

# Minimal Invasive Treatment for Defective Restorations: Five-Year Results Using Sealants

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## Clinical Relevance

Improvement of the marginal seal of restoration defects is a conservative approach that may improve their quality over time. Minimally invasive treatments of defective restorations showed similar outcome to replaced restorations after five years.

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## SUMMARY

Replacement of dental restorations has been the traditional treatment for restorations that are defective. In this five-year randomized clinical trial, restorations with localized marginal defects were treated with sealants.

Thirty-two patients (mean age, 26.8 years) with 126 Class I and Class II restorations with defective margins (amalgam n=69 and resin-based composite n=57) were recruited. Treatment was seal with pit and fissure sealant on localized marginal defects (group A: n=43) and was compared with total restoration replacement (group B: n=40) and untreated restorations (group C: n=43) as negative and positive controls. Restorations were assessed by two examiners using the modified US Public Health Service criteria, observing five clinical parameters: marginal adaptation, roughness, marginal stain, teeth sensitivity, and secondary caries at baseline and at five years after treatment.

**At the five-year recall examination, 23 patients with 90 restorations (71.4% recall rate) were examined. A significant improvement was observed in the marginal adaptation of the restorations in group A compared with group B. None of the treated group showed trends to downgrade in any parameter. Tooth sensitivity and secondary caries showed a low frequency in all groups. No significant difference in marginal adaptation of the restorations was found between amalgam and resin-based composite restorations ( $p=0.191$ ). This study demonstrated that marginal sealing of restorations is a minimally invasive treatment that may be used instead of the replacement of restorations with localized marginal defects.**

### INTRODUCTION

Dental restorations may demonstrate degradation in the intraoral environment over time, and the principal reasons for deterioration are marginal deficiencies, fracture, and wear, possibly leading to secondary caries and/or tooth sensitivity.<sup>1-3</sup> Traditionally, those failures have led to complete replacement of the restorations, including in the presence of minor imperfections. Restoration replacement represents a major concern in dental practice, reaching up to 60% of general dentistry interventions.<sup>4</sup>

In recent times, with more insight into cariology, tooth longevity, dental biology, and dental materials science, a minimally invasive philosophy has prevailed, and the advantages of repairing rather than replacing restorations have been progressively emphasized.<sup>5-11</sup>

Complete restoration replacement has the disadvantages of being time-consuming, leading to unnecessary removal of healthy tooth tissue, including in areas away from the localized defects. Unnecessary removal of sound tooth tissue may result in enlarged preparation and restoration size, which could alter the proposed treatment plan and possibly result in irreversible injuries to pulp tissues.<sup>7,8,12-15</sup>

During recent years, new strategies such as repair and refinishing or sealing of localized defects have shown an overall improvement in the clinical properties of defective restorations, thereby increasing their longevity through minimal intervention.<sup>9,15-17</sup> Whenever possible, repair of restorations can be more cost-effective and acceptable to patients than restoration replacement. Because it preserves tooth structure, it has the potential to allow patients to retain most of their teeth during their lifetime.<sup>18</sup>

In addition, the clinical results of these combined studies have changed education in operative dentistry as repair of restorations is routinely taught in most dental schools.<sup>10,19-21</sup>

The aim of this randomized clinical trial was to assess sealed defects at the margins of Class I and Class II amalgam and resin-based composite (RBC) restorations and to follow-up the results after five years. The hypothesis to be tested was that after five years, sealing the defects at the margins would show similar performance as restorations that were replaced.

### METHODS AND MATERIALS

Thirty-two patients (19 female and 13 male; mean age, 26.8 years) with 126 Class I ( $n=94$ ) and Class II ( $n=32$ ) amalgam ( $n=69$ ) and RBC ( $n=57$ ) restorations with defective margins participated in the study. The experimental treatment group was the application of a pit and fissure sealant on localized defects in the margins of restorations (group A:  $n=43$ ). The comparison groups were total restoration replacement (group B:  $n=40$ ) and untreated restorations (group C:  $n=43$ ), serving as negative and positive controls. Restorations were assessed using the modified US Public Health Service criteria (Table 1) observing five parameters: marginal adaptation, roughness, marginal stain, tooth sensitivity, and secondary caries by two examiners (E.F., J.M.).

