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## Can repair increase the longevity of composite resins? Results of a 10-year clinical trial<sup>☆</sup>

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### ABSTRACT

**Objectives:** The aim of this double-blind clinical trial was to assess the longevity of repairs to localized clinical defects in composite resin restorations that were initially planned to be treated with a restoration replacement.

**Methods:** Twenty-eight patients aged 18–80 years old with 50 composite resin restorations (CR) were recruited. The restorations with localized, marginal, anatomical deficiencies and/or secondary caries adjacent to CR that were “clinically judged” to be suitable for repair or replacement according to the USPHS criteria were randomly assigned to Repair ( $n = 25$ ) or Replacement ( $n = 25$ ) groups, and the quality of the restorations was scored according to the modified USPHS criteria. The restorations were blind and two examiners scored them at baseline (Cohen Kappa agreement score 0.74) and at ten years (Cohen Kappa agreement score 0.87) restorations. Wilcoxon tests were performed for comparisons within the same group (95% CI), and Friedman tests were utilized for multiple comparisons between the different years within each group.

**Results:** Over the decade, the two groups behaved similarly on the parameters of marginal adaptation (MA) ( $p > 0.05$ ), secondary caries (SC) ( $p > 0.05$ ), anatomy (A) ( $p < 0.05$ ), and colour (C) ( $p > 0.05$ ).

**Conclusions:** Given that the MA, SC, A and C parameters behaved similarly in both groups, the repair of composite resins should be elected when clinically indicated, because it is a minimally invasive treatment that can consistently increase the longevity of restorations. **Clinical significance:** The repair of defective composite resins as an alternative treatment to increase their longevity proved to be a safe and effective treatment in the long term.

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## 1. Introduction

The most common treatment by dentists for failed restorations after 10 years of placement has been to replace them. Although the replacement of a restoration is commonly preferred by most dentists, repairing it may be the more conservative treatment option. During a replacement, a significant amount of healthy tooth structure is disturbed when the preparation area is enlarged, and negative effects on tooth longevity have been observed. In addition, replacing a restoration has the drawbacks of being time-consuming, running the risk of converting it to a larger restoration, and the possibility of injuring the dentine–pulp complex.<sup>1</sup>

In contrast, repairing a failing restoration is a part of the minimally invasive dentistry philosophy, which seeks to ensure the preservation of healthy teeth, early detection of carious lesions, no or minimal surgical intervention, and keeping the teeth functional for life.<sup>2</sup>

Several studies of restoration repair have found it to be a simple and fast procedure that improves the clinical properties of the defective composite resins. In addition, it is often as effective as a total replacement and considerably improves the longevity of the dental restorations. With a modified surgical approach, including smaller tooth preparations with modified cavity designs, the repair of a restoration offers a minimal intervention with a good cost–benefit ratio for the patient.<sup>3–6</sup>

This alternative treatment option of repairing localized defects in composite resin restorations involves removing the damaged portion of the restoration and any defective tissue adjacent and subjacent to it and then rebuilding the prepared site.<sup>7</sup>

The aim of this double-blind clinical trial was to assess the longevity of repairs to localized clinical defects in composite resin restorations that were initially planned to be treated with a restoration replacement. The hypothesis was that repairing a restoration would recover its clinical condition, increase its longevity after the initial 10 years, and would be similar to replacing the restoration.

## 2. Materials and methods

### 2.1. Study design

Twenty-eight patients from 18 to 80 years old (mean 26.5 years), comprised of both females (58%) and males (42%), that had a total of 50 composite resin restorations were recruited at the Operative Dentistry Clinic at the Dental School of the University of Chile. The sample (restorations) presented localized, marginal, anatomical deficiencies and/or secondary caries adjacent to composite resin restorations that deviated from the ideal and were rated Bravo or Charlie according to the modified United States Public Health Service (USPHS) criteria.<sup>8</sup> The protocol was approved by the Institutional Research Ethics Committee of the Dental School at the University of Chile (Project PRI-ODO-0207/NCT02043873). All of the patients signed informed-consent forms, completed

registration forms, and agreed to participate in the study blind to the treatment received. Patients whose restorations failed were removed from the study and treated, but were still included in the final analytical statistics according to intention to treat “CONSORT” protocol.<sup>9</sup> The selection criteria are summarized below.

