Sealing Composite With Defective Margins, Good Care or Over Treatment? Results of a 10-year Clinical Trial

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Clinical Relevance

Sealing the defective margins of the composite resin restorations improves the margins of restorations.

SUMMARY

Purpose: The objective of this study was to clinically evaluate sealed composite restorations after 10 years and compare their behavior with respect to controls.

Methods and Materials: The cohort consisted of 20 patients aged 18 to 80 years with 80 composite restorations. All participants in the sealing and no-treatment groups presented with clinical features for the marginal adaptation that deviated from the ideal and were rated Bravo (United States Public Health Service criteria). Composites with Alfa values for the marginal adaptation were used as the positive control.

Results: The marginal adaptation behavior was similar between the sealing and control (+) groups, with a high frequency of Bravo values

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in the 10th year (80% and 51%, respectively). Most of the no-treatment (-) group maintained the Bravo values (91%) for 10 years, although some restorations (9%) progressed to Charlie values. The anatomy parameter differed significantly between the first and 10th years, with deterioration in all three groups ($p<0.05$). The secondary caries parameter had a similar behavior in the three groups ($p>0.05$).

Conclusions: Sealing the margins of the composite resin restorations had no significant effect compared with the control groups, under the conditions of this study. Sealing the restorations substantially improved the marginal staining and marginal adaptation parameters, although by the tenth year they were similar to the group without intervention.

INTRODUCTION

The longevity of restorations is determined by the most common causes of failure: secondary caries, fracture, and marginal adaptation problems.[1,2] Clinicians have traditionally taken a mechanical approach with respect to restorations, replacing those that could have been treated with minimal intervention. This approach saves both time and healthy tissue.[3]

The most frequently reported causes for failure for adhesive restorations are marginal adaptation and retention loss, for which a high potential has been reported due to *in vivo* degradation of the adhesive bonding of the composite resins. Because Classes I through IV have macromechanical retention, retention loss is less clinically evident for those Classes than for Class V restorations. Therefore, marginal adaptation becomes an important sign of the adhesive degradation in composite restorations.[4]

The problems of marginal adaptation have been shown to be associated with the occurrence of secondary caries and the eventual loss of the restoration. All marginal deterioration and loss of substance, either at the expense of tooth structure or due to composite resin degradation, ultimately generates a risk of restoration failure. Gaps larger than 400 μm are associated with caries adjacent to restorations, especially at the gingival margin.[5]

Sealing defective margins of composite restorations appears to be a quick, inexpensive, and simple solution to improve the marginal integrity and prevent further problems. After etching the enamel and surface of the composite, the resin sealant penetrates the surface to adhere micromechanically. The resulting retention values typically support the masticatory functional load. It is also known that the mass of sealant will decrease over time, as the small proportion of filler does not support functional wear. However, the portion that remains on the tooth-restoration interface is maintained.[6]

Repair is defined as the partial removal of a restoration, which allows better examination and diagnosis of the underlying tissue, then the removal of carious tissue, and finally making the composite resin restoration.[7] There is a lack of quality evidence to support repair procedures. However, it is accepted and recommended as a fast, inexpensive, and minimally invasive treatment.[8,9] Also, it is important to remark that the seal is focused on solving small 1-mm minor imperfections on the margins of restorations without removing tooth structure or restoration, or filling a small gap.[10]

There are reports of sealed restorations that have been maintained over time with acceptable clinical results. Sealed restorations are an intervention that improves the marginal adaptation, which then progressively deteriorates over time. One report covered a seven-year timespan for amalgam restorations that were sealed at the margins.[10] Therefore, it is important to understand what occurs to composite restorations after 10 years of follow-up.

The objective of this study was to clinically evaluate sealed composite restorations after 10 years and compare their behavior with respect to controls.