#### Inclusion Criteria

The inclusion criteria were: 1) patients with amalgam (Am) and RBC restorations with marginal deficiencies that were judged to be suitable for sealing, 2) older than 18 years of age, 3) having more than 20 teeth in their mouth, and 4) being able to sign the consent form. In addition, the restorations had to be in functional occlusion with an opposing natural tooth and have at least one proximal contact area with an adjacent tooth.

#### Exclusion Criteria

The exclusion criteria were: 1) contraindications for regular dental treatment based on their medical history, 2) special esthetic requirements that could not be solved by this alternative treatment, 3) xerostomia or taking medication that significantly decreased salivary flow, 4) high caries risk, or 5) psychiatric or physical diseases that interfered with oral hygiene.

Table 1: US Public Health Service/Ryge Clinical Criteria<sup>20</sup>

Clinical Characteristic	Alpha	Bravo	Charlie
Marginal adaptation	Explorer does not catch when drawn across the restoration-tooth interface	Explorer falls into crevice or has one-way catch when drawn across the restoration-tooth interface	Dentin or base is exposed
Surface roughness	The surface of restoration has no surface defects	The surface of restoration has minimal surface defects	The surface of restoration has severe surface defects
Secondary caries	There is no clinical diagnosis of caries	N/A	Clinical diagnosis of caries
Marginal stain	There is no discoloration between the restorations and tooth	There is discoloration on less than half of the circumferential margin	There is discoloration on more than half of the circumferential margin
Teeth sensitivity	No sensitivity when an air syringe is activated for two seconds at a distance of half an inch from the restoration with the facial surface of the proximal tooth covered with gauze	Sensitivity is present when an air syringe is activated for two seconds at a distance of half an inch from the restoration with the facial surface of the proximal tooth covered with gauze and ceases when the stimulus is removed	Sensitivity is present when an air syringe is activated for two seconds at a distance of half an inch from the restoration with the facial surface of the proximal tooth covered with gauze and sensitivity does not cease when the stimulus is removed

**Sample Size Determination and Randomization**

Sample size was determined *a priori* using G\*Power 2,<sup>22</sup> with an error probability of  $\alpha=0.05$ , effect size 0.3, and power (" $\beta-1$  error probability) of 0.80. The restorations with marginal defects (Bravo) were randomly assigned (performed by PASS software version 2004, Keyville, UT, USA) to one of three groups of treatment: A, sealing of margins (n=43); B, replacement (n=40); and C, untreated (n=43).

The Institutional Research Board and Ethical Board of the Dental School at the University of Chile approved the study (project PRI-ODO-0207). Only faculty members were allowed to provide the restorative treatment, and all patients signed inform consent forms and completed a registration form.

**Caries Risk Assessment**

A graphical computed program (Cariogram) was used to assess individual patients' caries risk; the program weighted the interaction between the following 10 caries-related factors: caries experience, related general disease, diet contents, diet frequency, plaque amount by Silness Loe Index, semiquantitative detection of mutans streptococci and lactobacilli in saliva by caries risk test (CRT) bacteria (Ivoclar, Vivadent AG, Schaan, Lichtenstein), fluoride program, amount of saliva stimulated secretion by CRT

buffer (Vivadent), saliva buffer capacity, and clinical judgment. Patients were classified as high, intermediate, and low caries risk. In addition, the results also indicated where targeted actions to improve the situation would have the best effect.<sup>23</sup>

