

Seal, replacement or monitoring amalgam restorations with occlusal marginal defects? Results of a 10-year clinical trial



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ABSTRACT

The aim of this prospective and blind clinical trial was to assess the effectiveness of sealing localized marginal defects of amalgam restoration that were initially scheduled to be replaced.

A cohort of twenty six patients with 60 amalgam restorations ($n=44$ Class I and $n=16$ Class II), that presented marginal defects deviating from ideal (Bravo) according to USPHS criteria, were assigned to either sealing or replacement groups: A: sealing $n=20$, Replacement $n=20$, and no treatment ($n=20$). Two blind examiners evaluated the restorations at baseline ($K=0.74$) and after ten years ($K=0.84$) according with USPHS criteria, in four parameters: marginal adaptation (MA), secondary caries (SC), marginal staining (MS) and teeth sensitivity (TS). Multiple comparison of restorations degradation/upgrade was analyzed by Friedman test and the comparisons within groups were performed by Wilcoxon test.

After 10 years, 44 restorations were assessed (73.3%), Group A: $n=14$ and Group B: $n=16$; and Group C: $n=14$ sealing and replacement amalgam restorations presented similar level of quality in MA ($p=0.76$), SC ($p=0.25$) and TS ($p=0.52$), while in MS ($p=0.007$) presented better performance in replacement group after 10-years.

Most of the occlusal amalgam restorations with marginal gaps showed similar long term outcomes than the restorations were sealed, replaced, or not treated over a 10-year period. Most of the restorations of the three groups were clinically acceptable, under the studied parameters. All restorations had the tendency to present downgrade/deterioration over time.

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1. Introduction

Amalgam has been widely used in dentistry for over 150 years, due to its low cost, easy placement, durability, strength and bacteriostatic effect, [1–3] however, the popularity of amalgam as a restoration material has significantly decreased due to concern for potential effects on health, lack of adhesion to tooth, poor aesthetics and environmental pollution. This causes that alternative tooth colored fillings materials have become more popular, independent of the risk management decision. Amalgam as a restorative material has posted several questions worldwide and banned in several countries. Despite these recent events, there are patients who have benefitted from amalgam restorations over the

years. Although amalgam was widely accepted in past as a restorative material, just like many other restorative material it deteriorated over time due to mechanical or biological reasons [1–7]. The two major dental organization (FDI, 2009 and IADR, 2004) stated that dental amalgam has a well-documented history of safety and efficacy. It is widely used, particularly in the most disadvantages communities, for restorations in stress-bearing areas and the WHO calls for phasing down instead of phasing out of dental amalgam [8].

The longevity of amalgam restorations in the oral environment is limited between 5 and 12 years of use [9,10], and the main reasons for failures have been identified as secondary caries, marginal deficiencies, fracture, wear and postoperative sensitivity [11,28].

There is increasing support for the concept that amalgam repair is preferred over replacement of the entire restoration when the restoration in question is deemed defective [12–15,41].

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Additionally, there are conclusive reports attesting that mercury contamination is highest during the removal of the amalgam [16–18]. Moreover, it is highly desired that dentists should be able to provide treatment alternatives for replacing restorations to patients without risking their health.

The margins are the weakest area of a restoration. This interface is affected by bio-physical and chemical processes in the mouth that result in degradation of the marginal integrity, which is linked to the development of new caries adjacent to the margin of the restoration that subsequently could damage the remaining tooth structure. Marginal gaps greater than 400 μm are associated with secondary, most frequently located at the cervical margins [22].

In recent years, non-invasive strategies and minimally invasive techniques, such as repairing, sealing or refinishing localized defects, have resulted in an overall improvement in the clinical properties of defective restorations. These strategies increase the longevity of restorations through minimal intervention, particularly because it is well established that when a restoration is replaced, parts of healthy dental tissues are lost during the preparation, including areas unrelated to the defects [20,21,23,38]. Alternative treatments to replacing defective restorations, such as sealing marginal gaps, are easy, quick and simple solutions that improve the overall clinical properties of restorations that have defective areas with minimal intervention [23,24].

A previous study showed that the application of resin sealants at the margin of defective restorations achieved similar marginal adaptation results as replacement of the restoration after five years, demonstrating that sealants are a simple and acceptable alternative to replacing restorations with marginal defects [20,23]. Therefore, the longevity of the tooth is increased with minimal intervention, cost and trauma to the adjacent tooth structures.