#### Inclusion criteria:

- Patients with localized, marginal, anatomical deficiencies and/or secondary caries adjacent to composite resin restorations that were “clinically judged” to be suitable for repair or replacement according to the USPHS criteria (Table 1).
- Patients with more than 20 teeth.
- Restorations in functional occlusions with an opposing natural tooth.
- Asymptomatic restored tooth.
- At least one proximal contact area with a neighbouring tooth.
- Patients older than 18 years.
- Patients who agreed to and signed the consent form for participating in the study.
- Region outside of the restoration’s failure was in good condition.

#### Exclusion criteria:

- Patients with contra-indications for regular dental treatment based on their medical history.
- Patients with special aesthetic requirements that could not be solved by repair treatments.
- Patients with xerostomia or taking medication that significantly decreased salivary flow.
- Patients with a high risk of caries.
- Patients with psychiatric or physical diseases, which interfered with oral hygiene.
- Composite restorations with localized defects by secondary caries or marginal defects greater than 3 mm, and located and/or in the proximal surfaces.
- “Clinical judgement” that repair was not indicated in resin restorations.

### 2.2. Treatment group criteria

Initially, 356 restorations (66 patients) were evaluated between January 2002 and September 2003 and assigned based on the modified USPHS criteria, from which 50 were selected (28 patients) in accordance with the inclusion criteria. Restorations with clinically diagnosed secondary caries (Charlie), marginal defects (Bravo), and/or under-contoured anatomical form defects (Bravo) were randomly assigned to the Repair ( $n = 25$ ; class I = 12; class II = 13) or Replacement ( $n = 25$ ; class I = 13; class II = 12) groups (Fig. 1). The randomization was performed by the Power Analysis, and Sample Size System programme (Excel 2000, Seattle, WA, USA), and Ekstrand criteria were utilized to diagnosis active secondary caries and risk caries assessment was made by Cariogram software.<sup>10</sup>

**Table 1 – Modified USPHS clinical criteria.**

Clinical characteristic	Alpha	Bravo	Charlie
Marginal adaptation	Explorer does not catch or has one way catch when drawn across the restoration/tooth interface	Explorer falls into crevice when drawn across the restoration/tooth interface	Dentine or base is exposed along the margin
Secondary caries	There is no clinical diagnosis of caries	NA	There is clinical diagnosis of caries
Anatomic form	The general contour of the restorations follows the contour of the tooth	The general contour of the restoration does not follow the contour of the tooth	The restoration has an overhang
Colour	The restoration matches in colour and translucency to the adjacent tooth structure	The mismatch in colour and translucency is within the acceptable range of tooth colour and translucency	The mismatch is outside the acceptable range of colour and translucency