**Restoration Assessment**

The quality of the restorations was evaluated using the modified US Public Health System/Ryge criteria (Table 1).<sup>24</sup> Two examiners (J.M. and E.F.) assessed the restorations independently and by visual (mouth mirror number 5, Hu Friedy Mfg Co Inc, Chicago, IL, USA) and tactile examination using an explorer (N° 23 Hu Friedy) and indirectly by radiographic (Sirona Heliodent Vario, Charlotte, NC, USA) examination (Bite Wing, DF57, Kodak Dental System Healthcare, Rochester, NY, USA). All the restorations were examined at baseline and each year up to five years. The five parameters used in the examination were marginal adaptation, roughness, secondary caries, marginal stain, and tooth sensitivity (Table 1). If any difference was recorded between the two examiners and an agreement could not be reached, a third clinician (G.M.) was called to assist with the decision process. If the three clinicians did not reach an agreement, the lower score was recorded. All three clinicians participated in calibration exercises at the beginning and before the last examination took place, and the interexaminer reliability results were

Kappa=0.74 at the baseline and Kappa=0.87 at the fifth year.

A change from Bravo to Alpha was considered an improvement, and a change from Alpha to Bravo was considered deterioration.

**Treatment Groups**

- A. Sealing of margins: Defective areas were acid etched with 35% phosphoric acid for 15 seconds. A resin-based sealant (Clinpro Sealant, 3M ESPE) was applied over the defective area. The sealant was polymerized with a photocuring unit (Curing Light 2500, 3M ESPE) for 40 seconds. Rubber dam isolation was used for this procedure. All treatments were provided by the same clinician (G.M.).
- B. Replacement group: The defective restoration was totally removed and replaced with either a new amalgam (Tytin, Kerr Corporation, Orange, CA, USA) or RBC restoration (Filtek Supreme, 3M ESPE). Rubber dam isolation was used for this procedure. All treatments were provided by the same clinician (J.E.).
- C. Untreated group: The defective restorations did not receive any treatment.

Patients were recalled each year for five years for clinical evaluation by the same examiners, using the same criteria as used at baseline.

Failed restorations were removed from the study and treated according to their diagnosed needs.

Digital photographs and bitewing radiographs were taken for all the restorations before and after treatment and every year prior to the examination.

**Statistical Analysis**

Wilcoxon test was used to compare the preoperative and postoperative conditions at the fifth year, and the Kruskal-Wallis test and Mann-Whitney post hoc tests were used for comparisons among groups at the error probability of  $\alpha=0.05$  (SPSS version 15.0, SPSS Inc, Chicago, IL, USA).

**RESULTS**

Twenty-three patients (14 female, 9 male) with 90 amalgam (n=53, 43-Class I and 10-Class II), and resin based composite (n=37, 34-Class I and 3-Class II) restorations distributed in three groups (group A: n=37; group B: n=23; group C: n=30) were evaluated every year and up to five years. The study had an overall attrition rate of 28.6% (5.7% per year), with nine patients with 36 restorations who were unable to be contacted.

When comparing the baseline assessment of restorations with the results after five years (Figure 1), group A showed a statistically significant improvement in marginal adaptation ( $p=0.0001$ ). No significant difference was found for tooth sensitivity and secondary caries. In contrast, a significant downgrade was observed for surface roughness and marginal staining ( $p=0.0001$  and  $p=0.005$ , respectively).

The results for Group B (Figure 2) after 5 years showed a significant improvement ( $p=0.022$ ) for marginal adaptation, with secondary caries being less prevalent ( $p=0.008$ ). No significant differences could be seen for marginal stain, roughness, and sensitivity.