The aim of this prospective blind cohort study was to assess the effectiveness of sealing occlusal marginal defects in amalgam restorations (less than 1 mm) compared to control groups over a 10-year follow-up. The hypothesis was that sealant of amalgam restorations with occlusal marginal defects will improve their clinical conditions, increasing their longevity, similar to replacement and better than untreated, after 10 years of clinical service.

2. Methods and materials

2.1. Study design

This prospective study recruited a cohort of twenty-six patients (16 females and 10 males, mean age=27 years old) with 60 amalgam restorations ($n = 44$ Class I, and $n = 16$ Class II) that had one or more localized defects in the margins of the restorations

(Bravo, according to modified United State Public Health Service (USPHS) criteria (Table 1)). The restorations with defects in occlusal marginal adaptation, were randomly assigned to the sealed ($n = 20$) or untreated ($n = 20$) groups, by a random number generator (Microsoft Excel 97, Redmond, WA, USA), if the restorations was diagnosed with secondary caries, they were assigned to the replacement ($n = 20$) group (Flow diagram, Fig. 1) [14]. The protocol was approved by the Institutional Research Ethics Committee of the Dental School at the University of Chile (Project PRI-ODO-0207), and all patients signed a consent form and completed a registration form. Only faculty members provided diagnoses and treatments. The protocol of the study was registered under No. NCT02075801 (ClinicalTrials.gov).

2.2. Inclusion criteria

(1) Patients with amalgam (Am) restorations with Bravo ratings that had marginal gaps between 0.5 and 1 mm wide as measured by a periodontal probe (North Carolina PCN12, Nordent, 610 Bonnie Ln, Elk Grove Village, IL 60,007, USA), (2) patients older than 18 years of age, (3) patients with more than 20 teeth in their mouths, (4) restorations with functional occlusion against an opposing natural tooth, (5) restorations with at least one proximal contact area with an adjacent tooth, (6) the area outside of the restorations failures in good condition, and (7) patients who signed the consent form for participating in the study.

2.3. Exclusion criteria

(1) Patients with contraindications for regular dental treatment based on their medical history, (2) patients with special aesthetic requirements that could not be addressed by this alternative treatment, (3) patients with xerostomia or who were taking medication that significantly decreased salivary flow, (4) patients with a high caries risk (excluded based on the Research Ethics Committee recommendation), or (5) patients with psychiatric or physical diseases that interfered with oral hygiene.

2.4. Restoration assessment

The quality of the occlusal restorations was evaluated using the modified USPHS modified criteria. Two examiners (JM and EF) assessed the restorations independently by visual and tactile (mouth mirror number 5, Hu Friedy Mfg. Co. Inc. 3232 N Rockwell, Chicago, IL 60618-5982, USA) examination using an explorer (No. 23Hu Friedy) and indirectly by radiographic (Sirona Heliodent Vario, Sirona Drive Suite 100Charlotte, NC 28273, USA) examination with interproximal radiographs (Bite Wing, DF57, Kodak

Table 1
USPHS/Ryge clinical criteria.

Clinical characteristic	Alpha	Bravo	Charlie
Marginal adaptation	Explorer does not catch when drawn across the restoration/tooth interface	Explorer falls into crevice or has a one-way catch when drawn across the restoration/tooth interface	Dentin or base is exposed
Secondary caries	There is no clinical diagnosis of caries	N/A	Clinical diagnosis of caries
Marginal stain	There is no discoloration between the restoration and tooth	There is discoloration on less than half of the circumferential margin	There is discoloration on more than half of the circumferential margin
Tooth sensitivity	No sensitivity when an air syringe is activated for 2 s 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 2 s 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 2 s 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

