carried out. One calibrated evaluator, who played no part in the trial, assessed the restorations by means of images taken by a Sony Mavica FD90 (Sony Corp, United States) with a magnification of X16. This assessment was performed just after the restorations were placed and at 6- and 12-month intervals.

The following scale was used in evaluating the restorations:

- 0= satisfactory; in place, without clinically visible alterations.
- 1= satisfactory; in place, little wear, gap without exposure of dentin, not needing repair.
- 2= unsatisfactory; in place, waste or rift with dentin exposure, needing repair.
- 3= unsatisfactory; missed; total loss of the restoration.
- 4= missing; missed and replaced.

Duplicate examinations were performed with an interval of 15 days between the first and the second examinations using a Power Point file containing 26 teeth to establish the intraexaminer reliability. The kappa value was 0.90.

STATISTICAL ANALYSIS

For the data analysis, EPI INFO version 6.04d (CDC, United States) and SAS for Windows 8 (SAS Institute Inc, Cary, NC) were used. The differences between the proportions were compared using the chi-square test with or without the Yates correction and with the statistical significance being smaller than or equal to 5%.

The degree of accuracy of the logistic regression model was evaluated via the chi-square test for the likelihood ratio to test the null hypothesis, with a P value lower than or equal to 5% being considered statistically significant. For each model, the following values were presented: beta coefficient, odds ratio estimate, confidence interval of 95%, and the P value corresponding to the chi-square test for each variable included in the final model.

RESULTS

The study sample consisted of 110 children from 4 to 6 years of age—41 (37%) males and 69 (63%) females. The 245 teeth were randomly divided into 6 groups, according to the proposed groups. The total loss by the end of the study was 46 teeth (19%; Table 1).

In groups 5 and 6, the number of teeth suitable for inclusion in the trial was insufficient because of early pulpal exposure. The number of treated molars was, therefore, reduced to avoid compromising the statistical analysis. Groups 5 and 6 were excluded, and groups 1, 2, 3, and 4 were left for comparison, comprising a total of 235 treated teeth.

There was no report of postoperative pain indicative of irreversible pulp pathology, and none of the patients presented with a fistula, swelling of periodontal tissues, or enhanced tooth mobility.

The majority of teeth had contaminated dentin (82%), as opposed to sclerotic dentin (18%). Group 4 (Ketac-Molar, 2 surfaces) presented with the highest percentage of contaminated dentin (91%); and group 1 (Vidrion R, 1 surface) had the highest percentage of restorations lined by sclerotic dentin (37%; Table 2).

Figure 1 shows the distribution of the scores attributed to each group at the 6-month follow-up. The fillings placed in a single tooth surface (groups 1 and 3) most frequently presented the best score (0), at 58% and 76%, respectively, at the 6-month follow-up.

Table 1. Number and Percentile Distribution of the Molars Treated by Each Glass Ionomer Cement and Number of Surfaces Involved and Losses after 6 and 12 Months

Groups	Start	6-mo evaluation		Losses at 6 mos		12-mo evaluation		Losses at 12 mos		Total losses	
	n	n	%	n	%	n	%	n	%	n	%
Vidrion R: 1 surface	43	38		5	12	35		3	8	8	19
Vidrion R: 2 surfaces	72	61		11	15	56		5	8	16	22
Ketac-Molar: 1 surface	45	41		4	9	39		2	5	6	13
Ketac-Molar: 2 surfaces	75	67		8	11	64		3	5	11	15
Vidrion R: 3 or 4 surfaces	4	3		1	25	2		1	33	2	50
Ketac-Molar: 3 or 4 surfaces	6	5		1	17	3		2	40	3	50
Total	245	215		30	12	199		16	7	46	19

Table 2. Number and Percentile Distribution of the Type of Dentin Left Lining the Cavity by Each Group

Groups	Dentin type					
	Contaminated		Sclerotic		Total	
	n	%	n	%	n	%
Vidrion R: 1 surface	27	63	16	37	43	18
Vidrion R: 2 surfaces	59	82	13	18	72	31
Ketac-Molar: 1 surface	38	84	7	16	45	19
Ketac-Molar: 2 surfaces	68	91	7	9	75	33
Total	192	82	43	18	235	100