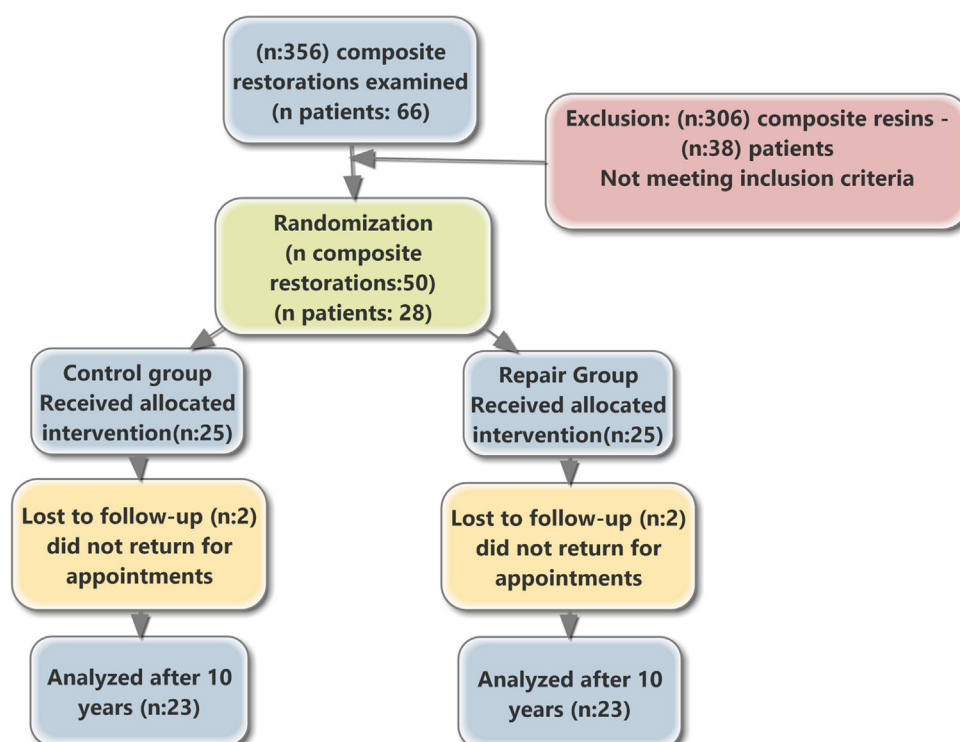
**2.3. Restoration assessment**

The quality of the restorations was scored based on the modified USPHS criteria. Two examiners underwent calibration exercises each year (JM and EF). The Cohen’s Kappa inter-examiner coefficient was 0.74 at the baseline and 0.87 at ten years. Immediately after the treatment (baseline) and 10 years later, the examiners assessed the restorations independently by direct visual and tactile examination with mouth mirror number 5 and explorer number 23 (Hu Friedy Mfg. Co. Inc., Chicago, IL, USA), and indirectly by radiographic examination (bite wing). The four parameters examined were marginal adaptation, secondary caries, anatomic form, and colour. If a difference was recorded between the two examiners and they could not reach an agreement, a third clinician, who also underwent the calibration exercises (GM), made the final decision.

**2.4. Treatment groups**

**2.4.1. Repair**

The clinicians (PV and GM) used carbide burs (330-010 Komet, Brasseler GmbH Co., Lemgo, Germany) to explore the defective margins of the restorations, beginning with the removal of part of the restorative material adjacent to the defect to act as an exploratory cavity; this allowed a proper diagnosis and evaluation of the extent of the defect. Provided the defect was limited and localized, the clinician then removed any defective tooth tissue. When this material was removed, an exploratory cavity preparation was done that included removal of any demineralized and soft tooth tissue. A self-priming resin bonding system was used (Adper Prompt L-Pop; 3M ESPE, St. Paul, MN, USA), followed by a restoration with composite resin restorative material (Filtek Supreme; 3M ESPE). Rubber dam isolation was used for this procedure.



**Fig. 1 – Flow diagram of the study phases.**

### 2.4.2. Replacement

The clinicians totally removed and replaced the defective restorations. After completing the cavity preparations, it was restored with a new resin composite (Filtek Supreme; 3M ESPE). The elimination of the soft tooth tissue caries infection was made using carbide burs at high speed under full water irrigation. During the cavity preparation, no preventive extension or undercut area was created, and all of the cavity angles were rounded. In the deep dentine, a glass-ionomer liner (Vitrebond; 3M ESPE; USA). Adper Prompt L-Pop, (3M ESPE) was used per the manufacturer instructions, and the resin composite (Filtek Supreme; 3M ESPE) was applied by the incremental technique. The occlusion was checked, and the restorations were finished and polished following the manufacturer instructions.

### 2.5. Statistical analysis

The sample size was defined by setting a beta error rate of 0.2. A Wilcoxon test was performed for comparisons within the same group with a significance level of 0.05. A Friedman test was utilized for multiple comparisons between different years of the same group with a significance level of 0.05 using SPSS 21.0 (IBM, New York, NY, USA) statistical software.