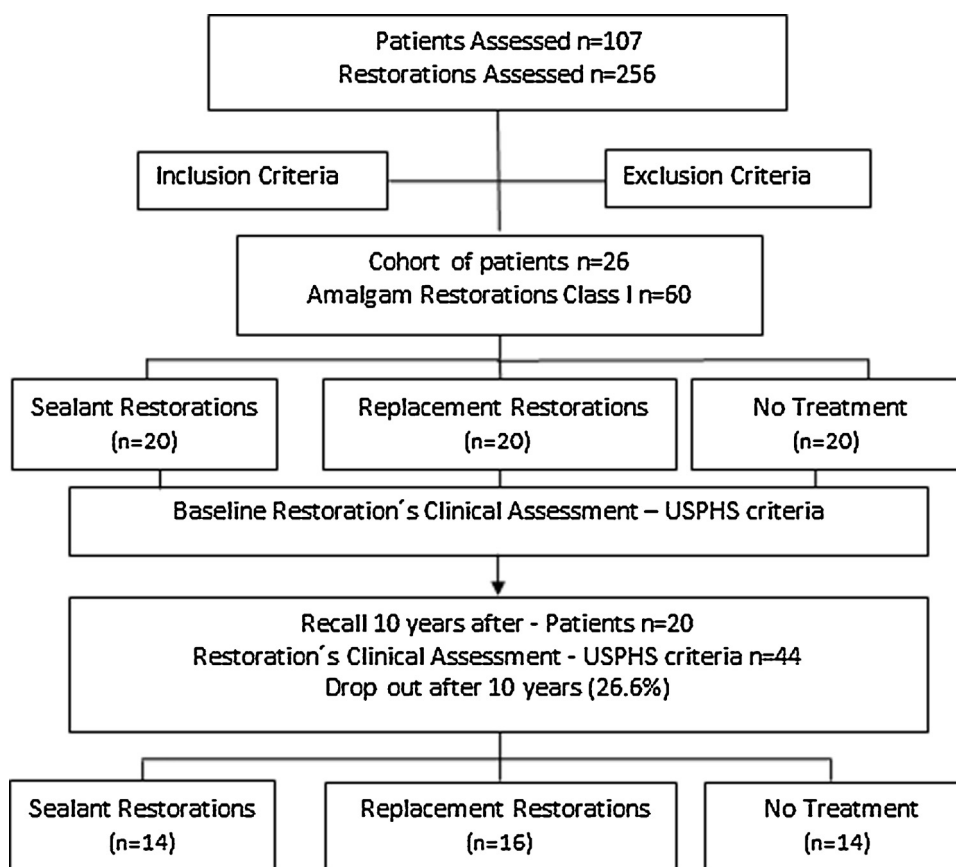


Fig. 1. Flow diagram.

Dental System, Healthcare, Rochester, NY14608, USA). All the restorations were assessed at baseline, annually for the first four years, and then ten years after treatment. The restorations were evaluated according to four parameters: marginal adaptation (MA), secondary caries (SC), marginal stain (MS) and tooth sensitivity (TS) (Table 1). If any difference was recorded between the 2 independent examiners and no agreement could be reached, a third clinician (GM) was called to assist with the process. If the three clinicians did not agree on the score, the lowest score was recorded. All three clinicians were professors of Operative Dentistry with a minimum of 15 years of experience in clinical research. All researchers participated in calibration exercises at the beginning of the study and before each recall evaluation period. The inter-examiner reliability results were Kappa = 0.74 at baseline and Kappa = 0.84 at year ten.

The quality of the restorations was scored and analyzed for each individual parameter. Therefore, a restoration that received a Bravo score in marginal adaptation did not necessarily have a Bravo score in the other three clinical parameters. A change from Bravo to Alpha was considered an improvement, and a change from Alpha to Bravo was considered a downgrade.

As the goal of the study was to observe the restorations through a longitudinal cohort, three clinical parameters in addition to marginal adaptation were included as additional information.

2.5. Caries risk assessment

A graphical software program (Cariogram) was used for each individual patient's caries risk assessment. The program analyzed the interactions among the following 10 caries-related factors: caries experience, related general disease, diet contents, diet frequency, plaque score by the Silness Løe Index, semi-quantitative

detection of mutans streptococci and lactobacilli in saliva by CRT bacteria (Caries Risk Test, Ivoclar, Vivadent AG, Bendererstrasse 2, 9494 Schaan), fluoride program, amount of stimulated saliva secretion, saliva buffering capacity by CRT Buffer (Vivadent), and clinical judgment. Patients were classified as at high, medium or low caries risk.

2.6. Treatment groups

- (A) Sealing of margins: defective areas were acid etched with 35% phosphoric acid for 15 s. A resin-based sealant (Clinpro Sealant, 3 M ESPE) was applied over the defective area. The sealant was polymerized with a photo-curing unit (Curing Light 2500, 3 M ESPE) for 40 s. Rubber dam isolation was used for this procedure. All treatments were performed by the same clinician (JE), who did not serve as an examiner.
- (B) Replacement Group (positive control): The clinician completely removed and replaced the defective restoration with a new amalgam restoration (Tytin, Kerr Corporation, Orange, CA, USA). Bonding agent and/or liner were not used in this study. Rubber dam isolation was used for this procedure. All treatments were performed by the same clinician (JE), who did not serve as an examiner.
- (C) No-treatment Group (negative control): amalgam restorations that had marginal defects did not receive any treatment.