METHODS AND MATERIALS

Study Design

A cohort of 20 patients between 18 and 80 years of age (mean 28.35 years; 35% men, 65% women) with 80 composite restorations (Class I: 45; Class II: 35) (Figure 1) were recruited at the Operative Dentistry Clinic at the Dental School of the University of Chile. All participants in the sealing and no-treatment (-) groups presented with clinical features for the marginal adaptation that deviated from the ideal and were rated Bravo according to the modified United States Public Health Service (USPHS) criteria.[11,12] Composites with Alfa values for marginal adaptation were used as positive controls. All patients signed informed consent forms and completed registration forms. The selection criteria are summarized below.

General inclusion criteria included:

- patients with more than 20 teeth;
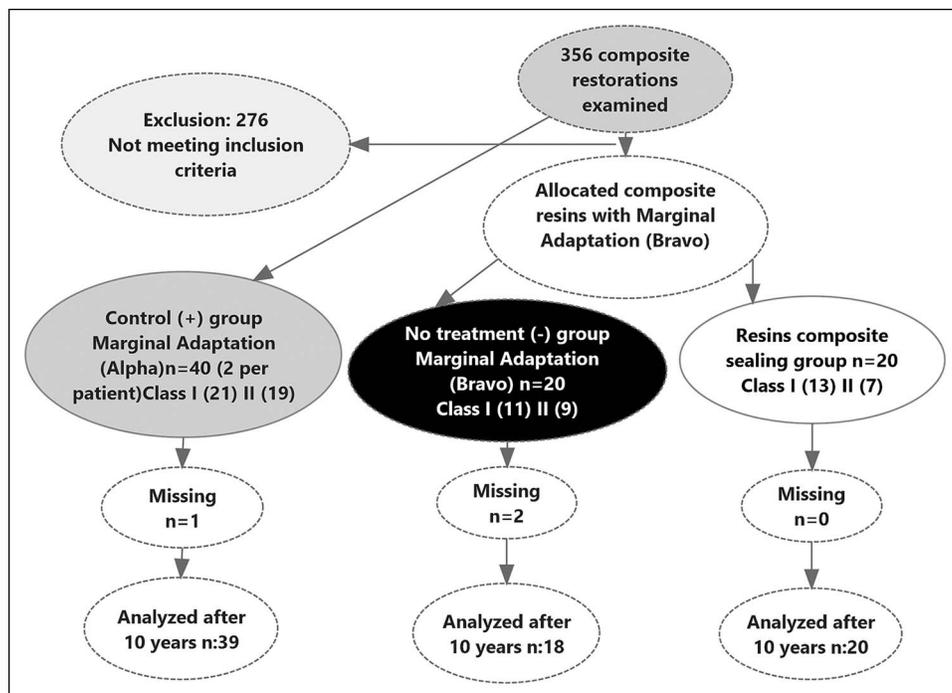- restorations in functional occlusion, with an opposing natural tooth;

Figure 1. *Flow diagram of study phases and group distributions.*

- asymptomatic restored tooth;
- at least one proximal contact area with a neighboring tooth;
- patients older than 18 years;
- patients who agreed and signed a consent form for participating in the study; and
- area outside of the restoration failure in good condition.

General exclusion criteria included:

- patients with contraindications for regular dental treatment based on their medical history;
- patients with xerostomia or who are taking medication that significantly decreased salivary flow;
- patients at a high risk of caries;
- patients with psychiatric or physical diseases, which interfered with oral hygiene; and
- resin-based restorations with localized marginal deficiencies >1 mm and/or secondary caries or major defects adjacent to the restorations.

Inclusion criteria for the allocated groups (Figure 1) included patients with localized marginal defects of less than 1 mm (Bravo Ryge criteria) on composite restorations that were clinically judged to be suitable for sealing according to the USPHS criteria.

Inclusion criteria for the positive control group (Figure 1) included composite resins with Alfa values for the marginal adaptation criteria.