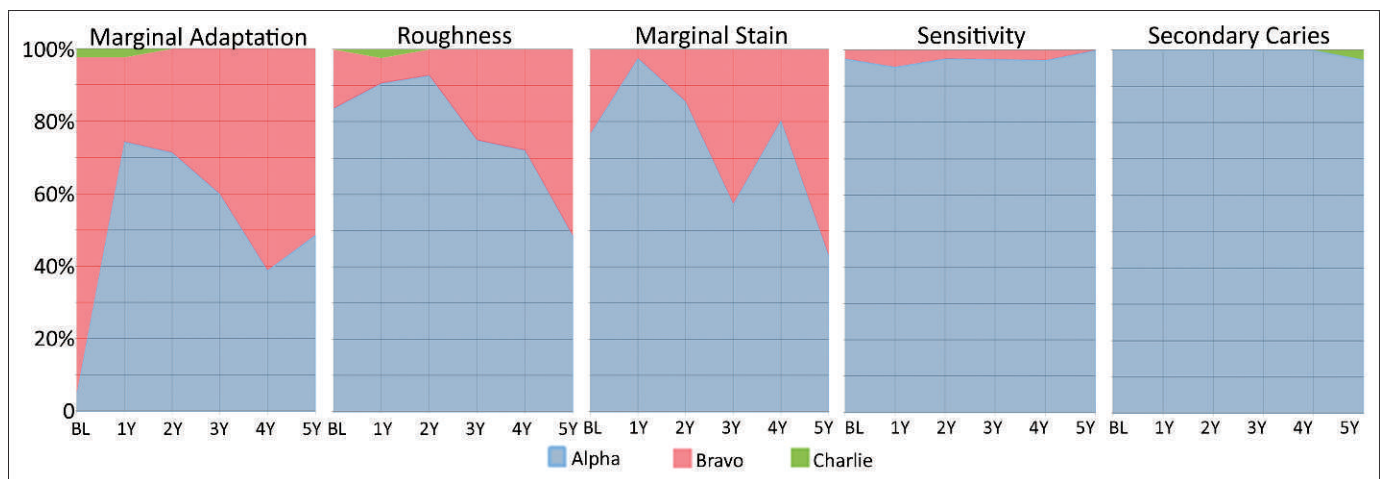


Figure 1. Yearly summary results from group A according to the US Public Health Service/Ryge scores for each clinical parameter. BL = baseline; 1Y-5Y observation periods.

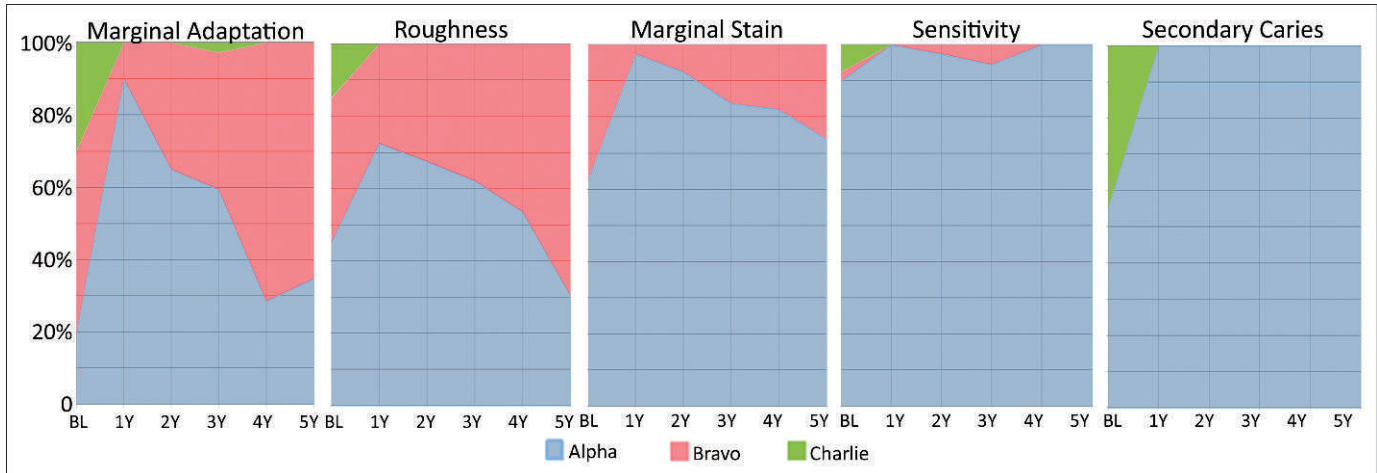


Figure 2. Yearly summary results from group B according to the US Public Health Service/Ryge scores for each clinical parameter. BL = baseline; 1Y-5Y observation periods.