Table 3. Number and Percentile Distribution of Results of Each Glass Ionomer Cement and Number of Surfaces Involved at 6-month Evaluation

Result	Vidrion R: 1 surface		Vidrion R: 2 surfaces		Ketac-Molar: 1 surface		Ketac-Molar: 2 surfaces	
	n	%	n	%	n	%	n	%
Satisfactory (score 0 and 1)	33	87*	30	49†	39	95*	43	64†
Unsatisfactory (score 2 and 3)	5	13	31	51	2	5	24	36
Total	38	100	61	100	41	100	67	100

*For comparison of Vidrion R—1 surface with Ketac-Molar—1 surface: chi-square=0.81 with the Yates correction, $P=.3693$ (not statistically significant).

†For comparison of Vidrion R—2 surfaces with Ketac-Molar—2 surfaces: chi-square=2.93, $P=.0869$ (not statistically significant). $P<.05$ =statistically significant.

At 12 months, the proportion of satisfactory results (scores 0 and 1) dropped for all groups, especially those involving 2 tooth surfaces. Only 4% of group 2 and 11% of group 4 patients had their restorations in place without clinically visible alterations (score 0; Figure 2).

For better understanding of the results and to make the statistical analysis possible, the scores were then collapsed into the categories “satisfactory” (scores 0 and 1) and “unsatisfactory” (scores 2 and 3).

The clinical outcomes of the atraumatic restorations in primary molars restored with GIC were often considered satisfactory for cavities involving one surface, regardless of the material used (Tables 3 and 4).

Except for group 3 (Ketac-Molar, 1 surface), a statistically significant decrease of the satisfactory results was observed at the 12-month interval.

Attention should be drawn to the restorations placed in 2 tooth surfaces (groups 2 and 4), which showed lower scores (Table 5).

The logistic regression analysis for all the variables in relation to the chance of satisfactory results at 6 and 12 months indicated that the group and the surface type were statistically significant. Ketac-Molar restorations involving 1 surface (occlusal) presented the best outcomes (Tables 6 to 8). Other factors such as age, tooth type, number of treated teeth per child, and child's gender were also measured, but did not achieve statistical significance.

DISCUSSION

Prevention of caries has always been recommended, but in practice patients often present with advanced carious lesions. In many countries, the main method for treating dental caries is the extraction of the diseased tooth. Despite conventional treatment and prevention techniques for dental caries having been long known, in many locations they are either not available, not affordable, or require sophisticated, expensive equipment and extensively trained personnel.⁸

Conventional guidelines usually recommend complete removal of carious dentin and restoration of the cavity or placement a crown when the cavity preparation and the resultant outline form is large. Besides the increased cost, the complete removal of carious dentin from deep caries lesions may result in invasion of bacteria into the pulp by mechanical exposure.

Investigations into the caries process led to a better understanding of its dynamics. This has, in turn, resulted in a shift from the traditional approach of maximum intervention and the use of amalgam to the approach of minimal intervention and invasion, maximum caries prevention, and the use of adhesive restorative materials.²

One of these concepts is the atraumatic restorative treatment. It is based on removing infected tooth material using only hand instruments and filling the subsequently cleaned cavity with adhesive material such as glass ionomer.⁶

Table 4. Number and Percentile Distribution of Results of Each Glass Ionomer Cement and Number of Surfaces Involved at 12-month Recall

Result	Vidrion R: 1 surface		Vidrion R: 2 surfaces		Ketac-Molar: 1 surface		Ketac-Molar: 2 surfaces	
	n	%	n	%	n	%	n	%
Satisfactory (score 0 and 1)	22	63*	10	18†	32	82	20	31†
Unsatisfactory (score 2 and 3)	13	37	46	82	7	18	44	69
Total	35	100	56	100	39	100	64	100

*For comparison of scores 0 and 1 for Vidrion R-1 surface with Ketac-Molar-1 surface: chi-square=3.45, P=.0634 (not statistically significant).

†For comparison of scores 0 and 1 for Vidrion R-2 surfaces with Ketac-Molar-2 surfaces: chi-square=2.86, P=.0909 (not statistically significant). P<.05=statistically significant.