Treatment Group Criteria

Fifty-eight patients and 356 restorations were initially evaluated and assigned in accordance with the modified USPHS criteria,[11] and 80 were selected based on the inclusion criteria. Restorations with marginal defects (>0.5 mm and <1 mm) and/or marginal staining (Bravo) were randomly assigned to the sealing (n=20) or no-treatment (n=20) groups. The randomization was performed by the PASS software (NCSS, LLC, Kaysville, UT, USA). Patients who had at least four Class I or Class II posterior composite restorations were examined. Two restorations with <1 mm defects (Bravo) longitude corroborated by the North Carolina 15 periodontal probe (Hu-Friedy Mfg. Co, Chicago, IL,USA) at the margins were randomly assigned to be sealed or left untreated (-). Two other composite restorations that had excellent margins (Alfa) acted as a positive control. The patient was considered the statistical unit in this study (n=20).

Restoration Assessment

The quality of the restorations was scored in accordance with the modified USPHS criteria. The Cohen kappa interexaminer coefficient was 0.74 at the first year and 0.87 after 10 years for two examiners (JM and EF) who underwent calibration exercises each year. In the first, second, third, fourth, fifth, and 10th year, the examiners independently assessed the restorations for anatomic form,
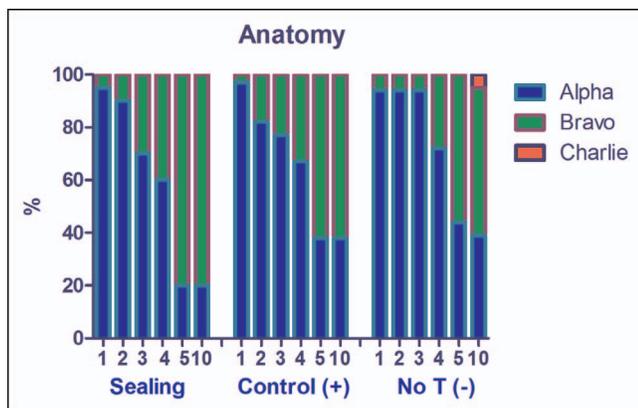
Figure 2. *Anatomy observations separated by groups and quality evaluation expressed as a percentage of USPHS/Ryge criteria per year.*

secondary caries, marginal staining, and marginal adaptation, both directly by tactile and visual examinations with mouth mirror number five and explorer number 23 (Hu Friedy) and indirectly by radiographic examination (bitewing). A third clinician (GM), who also underwent the calibration exercises, made the final decision if a difference was recorded between the two examiners and an agreement could not be reached.

Treatment Groups

Sealing—For this group, defective areas were acid etched with 35% phosphoric acid for 15 seconds, and then a resin-based sealant (Clinpro Sealant, 3M ESPE, St Paul, MN, USA) was applied to the area and polymerized with a photocuring unit (Curing Light 2500, 3M ESPE) for 40 seconds. Rubber dam isolation was used for this procedure.

Positive Control—Composite resins with Alfa values for the marginal adaptation criteria were used as the positive control and were made with resin composite (Filtek Supreme, 3M ESPE).

No Treatment—Composite resin restorations that had marginal defects, but were clinically acceptable, did not receive treatment.

Statistical Analysis

The sample size was defined by setting a beta error rate of 0.2. A Wilcoxon test was performed for comparisons between the same groups with a significance level of 0.05. A Friedman test was utilized for multiple comparisons between different years of the same group. The Kaplan-Meier survival curves were calculated, and Mantel-Cox test was used for the comparison of the curves. The statistical

analysis was performed using SPSS 21.0 (IBM, New York, NY, USA) and GraphPad Prism version 6.00 for Windows (GraphPad Software, La Jolla, CA, USA, www.graphpad.com).

Caries Risk Assessment

A graphical computer program (Cariogram, Malmö Högskola, Malmo, Sweden) was used to assess the risk of caries for the individual patients.[13] The results also indicated where targeted actions to improve the situation would have the best effect. This analysis was performed only for select patients from the study, according to the recommendations of the local ethics committee.