None of the patients refused the invitation to participate in the study, and all agreed to sign the informed consent. Patients were recalled each year during the first four years and ten years after the treatment for clinical assessment of the restorations. The same examiners used the same criteria that were established at baseline to examine the restorations at the 10-year mark. Failed restorations

were removed from the study and treated according to the diagnosed needs. (Fig. 1)

2.7. Statistical analysis

The sample size was defined by setting a beta error rate of 0.2. The data distribution was analyzed with the Kolmogorov–Smirnov test (K–S). The results from each group (for both degradation and upgrade) were analyzed according to the Friedman rank non-parametric test for comparison of both baseline and follow-up examinations. Additionally, the outcome of all groups was contrasted using the Wilcoxon signed-rank test to determine the differences between the upgrade and downgrade of the restorations. The statistical significance was set at 95%, $\alpha = 0.05$ and $\beta = 0.2$, SPSS 15.0 was used for the statistical analysis (SPSS Inc., Chicago, IL).

3. Results

Of the 60 restorations evaluated at baseline, 44 returned for the 10-year recall (73.3%) (Restorations withdrawn/Drop out = 2.6% per year).

The studied sample did not show a normal data distribution (K–S = $p < 0.001$).

All patients were classified as low (20%) or medium (80%) caries risk, and the radiographic examinations did not reveal caries in the studied teeth. During the study period, two restoration failures were observed; therefore, two restorations were removed from the study in untreated group. Due to local ethics committee requirements at the time when the trial was formulated, including high caries-risk patients proved to be impossible because sealing was classified as an experimental treatment ten years ago. The lack of that cohort was the main limitation of this study.

For the marginal adaptation parameter, 100% of the restorations in the sealant group had a Bravo rating at baseline. After 10 years, 54.6% of the restorations had an Alpha score and 45.4% had a Bravo score. No Charlie scores were given. In the replacement group, 91% of restorations at baseline had a Bravo score, and after 10 years, 54% had an Alpha score, 46% had a Bravo score, and none had a Charlie score. In the non-treatment group, 82% had an Alpha score at baseline and 18% had a Bravo score. After 10 years, 36.2% had an Alpha score, 59% had a Bravo and 4.8% had a Charlie score (Figs. 2–4). The three groups showing similar scores during the study period (Friedman range test $p = 0.76$)

The secondary caries parameter was not affected by time. From baseline to the 10-year recall, there was no overall change, as 100% of the restorations were Alpha in the sealant and replacement

groups. Conversely, none of the restorations in the non-treated group received a Charlie score at baseline and 4.8% received a Charlie score after 10 years. In spite of this result, the Friedman range test showed similar scores ($p = 0.25$) during the study period for the three groups (Figs. 2–4).

The marginal stain parameter in the sealed group at baseline had a 92% Alpha value, and it increased to 96.5% after 10 years. The Bravo value in this group reduced from 7.7% to 3.5%, and there were no Charlie scores at baseline or at the 10-year recall. In the replacement group, there was an increase in Alpha value from 52.4% at baseline to 84.6% at the 10-year recall. The Bravo value showed a reduction from 47.6% at baseline to 15.4% at the 10-year recall. There were no Charlie scores at baseline or at the 10-year recall. The non-treated group reduced in Alpha value from 92.7% at baseline to 71.7% after 10 years, and Bravo scores increased from 7.3% to 21.7%. Additionally, this group showed no Charlie values at baseline and 6.5% of this group had Charlie scores at the end of the study (Figs. 2–4). The comparison between groups showed better performance in replacement group according to Friedman range test ($p = 0.007$) at tenth year (Table 2).

In general most restorations of all groups were clinically acceptable after 10 years and showed similar scores during the study period based on the Friedman range test (Table 2).