## 3. Results

Over the 10 years, 2 patients dropped out of the Repair group (8%) and 2 dropped out of the Replacement group (8%) due to breaching of appointments. Over the course of the study, the two groups behaved similarly on the colour, marginal adaptation, secondary caries, and anatomy parameters.

### 3.1. Distribution of the parameter scores over time

The proportion of marginal adaptation Bravos increased similarly in both groups over the 10 years (Fig. 2). However, there was a higher proportion of failures (Charlies) in the Repair group restorations relative to the Replacement group (5:1 restorations), which acted as a control. The distribution of this group was asymmetric over the years. By the tenth year, the distribution was 36% Alphas, 60% Bravos, and 4% Charlies in the Repair group, while the Replacement group had 35% Alphas and 65% Bravos.

The secondary caries was predominantly classified as Alpha over the years for both groups, with some variation between them over the years. By the tenth year, both groups had 93% Alphas, and both had lost two restorations due to caries.

For the anatomy parameter, the Alphas predominated every year for both groups, although the Repair group had failures (Charlies) in the fifth and tenth year (Fig. 3). By the end of the 10 years, the distribution in the Repair group was 40% Alphas, 56% Bravos, and 4% Charlies, while it was 57% Alphas and 43% Bravos for the Replacement group. Only two restorations failed in the Repair group over the 10 years based on this parameter.

The distributions in the colour parameter show that by the tenth year there was an increase in the proportion of Bravos relative to the Alphas, with two failures restorations in the Repair group (Charlies) in the tenth year (Fig. 4). Although the trends were similar, the Replacement group had a higher proportion of Alphas than did the Repair group. After 10 years, the distribution for the Repair group was 75% Alphas, 17% Bravos, and 8% Charlies, while the Replacement group had 92% Alphas and 8% Bravos.

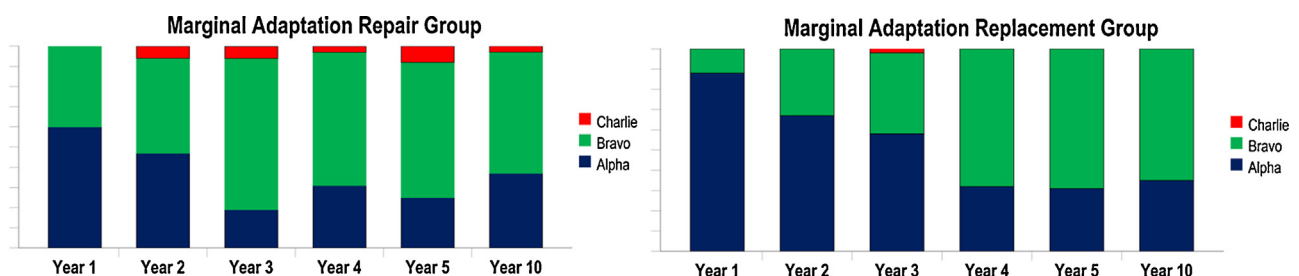


Fig. 2 – Marginal adaptation parameter. Group behaviour expressed as the proportion per year.

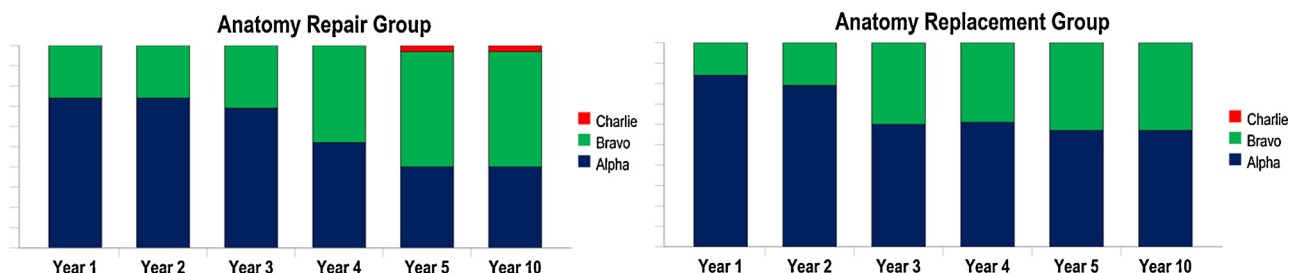


Fig. 3 – Anatomic form parameter. Group behaviour expressed as the proportion per year.