Table 5. Percentile of Satisfactory Results at 6 and 12 Months for Each Glass Ionomer Cement and Number of Surfaces Involved

Satisfactory result	6 mos (%)	12 mos (%)	Chi-square test	P value	Statistical significance
Vidrion R: 1 surface	87	63	5.64	.0175	SS*
Vidrion R: 2 surfaces	49	18	12.70	.0003	SS*
Ketac-Molar: 1 surface	95	82	2.24	.1348	NSS†
Ketac-Molar: 2 surfaces	64	31	14.20	.0001	SS†

*Statistically significant.

†Not statistically significant. P<.05=statistically significant.

Table 6. Logistic Regression Analysis Results for Each Group and Surface Type, in Relation to Achieving Satisfactory Results at 6-month Follow-up

Variables	Coefficient (B)	Odds ratio estimate	95% confidence interval	Chi-square test P value	Statistical significance
Groups*	0.7245	2.064	1.079-4.013	.0364	SS†
Surface type‡	2.0292	7.608	3.389-19.579	<.0001	SS

*Comparison between groups 1 and 2 (Vidrion R) with 3 and 4 (Ketac-Molar).

†Statistically significant. P<.05=statistically significant.

‡Comparison between occlusal surface with 2 tooth surfaces.

The 46 (19%) lost to follow-up restorations by the end of the study's 12 months was partially caused by the study subjects moving to another school. This was a low-income population, most of whom did not have a contact phone number. The dropout rate among subjects is similar to that seen in other studies and did not impact this study's results.⁹

No recurrent dental caries was observed in any of the treated teeth, which may be attributed to the release of fluoride by this kind of dental material cited in a number of studies.¹⁰⁻¹³ Other longitudinal follow-up trials on atraumatic restorative techniques, however, have reported the presence of recurrent caries on the margins of restorations performed with GIC.^{14,15}

Cavity size does affect the survival of restorations: The larger the preparation, the larger the chance for failure of the restoration.¹⁶ Even with experienced dentists, the Medeiros suggested that survival rates for multiple-surface restorations, when using the ART method, were low. Thus, in such cases, it is preferable to place amalgam restorations in conventional cavities^{9,16} or stainless steel crowns.¹⁷

The 12-month evaluation showed a lower percentage of success than the 6-month evaluation for all restorative groups, revealing that GIC presented a low resistance to abrasion and showed wear and tear over time.^{18,19} The material presented deterioration over the period of evaluation, with the change being even greater in the restorations involving 2 tooth surfaces. For this reason, there should be more caution in the indication of this material for permanent atraumatic restorative techniques. This should be the treatment of choice for deciduous teeth close to the exfoliation period, owing to the short time they remain in the oral cavity.

At the second evaluation, after the 12-month follow-up, it was found that restorations on the occlusal surface had good clinical outcomes, with a greater resistance to wear and tear seen for Ketac-Molar GIC.²⁰⁻²³ This agrees with other findings showing a 93% success rate in restorations with 1 surface after a 12-month follow-up.²³

Regarding the loss of restorations performed in cavities involving 2 tooth surfaces, the percentages were 50% and 39% for Vidrion R and Ketac-Molar, respectively. When the atraumatic restorative technique was performed in cavities with 2 tooth surfaces, a high number of missed restorations was

found at 12 months. Emphasis should, therefore, be placed on the importance of the longitudinal follow-up, with short recall examination times followed to avoid unwanted outcomes that would lead to pain and discomfort.²⁴

Logistic regression analysis, for the separate comparisons between groups 1 and 3 and between groups 2 and 4, was carried out only at the 12-month evaluation. The comparison of groups 1 and 3 showed that the restorative techniques and the size of the cavity were important variables. The finding favoring group 3 represents what was observed for this evaluation in the stratified analysis. The satisfactory results, however, were inversely proportional to the cavity's size, indicating that there was a greater retention of the material in smaller cavities. The low resistance of GICs to masticatory forces points out that this restorative technique appeared to be more suitable for small cavities, as the risk of fracture of the material increases when it is used in large cavities.^{5,6,15}