Group C (Figure 3) presented a significant downgrade in marginal adaptation ( $p=0.02$ ), roughness ( $p=0.001$ ), and marginal stain ( $p=0.001$ ), with no differences between the two restoration materials ( $p=0.130$ ). No changes were observed for sensitivity and secondary caries after the fifth-year examination ( $p=1.00$  for both).

No significant differences were observed between groups A and B ( $p=0.658$ ) for all the clinical parameters observed (Figure 4). However, both groups showed significantly improved results for marginal adaptation when compared with group C ( $p=0.0001$ ).

The comparison between groups in marginal staining showed a downgrade in group A and the same in group C ( $p=0.189$ ). Group B compared with

group A and C showed an upgrade in the period ( $p=0.001$ ). No significant differences were observed between the three groups ( $p=0.073$ ), but all groups showed downgrades. In the secondary caries parameter, the only group that showed changes was group B, with an upgrade statistically better than group A and C ( $p=0.000$  and  $p=0.001$ ; Figure 4).

No significant difference was found between amalgam and RBC restorations for any of the groups.

### DISCUSSION

The management of composite or amalgam restoration with localized defects is a common challenge in clinical practice. Some restorations may certainly require replacement, while others may be given

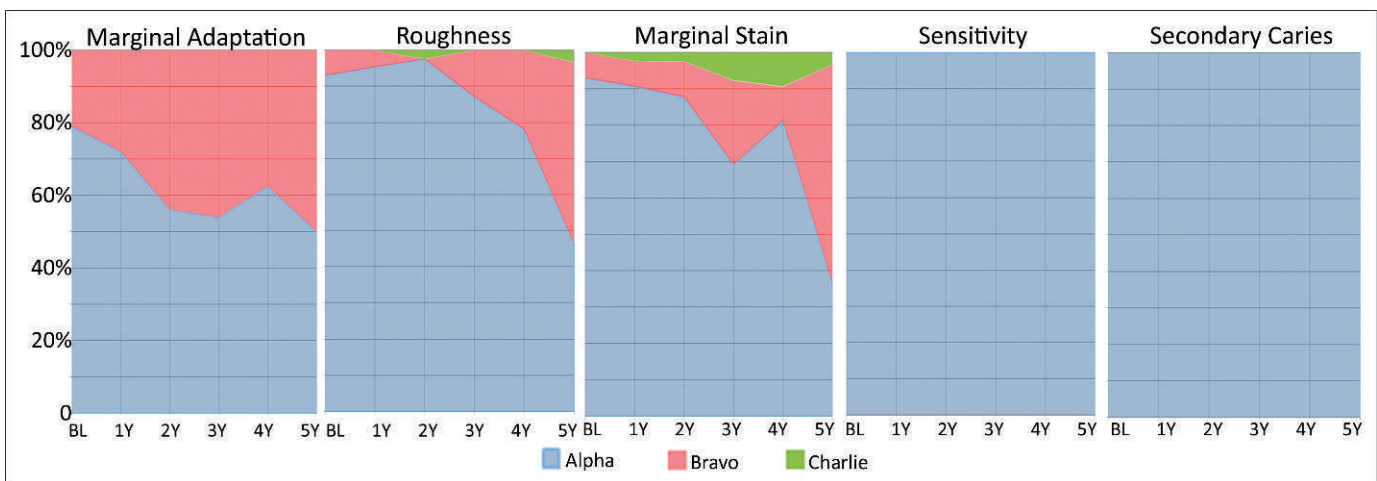


Figure 3. Yearly summary results from group C according to the US Public Health Service/Ryge scores for each clinical parameter. BL = baseline; 1Y-5Y observation periods.