RESULTS

The recall of this cohort of patients at 10 years was 100%. The distribution according to caries risk patients was medium caries risk 80% (n=18) and low risk 20% (n=2); three missing restorations (dropout=3.75%) were lost by orthodontic treatment. Due to local ethics committee requirements at the time this trial was initiated, including high caries risk patients proved to be impossible because the sealing was considered an experimental treatment at that time. This was considered a study limitation.

The anatomic criteria showed a similar trend in the three groups, with primarily Alfa values after the first year, which at the 10th year had deteriorated to Bravo values of 80%, 62%, and 56% for the sealing, control (+), and no-treatment (-) groups, respectively. The no-treatment (-) group also had a 5% frequency of Charlie values (Figure 2).

The secondary caries behavior was similar between the groups, with 11% of the sealing and no-treatment (-) groups having Charlie values in the 10th year, while the control group (+) had only Alfa values (Figure 3).

Regarding marginal staining, the frequency of Bravo values was similar in the sealing and no-treatment groups after 10 years, with 65% and 56%, respectively; only 15% of the control (+) group had Bravo values. The frequency of Charlie values was similar for all three groups in the 10th year, fluctuating between 5% and 6% (Figure 4).

The marginal adaptation behavior was also similar between the sealing and control (+) groups, with a high frequency of Bravo values in the 10th year (80% and 51%, respectively). Most of the no-treatment (-) group maintained the Bravo values (91%) for 10 years, although some restorations (9%) progressed to Charlie values (Figure 5).
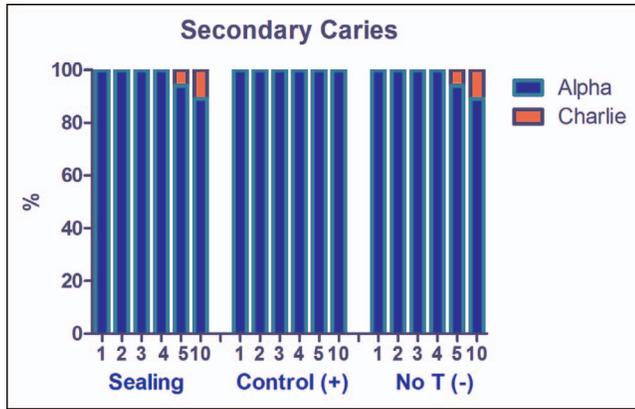
Figure 3. *Secondary caries observations separated by groups and quality evaluation expressed as a percentage of USPHS/Ryge criteria per year.*
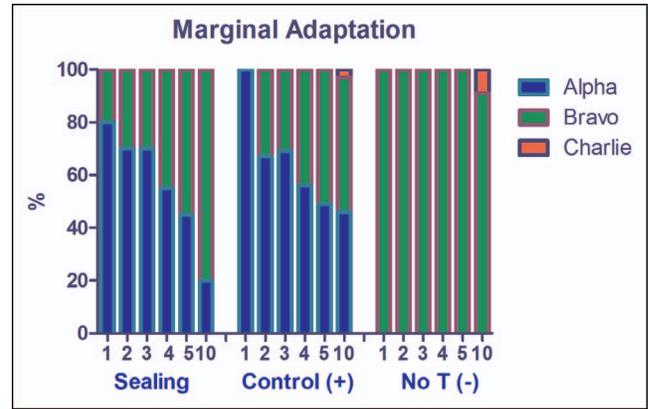

Figure 5. *Marginal adaptation observations separated by groups and quality evaluation expressed as a percentage of USPHS/Ryge criteria per year.*

Utilizing Wilcoxon tests to compare the parameters between the first and 10th years, the marginal adaptation parameter was significantly different in two groups, with deterioration occurring over time. The marginal adaptation behavior in the sealing and control (+) groups had similar levels of deterioration in the 10th year ($p<0.05$), and there was a statistically significant difference between the first and 10th years ($p<0.05$), whereas there was no significant difference over the 10 years for the no-treatment (-) group ($p>0.05$). The anatomy parameter differed significantly between the first and 10th years ($p<0.05$), with deterioration in all three groups. There were no statistically significant differences between the first and the 10th year for the secondary caries parameter ($p>0.05$).