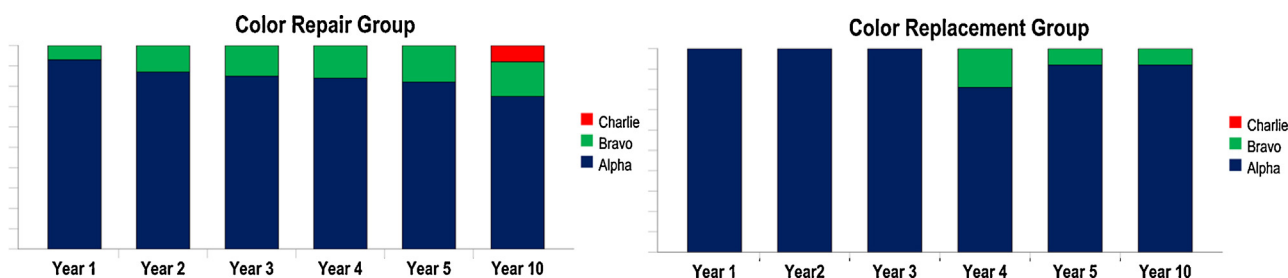


Fig. 4 – Colour parameter. Group behaviour expressed as the proportion per year.

3.2. Change in parameters over time (Friedman tests)

The average values for the marginal adaptation were near Alpha in the first year and were reaching values close to Bravo in the tenth year for both groups. There were no statistically significant differences between the age groups ( $p > 0.05$ ).

Both groups behaved similarly in the development of secondary caries, although the trends were asymmetric due to the occurrence of the caries lesions in different years for the two groups over the 10 years of observation. The differences between the groups were not statistically significant ( $p > 0.05$ ).

Over the course of the decade, the anatomy deteriorated to Bravo values, but remained clinically acceptable. The differences between the years within each group were statistically significant ( $p < 0.05$ ).

The colour parameter behaved similarly in both groups over the years, progressing from one step closer to an average value of Alpha to an average value of Bravo, with the colour remaining clinically acceptable. No statistically significant differences were found ( $p > 0.05$ ).

3.3. Comparisons between the first and tenth years after restoration (Wilcoxon tests)

For the marginal adaptation, the first and tenth years were significantly different for the Replacement group, but not for the Repair group (Table 2). For the parameters of secondary caries and anatomy, neither group showed statistically significant differences between the first and tenth year. In contrast, there was a significant difference in the colour parameter between the first and tenth year for the Repair group, but not for the Replacement group.

**Table 2 – Wilcoxon tests comparing the first and tenth years ( $p$  values) of the evaluated parameters for the Replacement (control) and Repair groups (statistically significant values in bold).**

	Marginal adaptation	Secondary caries	Anatomy	Colour
Repair	0.102	0.18	<b>0.046</b>	<b>0.035</b>
Replacement	<b>0.046</b>	1	0.317	0.083

4. Discussion

Clinical studies support the repair and replacement option for treating composite resins with minimal defects.<sup>11–18</sup> However, we did not know the long-term behaviour of these treatments and their true significance in increasing the longevity of composite resins.

The reported longevity of composite resins is below 10 years, which could mean an early treatment decision to repair a defective composite resin due to some localized carious lesion or a problem caused by mechanical damage. This study suggests that it is possible to double the half-life of the original restoration with minimal intervention and consequently increase the life of the tooth.<sup>19,20</sup> Increasing longevity based on a simple procedure with a low biological cost in localized defects could, in many cases, double the longevity of a defective restoration. In the past, decisions by dentists have been made oriented primarily towards composite resin replacements, but minimally invasive dentistry today requires finding conservative solutions to restore minimal and localized defects.<sup>2,21</sup>

This clinical trial was double-blind in which neither the evaluators nor patients knew which restorations belonged to which group, which strongly increases the external validity of the data. An initial assessment of 66 patients was made, from which 50 composite resin restorations were selected that had small and localized defects. Ideally, the patients had two defective restorations (24 patients) to enable randomization, but 4 patients with a single defective restoration were included. In the 24 patients with two restorations, the control (replacement) and repaired restorations were randomized. The 4 patients with a single defective restoration were randomized to either the Replacement or Repair group. The patients were considered to be the statistical unit rather than the restorations.