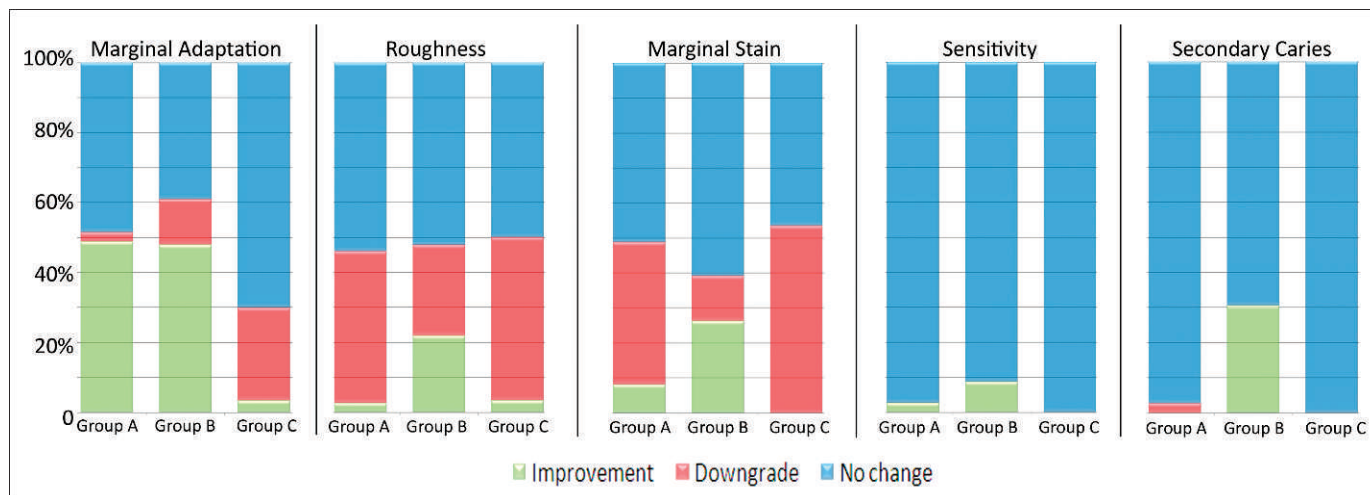


Figure 4. Summary of the changes in US Public Health Service/Ryge scores between baseline and fifth-year evaluation (results expressed in percentages).

extended longevity through the use of alternative procedures.<sup>25,26</sup>

A conservative approach to the management of defective restorations, if appropriate, has the potential to be less costly in terms of time and cost, less traumatic for patients, less likely to result in iatrogenic damage, possibly obviate the need for the use of local anesthesia and, more importantly, preserve tooth structure.<sup>17,27</sup> Furthermore, extended longevity of existing restorations may enhance patients' general health and satisfaction. Significant differences exist among dentists when deciding whether or not a restoration should be replaced.<sup>28–33</sup>

Although minimally invasive dentistry has been introduced in the dental curriculum, it has taken place only in recent years. Therefore, several dentists have not been trained on proper diagnosis and application of the minimally invasive procedures. McAndrew and others<sup>34</sup> concluded that it is possible to reduce examination time and provide convergence to a defined standard through a basic training program that can significantly influence the restoration replacement rate among general dental practitioners. In the dental school in Santiago, Chile, defined criteria are used by clinical students, and alternative methods to replacements are taught, including the repair of localized defects in restorations.

It is recognized that the chipping of margins of the restorations is an early sign of deterioration in clinical service, which tend to be restricted to a small part of the restoration, usually a short segment of the cavosurface margin.<sup>35</sup> Sealing with pit and fissure sealants, a minimally invasive

procedure, will reduce the indication for replacement of the restoration.

The longevity of dental restorations mainly depends on the continuity of the interface between the restorative material and adjacent tooth tissue.<sup>36</sup> Some marginal defects may be sealed to increase the life of restorations.