As happens with all types of restorations, survival rates decrease over time. At the 6-month evaluation, a high percentage of satisfactory results for the procedures carried out on a single surface was observed in groups 1 and 3. The logistic regression model showed that cavities placed in 1

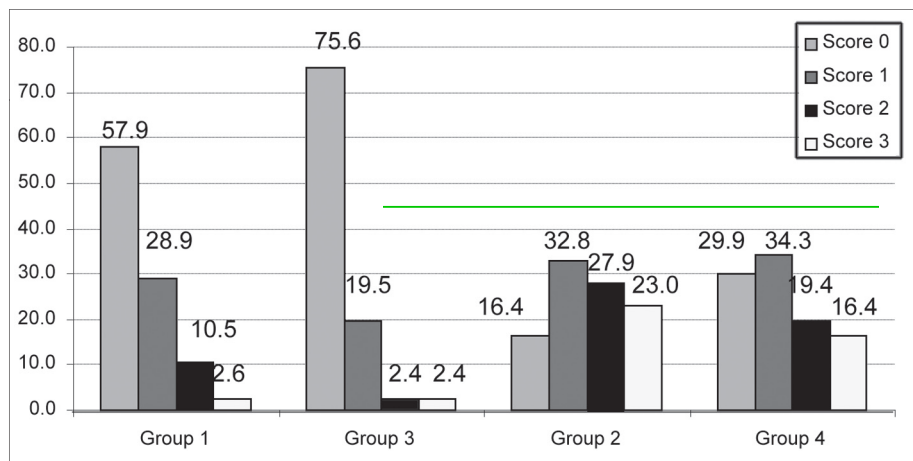


Figure 1. Percentile distribution of the scores attributed to the restorative materials at the 6-month recall evaluation.

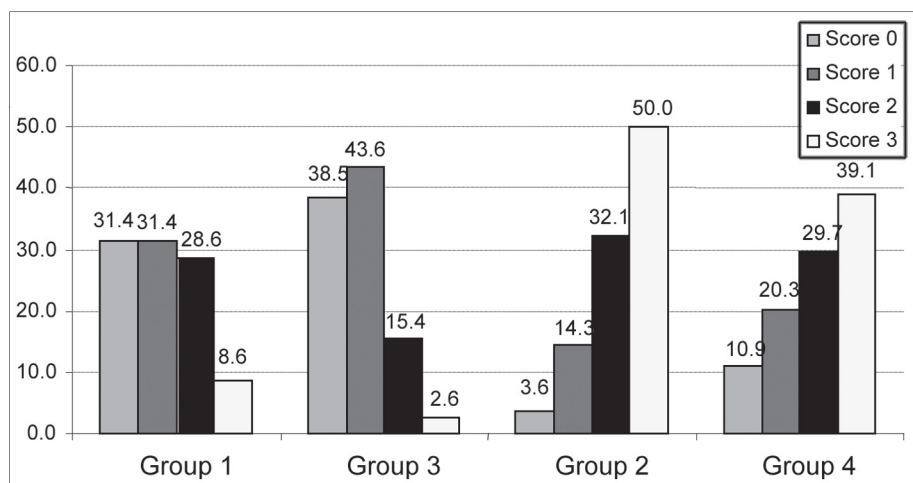


Figure 2. Percentile distribution of the scores attributed to the restoring materials at the 12-month recall evaluation.

surface were associated with a greater chance of a satisfactory outcome, which agrees with previous studies.^{20,21} The satisfactory results obtained in the present study, however, were better than that reported previously. This may be due to the use of a proper dental office facility favoring the quality of restorations and also to the dentist's greater clinical experience. The operator's experience may positively influence the trial's success rates.^{8,14}

Restorations involving 2 tooth surfaces assessed at 12 months showed a less satisfactory performance, which was already evident at the 6-month evaluation. Other similar studies carried out on deciduous teeth reported a small percentage of satisfactory results with the use of GIC for this type of cavity.^{18,21,22} Logistic regression analysis comparing the 2 techniques confirmed a higher chance of success using the Ketac-Molar GIC.