Alpha values in the tooth sensitivity parameter of the sealant group were 96.1% at baseline and 90.5% after 10 years, whereas the 3.9% of Bravo values at baseline increased to 9.5% at the 10-year recall. There were no restorations assessed with a Charlie value at baseline or after 10 years. In the replacement group, 90.5% had Alpha values at baseline and 84.6% after 10 years, whereas 9.5% of the restorations had Bravo score at baseline and 15.4% had at the 10-year recall. The replacement group did not have any Charlie values at baseline or after 10 years. The non-treated group had 100% Alpha values at baseline and 97.8% after 10 years, whereas no Bravo scores at baseline and 2.1% after 10 years.

For marginal staining, there were statistically significant difference between the baseline and the 10-year exam (Table 2).

The Wilcoxon test was used to compare the performance of different clinical parameters between baseline and the 10-year follow-up. Marginal adaptation, secondary caries, and tooth sensitivity showed similar performance scores in all groups, whereas marginal staining showed significantly better scores for the replacement group (Table 2), and post-hoc Wilcoxon test was carried out to determine low level of power and effect side (Table 3).

Three restorations were removed from the study for failures, all in untreated group in MA, SC and MS parameters. The comparison of survival curve showed no significant differences between sealed

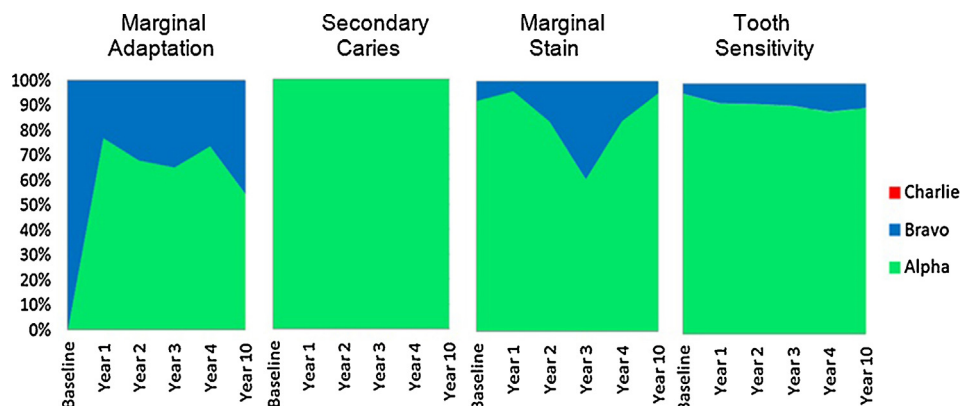


Fig. 2. The green area in the graph represents the percent of sealed restorations that scored Alpha from baseline to 10-year clinical observation period. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

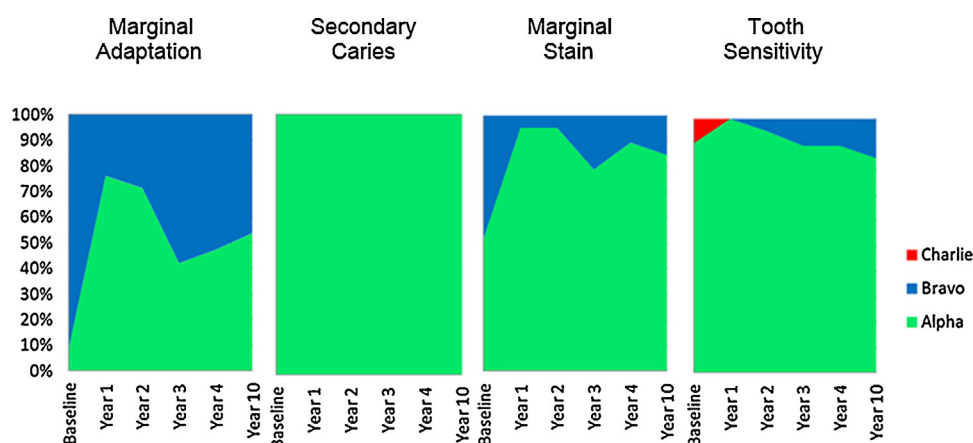


Fig. 3. The green area in the graph represents the percent of replaced restorations that scored Alpha from baseline to 10-year clinical observation period. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