The results of the present study showed that sealing defective margins had similar results to restoration replacement for marginal adaptation after five years. The benefit of this procedure is that it is prompt, minimally invasive to patients, and less involved than replacement for clinicians. In addition, if a sealant fails, it does not necessarily mean the presence of secondary caries, and therefore, the procedure could be repeated multiple times. In this study, only 5% of sealed restorations showed alpha value at baseline, increasing to 74% during the first year, followed by continuous margin deterioration during the next years, reaching 49% alpha value at the fifth year. The experimental and the control groups showed the same trend of downgrade of marginal adaptation over time. Amalgam and RBC restorations in marginal adaptation showed comparable annual failure rates, as shown by Manhart and others<sup>1</sup> in their prospective clinical studies. However, three other published studies reported better longevity of amalgam restorations compared with composite restorations.<sup>37–39</sup>

Despite the evident loss of restorative material at the margins of the existing restorations, observed by macroscopic clinical and photography detection, sealant was able to maintain the marginal integrity of both amalgam and RBC restorations, even though



no chemical bond occurred between amalgam and pit and fissure sealant.

At baseline, the experimental group presented an alpha score of 77% for the marginal stain parameter. After one year, it increased to 98%, but the next years showed deterioration, achieving 43% at the fifth year. Similarly, the control groups showed the same direction of downgrade, possibly because of the cavity design defects or traumatic occlusal forces that may have been inherited restoration factors were not modified.

Roughness was a parameter that presented improvement only for the replacement group during the first year (from 45% to 73% alpha value). After that, it showed constant deterioration, similar to the other groups. Logically, the sealant treatment was limited to the areas marginal to the restoration, not including other parts of the restoration. Thus, to improve roughness and the margins of the restoration, it is recommended that, in addition to sealing the margins, the surface of the restorations be polished to reduce development of surface roughness, which could potentially increase the adherence of plaque and biofilm to teeth and restorations.<sup>26,40</sup>

Tooth sensitivity showed a slight but not significant improvement in restorations that were sealed when compared with those that were not in the first year. Sensitivity gradually disappeared (100% alpha), and at the fourth and the fifth years, teeth showed no sensitivity. However, no significant differences could be observed among groups, and the limited sensitivity that was present was probably related to other preexisting conditions such as dentin exposure areas or reversible pulpitis.

Restorations with marginal defects without visible evidence of soft dental tissues on the wall or base of the restoration should be monitored, repaired, or sealed instead of replaced.<sup>36</sup> Alternative treatments are specially indicated for the highly dental-motivated patient who presents a good standard of oral health and seeks care regularly,<sup>35</sup> as it is important to consistently check that the sealants are present and functional. In addition, as in any planned procedure, it is important that the patient is completely informed of the advantages and possible disadvantages of the treatment.<sup>35</sup>

The low attrition rates in the current study (5.5% per year) are probably related to the fact that patients have regularly attended the Dental School.

An uncontrolled event of this study was related with the restorations of group C that belonged to the control group and had been previously placed by

different and nonstandardized clinicians. Despite this fact, all groups showed a similar trend of restoration downgrade during the observation period.

The application of pit and fissure sealant has been considered a good preventive agent for use against the development and progression of pit and fissure caries.<sup>41</sup> Sealants have also been used to successfully arrest occlusal caries lesions.<sup>42</sup> The present study shows an improvement in marginal adaptation of defective restorations sealed with pit and fissure sealants after five years when compared with restorations that were not treated. It also shows similar results to restorations that were replaced, therefore questioning the need for replacement when sealant is a viable option of treatment.

## CONCLUSIONS

The application of a resin sealant at the margin of a defective restoration presented similar marginal adaptation results as restoration replacement after five years. The sealing of defective margins of Class I and II amalgam and RBC restorations is a viable alternative to the replacement of restorations. It increases the restoration longevity with minimal intervention, cost, and trauma to the adjacent tooth structures.

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## Conflict of Interest

The authors of this article certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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