Comparing the different years with Friedman tests, the marginal staining and anatomy parameters were similar for the three groups, and all had

statistically significant differences ($p<0.05$). The marginal adaptation parameter was significantly different in the sealing and control (+) groups ($p<0.05$), but there were no significant differences in the no-treatment (-) group ($p>0.05$). There were also no statistically significant differences in the three groups for the secondary caries parameter ($p>0.05$).

In the Kaplan-Meier survival analysis, the sealing group and no treatment group (-) exhibited exactly the same behavior in terms of failures of restorations per year: first, fourth, and 10th year (Figure 6). The control group (+) had a curve with one less failure, and showed failures in the fifth and 10th year. However, the Mantel-Cox analysis revealed no significant difference between the curves with a log-rank of $p=0.336$. Survival rates for the three groups were high, but the most striking fact was that the control group showed the same results as the sealing group (Table 1). All restorations that failed were Class II composite resins.
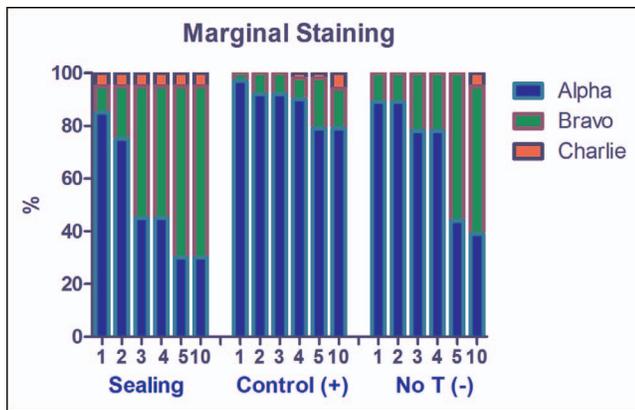

Figure 4. *Marginal staining observations separated by groups and quality evaluation expressed as a percentage of USPHS/Ryge criteria per year.*
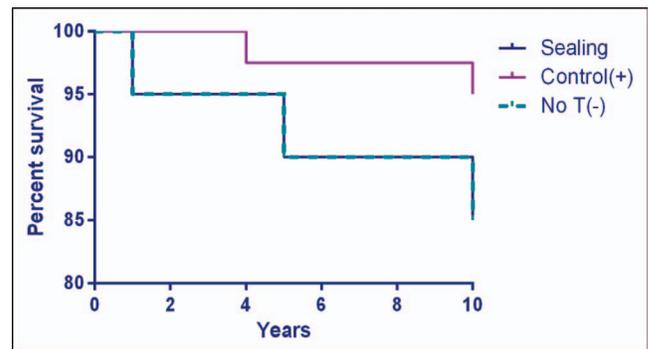

Figure 6. *Kaplan-Meier survival curves for the clinical evaluation. Log-rank, p=0.3368.*

Table 1:	*Survival Rates of Groups Specifying Only the Years of Failures Expressed as a Percentage*			
	1 Year	**4 Year**	**5 Year**	**10 Year**
Sealing	95%	95%	90%	85%
Control (+)	100%	97.5%	97.5%	95%
Control (-)	95%	95%	90%	85%

DISCUSSION

This trial was prospective, randomized, and blinded clinical work following patients for 10 years with regard to the behavior of composite restorations with defective margins that were sealed or left without intervention in comparison to a group with excellent margins at the first year. Sealing the margins of a restoration is a fast, low-cost, minimal intervention that could solve existing small (<1 mm) defects, which was one of the inclusion criteria for this study.

There are several clinical studies that show repair, which means a correct solution for localized defects under a certain indication.[14,15] In the work of Opdam and others,[16] repairs were in larger defects and bigger reconstructions and were perhaps therefore less successful. The question that we sought to answer in this study was whether to seal minor defects or only monitor them over time. According to the results and considering the conditions and limitations of this work, it appears that monitoring restorations with minimal defects is completely permissible.