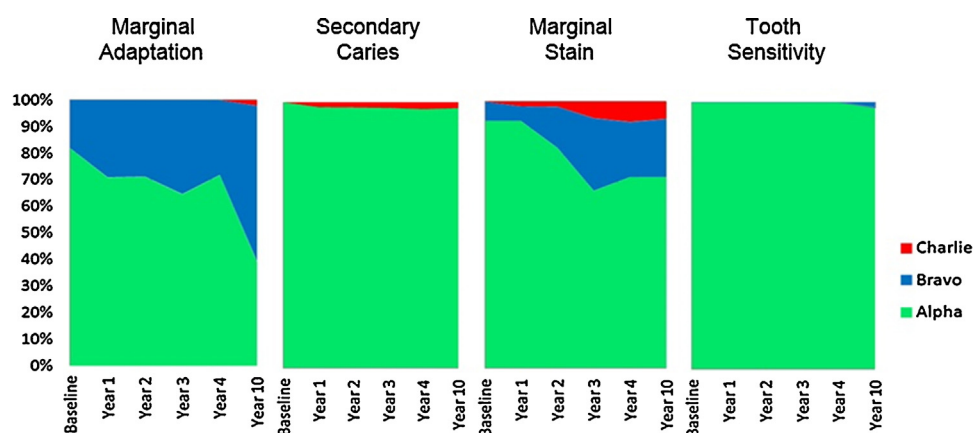


Fig. 4. The green area in the graph represents the percent of sealed restorations that scored Alpha from baseline to 10-year clinical observation period. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

Table 2

Comparison of the four parameters between baseline and the 10-year follow-up between groups using the Wilcoxon signed-rank test.

	Marginal Adaptation	Secondary Caries	Marginal Staining	Tooth Sensitivity
<i>p</i> =	0.76	0.248	0.007*	0.516

* Statistically significant.

Table 3

Power and effect side post-hoc results of sealing and replacement groups, separated by studied parameter, according to Wilcoxon test.

Sealing/replacement				
	MA	SC	MS	TS
Power	0.05	0.05	0.028	0.05
Side Effect	0.00	0.00	0.035	0.00

and untreated groups, according to Mantel Cox long rank test ($p=0.40$), and there was a low hazard ratio, according to Mantel Haenszel test (0.18) (Fig. 5).

4. Discussion

The quality of the restorations and their years of service are relevant information for patients, governments, and dentists as they can dictate the cost of dental treatment. New approaches using sealants on defective restoration margins are less invasive, quicker, and cause less patient anxiety. Such approaches could be

considered as an alternative treatment to replacing dental restorations and with potential to increase the longevity of amalgam restorations and the affected teeth.

This clinical, prospective and blinded study assessed patients for 10 years by observing the performance of amalgam restorations with marginal defects that were sealed and compared to positive and negative control groups. During this observation period, no tooth fractures were observed and there was no pulp injury, which could be explained by the low level of trauma that this technique imposes on the teeth [23,26].

As previously reported, sealant and replacement treatments were equally efficient in improving marginal defects in occlusal amalgam restorations during the first four years of service [20]. After ten years, some of sealed restorations received Bravo values for marginal adaptation, reaching similar scores to the restorations in the replacement group ($p=0.76$). However, it is important to note that the sealant group did not have any Alpha scores at baseline and the replacement group had a low number of Alpha scores (10%) at baseline, but these groups obtained the same level of Alpha scores after ten years. Additionally, the data showed that if

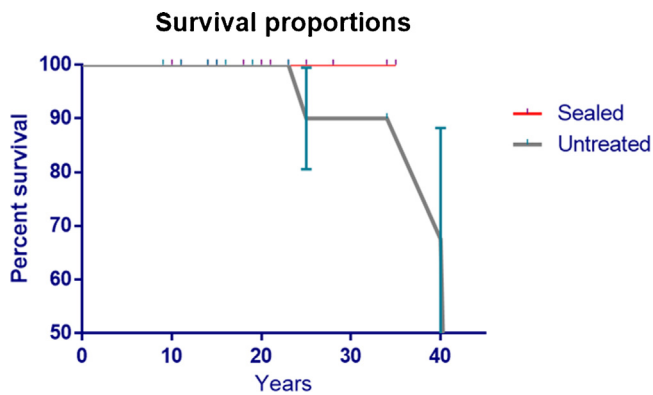


Fig. 5. Survival proportions of sealed and untreated groups, according to Mantel-Cox long rank test.

localized defects are present, alternative treatments delay the process of failure, similar to the replacement group during the first four years. Although most of the restorations in the control group had Alpha scores at baseline, they showed a continuous deterioration of marginal adaptation parameter during the study period, even without knowing its source material alloys (traditional or high copper content). The result of this cohort of amalgam restorations are similar to that reported by Gordan et al. who studied sealed amalgam restorations over a seven-year period [23], and comparable with Fernandez et al. who studied the sealing of resin composite restorations for ten-years [27].