The defects in this study were considered to be those no larger than 2–3 mm diameter and included problems in the anatomy, marginal fractures, or caries adjacent to the restorations, but they were restricted to those on the occlusal surface of class I or II restorations. The design of the cavities to perform the repairs was with one wall on the composite resin and the remaining walls in the enamel, which allowed for clinical observation and optimal self-cleaning by the patient.

The local ethics committee did not allow consideration of further injury or repair of proximal caries in the cervical



region, because at the time the study was initiated, this technique was considered an experimental treatment with insufficient evidence.

Doing a repair means that a large portion of the original restoration remains in place. The Ryge criteria do not include any specific classifications for these areas (repaired versus existing).<sup>22,23</sup> Therefore, the results obtained over the 10 years included the performance of both the repaired and existing sections of the restorations. Most of the repaired restorations remained in acceptable condition for a decade, and we can therefore conclude that repairing solved the existing problem.

A self-etching adhesive system (Adper Prompt L-Pop) was used on the cavity designed for the repairs (adjacent enamel and composite resin) in this study following the manufacturer instructions. Although this adhesive system presented poor results in a later work,<sup>24</sup> the repairs in this current study showed a clinically acceptable performance for up to 10 years, which further validates this treatment as an alternative to replacement. Considering the advent of new strategies and better adhesive systems for composite resins, improved results could be expected when using them today.<sup>5,6</sup>

Regarding the failure of the restorations, when a restoration parameter was evaluated as Charlie (failure), the restoration was replaced, following the ethical guidelines. However, these restorations were still included in the Friedman within-group statistical analysis to gain an understanding of the tendencies of the two groups over time according to intention to treat CONSORT protocol.<sup>9</sup>

In this study, the most frequent reason for repairing the resin was a problem of the anatomical form or marginal adaptation. Four modified USPHS criteria were used to evaluate the performance of the restorations annually for the first five years, and then again after 10 years of performance: anatomical form, marginal adaptation, colour, and the presence of secondary caries. Comparing the differences in the Repair and Replacement groups between the evaluations from the first and tenth years, there were no statistically significant differences ( $p > 0.05$ ), indicating that the behaviour of the restorations in this period was similar.

The primary reason restorations need replacing is secondary caries. Perhaps if these injuries were diagnosed at an early stage of destruction, there would be a high potential for successfully repairing and solving the clinical problem.<sup>25</sup> Repairing composite resins with poor occlusal or proximal anatomy also improves the prognosis and corrects for these commonly occurring problems of insufficient contact.<sup>26</sup>

The marginal adaptation improved in the localized defective area and maintained a behaviour over time similar to that of the replaced restorations. The difficulty of this analysis is that the clinical assessment criteria do not distinguish whether the marginal deterioration corresponds to the repaired area or to areas of the original restoration, which is a disadvantage of the USPHS criteria. However, to offset this deterioration, a marginal seal can be performed in parallel to compensate.<sup>27</sup> A seal accompanied by a repair could ensure more stable margins of the composite resins over time. The behaviour of the two groups on this parameter was similar, showing a significant improvement between the baseline and the evaluation after the first year, and then similar impairments in both groups until reaching a similar status after 10

years. The scores also increased from Alpha to Bravo, which meant the restorations remained clinically acceptable, but had deteriorated in their marginal adaptation.