The sealant used in this trial was a light-polymerizing resin base shown in a meta-analysis by Kuhnisch and others[17] to have retention rates of 77.8% at three years, 80.4% at four years, and 83.8% at five years, which suggests it could still be partially present on the composite resins after 10 years, the length of our study. According to several systematic reviews, pit and fissure sealants are effective measures to prevent caries in young children. Knowledge regarding composite restorations is far from complete, and the question is whether the sealant achieved its goal and remained in the composite. The frequency of new caries lesions after 10 years was similar in the sealing and no-treatment (-) groups, but the control (+) group had no caries lesions appear in the course of 10 years. Thus, the clinical decision passed, because if the group that began the study with Alfa marginal adaptations did not have caries lesions after five years, and the other two groups did, we could propose that the seal was completely effective in preventing new caries lesions around composite resins for up to four years, and if

necessary, the composite resin could be resealed in this period.

The results for this cohort of restorations coincide with those of Gordan and others[10] for amalgam restorations sealed for seven years. There are no other reports of sealed composite resins with a longer follow-up.

Clearly, the question of deciding how to treat a composite resin restoration with marginal adaptation problems has not been resolved. The criteria used for the clinical assessment are very important because, in this case, the Ryge criteria lack accuracy for finding differences when evaluating sealing and probably this could be solved with the criteria proposed by Hickel and others.[18]

Marginal adaptation problems represent one of the most important causes for replacing composite restorations, and on many occasions, a replacement leads to more damage to healthy tissue.[19,20] The marginal adaptation problems can entail an increased risk to the pulp of an injury, endodontic treatment, weakening of the structure, and ultimately tooth loss.[21-23]

Many studies support the use of a sealant as a minimally invasive treatment to seal minimal marginal defects between composite resins and the enamel. However, most of these trials have been *in vitro* and do not examine the clinical behavior of the seal over time.[24,25]

The anatomy parameter showed a similar pattern in all three groups, and the comparisons using Wilcoxon and Friedman tests were statistically significant ($p<0.05$), which means the form of the restorations showed similar deterioration in the 10th year. This parameter could be considered a "control," providing evidence of the deterioration of the composite resins over time.[26]

The presence of secondary caries is the most critical parameter that defines whether the seal was able to prevent the emergence of new caries adjacent to the restorations and increase their longevity. Despite losing two restorations for caries in the fifth and 10th years in the sealing group, the behavior of the sealed restorations over the years was similar to that of the controls, which validates the mechanical seal as a preventive therapy in this cohort of composite resins.

There was a similar pattern between the sealing and no-treatment (-) groups in the marginal staining, which differed from the control (+) group pattern that showed a higher frequency of Alfa

values in the 10th year. This means the initial state of the margins is related to the appearance of marginal staining in the future. Compared to the first year, all three groups showed statistically significant differences, although the multiple comparisons of all years had no statistically significant differences.

Survival curves were very similar, with log-rank of 0.336, which means that there was no difference among the three survival curves. It was not possible to calculate the half-life of composite resins due to the low rate of failure. This result presumes that this cohort of restorations should be evaluated at a time to get a clearer idea of whether there was an influence of the sealed margins on the time and the relationship of the sealing to failure. As the patient cohort was medium or low caries risk, it is possible that few of these restorations would fail from this cause. It would accordingly be very interesting to conduct future studies with populations of individuals with a high risk of dental caries to measure the actual influence of sealing margins on composite restorations. Such studies could also evaluate other less self-cleaning surfaces with greater local risks, including sealed margins on interproximal areas, or even in the cervical cavity margin of proximal boxes, which will provide a challenge for clinical dentists in the future. The sealant does not increase the bond strength, applying it on the margins of composite resin restorations does not mean there is an adhesive reinforcement of the restoration surface area.[27]

The protocol of this study was to seal without applying an acid conditioning adhesive, which implies, according to current evidence, that if this protocol had been used, adhesive results could have been better.[28] For the clinical dentist, it is important to consider this option in decision-making along with improved clinical techniques to obtain best possible results.