The restorative groups involving 1 and 2 tooth surfaces displayed better performance at both recall evaluations when the Ketac-Molar GIC was used. This was confirmed by the logistic regression analysis, suggesting that it is due to the well-known superior mechanical qualities of this dental cement.¹⁴

The treatment in cavities lined by sclerotic dentin presented a greater chance of success, a fact that has not yet been reported in the literature. This may be attributed to the chemical composition of such dentin, which exhibits occluded dentin tubules and a lower mineral content than healthy dentin, but is more mineralized than contaminated dentin.²⁵ It is possible that this characteristic favored the GIC's chemical reaction with the tooth structures, since the material's adhesion to the tooth occurs when the tooth's surface is wet by the ionomer liquid. The hydrogen ions react with the mineralized surface, displacing the calcium and phosphate ions that are bound to the carboxylic groups and to the tooth.¹ The material's better adhesiveness to the sclerotic dentin may be due to the fact that:

- 1. the chemical adhesive reaction occurs on the mineralized surface; and
- 2. the sclerotic dentin is more mineralized than the contaminated dentin.

In addition, in the present study the dentin conditioner of the glass-ionomer cement was applied to the tooth surface to promote its cleaning, resulting in better adhesion of the restorative material to the teeth.

The success rates found in the present study for the employed

materials favored a more reliable indication for their use in atraumatic restorative techniques in cavities on 1 tooth surface.¹⁵ Their application in restorations in 2 tooth surfaces should be viewed with greater caution.

The present study analyzed a number of factors that might hinder the achievement of satisfactory results in the evaluation of atraumatic restorations in deciduous molars. Thus, logistic regression analysis indicated a greater chance of success in small cavities involving only the occlusal surface lined with sclerotic dentin and in mixed dentition. These findings will help the dentist decide which technique to use, taking into consideration not only the teeth, but also the child who receives the treatment.

CONCLUSIONS

The results of this study indicated that:

- 1. Both Ketac-Molar and Vidrion R restorations gave satisfactory results when placed in a single tooth surface.
- 2. The best clinical outcome was seen in single-surface cavities restored with Ketac-Molar glass ionomer cement.
- 3. The number of unsatisfactory restorations was greater in cavities with 2 tooth surfaces, being larger in group 2 (cavity in 2 tooth surfaces filled with Vidrion R) than in group 4 (cavity in 2 tooth surfaces filled with Ketac-Molar) at 6- and 12-month recall evaluations.

Table 7. Logistic Regression Analysis Results for Each Group and Surface Type, in Relation to Achieving Satisfactory Results at 12-month Follow-up

Variables	Coefficient (ß)	Odds ratio estimate	95% confidence interval	Chi-square test P value	Statistical significance
Groups*	0.4211	1.524	1.092 – 2.1572	.0131	SS†
Surface type‡	2.6770	14.541	6.530 – 35.378	<.0001	SS

*Comparison between groups 1 and 2 (Vidrion R) with 3 and 4 (Ketac-Molar).

†Statistically significant. P<.05=statistically significant.

‡Comparison between occlusal surface with multiple surfaces.

Table 8. Logistic Regression Analysis Results for Comparison Between Groups 2 and 4, in Relation to Achieving Satisfactory Results at 12-month Follow-up for Dentin Type and Dentition Type

Variables	Coefficient (ß)	Odds ratio estimate	95% confidence interval	Chi-square test P value	Statistical significance
Groups 2 and 4*	0.4602	1.584	1.011-2.572	.0476	SS†
Dentin type‡	1.5149	4.549	1.305-16.667	.0110	SS
Dentition type§	0.9826	2.671	1.069-7.246	.0489	SS

*Comparison between groups 2 (cavity placed in 2 surfaces, restored with Vidrion R) with 4 (cavity placed in 2 surfaces, restored with Ketac-Molar).

†Statistically significant. P<.05=statistically significant.

‡Comparison between sclerotic dentin with contaminated dentin.

§Comparison between deciduous dentition with mixed dentition.

4. The high percentage of unsatisfactory scores for multisurface restorations requires proper long-term, cost-effective analysis to justify the routine use of the atraumatic restorative technique for more than 1 surface cavity preparation.
5. Logistic regression analysis indicated a better chance of satisfactory results for the cavities in the occlusal tooth surface lined by sclerotic dentin after 6- and 12-month evaluations.

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