Secondary caries is the most common reason for needing a restoration replacement. Therefore, improving the behaviour in this parameter is key to understanding whether the repair has been an effective treatment.<sup>19</sup> Comparing the differences in the behaviour of the restorations between the first and tenth years, there were no statistically significant differences ( $p > 0.05$ ), which means that the behaviour of the repaired restorations was similar to that of the replacements. This suggests improved clinical safety, as the treatment proved to be safe over a period of 10 years.

The anatomy of a composite resin is important in re-establishing the function of a restoration, and anatomical problems are an indication of the need for a composite repair. It is very common to find that composite resins with poor anatomy generate problems with food packaging or insufficient contacts.<sup>25</sup> The behaviour between the repair and replacement groups was similar ( $p < 0.05$ ) for this parameter, which indicates that there were minimal defects in the shape of the restorations during this period, maintaining clinical acceptability.

Composite resins reportedly change colour over the years.<sup>28</sup> It is interesting that a group of new composite resins and the composite resins in the Repair group behaved similarly. There was an improvement for both groups in this parameter in the evaluation after the first year in comparison to the baseline ( $p < 0.05$ ), and then the scores changed to Bravo values as the decade progressed, although they were still clinically acceptable. The result between the Repair and Replacement groups was similar.

Repairing defective composite resins with secondary caries, poor anatomy, or marginal adaptation problems should be the treatment of choice to prevent further damage to the dental pulp and to save the healthy tissue.<sup>29</sup> In addition, treatment with a composite resin repair results in a lower cost to the patient and a time savings for the dentist. Therefore, it is necessary to include dental education programmes in dental schools, the contents of repair of defective composite resins.<sup>30–33</sup>

This study agrees with the results described by Opdam et al.,<sup>21</sup> Gordan et al.,<sup>15</sup> and Popoff et al.<sup>27</sup> Opdam et al.,<sup>21</sup> concluded that repairs could considerably increase the longevity of dental restorations that were failing due to fractures or secondary cavities, primarily those in replacements of cusps and proximal boxes. In contrast, this study was only of the most likely to be controlled small localized defects on the occlusal surface of class I and II composite restorations. Nevertheless, both studies agree that the indications of the repaired defect are key to the future success of the treatment.

This cohort includes data of restorations previously reported<sup>11–14,18</sup> and patients subsequently recruited. In a study by Moncada et al.<sup>34</sup> data of amalgam restorations is reported with similar methodology. It is important to remark that, besides the difference in the material, the patient cohort is also different.

Conducting a clinical study has many limitations, beginning with the process of patient recruitment, then the treatment, and later the evaluations.<sup>23</sup> Despite not considering the type of restorations (class I or class II) when forming the groups, which we consider a limitation of this trial, we believe

that the class had no influence on the results. However, it is advisable that future studies isolate the variables properly and include a well-established randomization process, a more homogeneous age group, and include those patients with a high risk of caries. Due to the local ethics committee requirements at the time this trial was initiated, including high risk of caries patients proved to be inadvisable.

The patients who were recruited from the clinic at the Faculty of Dentistry at the University of Chile were patients who had come for restorative dentistry treatment. Despite this, the conditions were fully standardized, and the repairs and replacements of the composite resins were done by professionals who teach restorative dentistry. The patients could not be categorized by restoration's mechanical risk for fracture, which would have allowed better predicting of what the individual behaviour of each restoration would have been. Although the evaluations of the restorations were performed by different operators that received calibration training each year, this does not ensure the complete reliability of the results. The drop-out rate in this study corresponds to that reported for other related clinical trials, and it was low for a 10-year follow-up study, because the patients were from a university dental clinic where their commitment was greater.

## 5. Conclusions

Over the 10 years, the performance of the repaired restorations was similar to that of the resin composites that were replaced, with the parameters of marginal adaptation, secondary caries, and anatomy behaving similarly in both groups. Thus, the hypothesis of this study has been accepted, and we can be assured that repairing restorations is an alternative treatment that works well, with the original restoration behaving as would a replacement. The repair of composite resins should therefore be elected when it is clinically indicated, as it is a minimally invasive treatment that can consistently increase the longevity of the restoration.

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