It is important to note that for the marginal adaptation parameter, more than 50% of the sealed composites had good Alfa values after 4 years, while more than 80% had deteriorated to Bravo values after 10 years, although they remained clinically acceptable restorations.[12,29-31] The take-away point to understand is at what stage the restorations can be conveniently resealed to ensure lowering the risk of mechanical and biological sealing defects.

There are very few clinical reports regarding sealed composite restorations, but previous reports for this cohort of resin restorations agree that the use of pit and fissure sealant in minimum marginal defects increases the life of the composite.[12,29,30,32] The use of pit and fissure sealant has been considered a good preventive agent for use against the development and progression of pit and fissure caries. Sealants have also been used to successfully arrest occlusal caries lesions.[33,34] In comparison to untreated restorations, our study shows an improvement in the marginal adaptation of defective restorations sealed with the pit and fissure sealants after five years. The results are also similar to restorations that were replaced, thus questioning the need for replacement when sealant is a viable treatment option.[31]

Although, there were many Bravo values for the marginal adaptation criteria in the sealed group by the 10th year, there were few secondary caries in the group, which may be due to the preventive action of the sealant. Having a Bravo value in a sealed restoration does not mean that the mass of the sealant was completely lost, only that, at least at one point of the restoration, the margin retains the explorer. Despite this evidence, there is contradiction in the control group (-) where increased deterioration was not detected in marginal adaptation at 10 years, which may be due to limited explanation given by the amplitude of Bravo criteria of the USPHS and could be better explained by the evaluation criteria proposed by Hickel and others.[18]

These results are consistent with those of Kuper and others[35] that suggest that irrespective of the size of the gap, the caries risk is more important in the formation of new lesions. When risk is high, even a gap size of only 68 μm may allow for development of a secondary wall lesion next to a composite restoration.[35]

This study commenced examinations after the first year, and there are no records assessing the sealing immediately after the restoration, which we consider to be a limitation of this work. However, we believe that the only parameter that might have changed markedly would have been the marginal adaptation. Furthermore, it is important to emphasize that the sealing was made by professors of restorative dentistry at the University of Chile calibrated for this procedure, which ensured the reliability of the protocol.

Despite not considering the type of restorations (Class I or Class II) when forming the groups, which we consider a great limitation of this trial, we believe that the Class had no influence on the results. The evaluation in this trial was considering only the

occlusal surface of the restorations. The sample size of this study was low; subsequent results at baseline showed data that likely helped to obtain an estimate of an adequate sample. Considering the differences obtained in the different study groups, a sample size of more than 100 would be required to reach statistical significance.

Another limitation is that the presence of the white sealant prevented blind evaluations of the restorations for this group, which could have influenced the evaluators, although they were blind for the other two groups (no treatment and control).

Although the evaluation at the 10th year indicates that no-treatment (-) and sealing groups had a similar situation, it is important to note that the measuring instrument used has very wide ranges that are not sensitive to small changes in quality of the margins; for example, the Ryge Bravo criteria might consider a marginal defect from 200 μm to even 3 mm. Therefore, it is important to know next assessments in time because without knowing the extent of the defects, it could be assumed that initial small defects might increase in size, and according to Ryge criteria, it would be impossible to detect differences until they reach a Charlie value.

Even though the Kaplan-Meier curve results were similar, it is important to explain that this curve represents a dichotomous analysis without considering differences between excellent or damaged, but clinically acceptable restorations. This is better represented on the percentage charts, which could guide the clinical dentist to make the decision of resealing or repairing the sealant after a particular time to achieve a marginal maintenance of excellence in resin composite restorations.

CONCLUSIONS

- Sealing the margins of the composite resin restorations had no significant effect, under the conditions of this study in the 10th year.
- Sealing the restorations substantially improved the marginal staining and marginal adaptation parameters, though by the 10th year they were similar to the group without intervention, considering the limitations of evaluation.
- After 10 years, the three groups, with the parameters studied, remained clinically acceptable.

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