The trend in downgraded margin scores during the study may have been due to the normal degradation of the restoration in the oral environment or related to other variables not included in this study that may have involved other individual clinical characteristics, such as size and cavity design, occlusion and function, or other clinical features. This lack of confidence in pinpointing the effect of other potential variables is a limitation of the present study.

Sealed and replaced restorations showed significant improvements during the first year of service and gradually reduced in quality in subsequent years. Previous studies have also described this issue [24,25]. However, all restorations of sealed and replaced groups were assessed as clinically acceptable (Alpha or Bravo) in the marginal adaptation parameter after 10 years. These observations suggest that instead of replacing amalgam restorations with marginal gaps that are no larger than 1 mm, the placement of a sealant might be a simpler alternative to improve the quality of defective restorations. However, the sealant may require reapplication [19] and should be monitored; the light-cured resin-based sealant used in the present study showed early partial loss at the occlusal surfaces, but seemed to have remained partially sealed at the bottom of the gap.

Caries around restorations is considered the main reason for replacement restorations [12,28] in the present study, the sealant and replacement groups were equally effective in preventing secondary caries after 10 years (Friedman test $p=0.248$). The untreated group showed a few cases with new caries around amalgam restorations, which in this group occurred because the margins continued aging over time without any intervention. In addition, the early clinical diagnosis of secondary caries in occlusal areas is difficult and often arbitrary [22,31] because the blue-grey color of the margins of amalgam restorations is not considered a predictable indicator of the presence of secondary caries. The validity of staining and marginal ditching as criteria for the diagnosis of secondary caries around occlusal amalgam restorations is also questionable and not accepted today [22,30,31,37]. Conversely, the size of marginal gaps has been correlated to the

presence of carious lesions if the gap is wider than 0.4 mm, which is difficult to measure clinically [22,31].

The determination of the patient's caries risk level is the typically used instrument for predicting caries performance for patients, and in the present study this evaluation was only made at baseline, at this time. Caries risk, considered as a dynamic index, may change over time, but the caries risk was not evaluated each year, and it would have been important to know and to explain the results of the untreated group in secondary caries parameter. In cariogram evaluation, clinical judge parameter was included, and it did not show major influence over final score, because patients live in a high caries risk area, according to WHO, this fact probably reduces the bias of the clinical judge over final score.

On the other hand, one might think that a limitation of this study is the possibility of inadvertently leaving carious lesions underneath the sealed area. However, previous studies showed that sealing such lesions improves their prognosis and promotes the arrest of occlusal caries [32–35].

The cohort included patients with medium and low caries risk, since secondary caries is the most important reason for amalgam restoration failures, it would have been valid to study the treatment outcome in a group of patients classified as at high caries risk in the future, because caries risk of patients plays a significant role in restorations survival [29].

Repairing restorations with larger defects has a lower success rate, as described in the Opdam study [40]. The present study, however, only addressed sealing amalgam defects with defective margins no larger than 1 mm.

Marginal staining is an important aesthetic concern for patients, but it is not necessarily associated with teeth disease, although the lack of marginal staining is considered a good predictor of healthy teeth [22,31,36].

The clinical importance of the marginal gaps is associated with micro-organism form a biofilm not only on oral tissues but also on dental biomaterials. Biofilm formation is depending on physicochemical characteristics of the material's and marginal gaps play a role in the failure probability [36].

Marginal staining parameter, during the third year of the study showed an increase in Bravo scores in the sealant group when compared with the replacement group. The replacement group showed significantly better results after 10 years when compared with the sealant group ($p=0.007$). However, replacement can be destructive to dental tissues, and in the long run, it may compromise the tooth as it enables the re-restoration cycle [40]. The sealant treatment can be easily re-applied to defective restorations when the sealant wears off. It is important to highlight that neither sealed restorations received any Charlie scores during the 10-year observation period. Additionally, it is possible that the sealant may have contributed to sealing cracks in the surface of the teeth as it bonded to the tooth structure [42]. The explanation for the lower marginal stains in the replacement group than the sealant group may be that the sealant group continued to accumulate pigments over time. The non-treated group exhibited similar results to the sealant group. However, there were a few cases with Charlie scores in the non-treated group, which can be interpreted as the natural tendency for marginal staining in amalgam restorations.

The tooth sensitivity parameter showed very similar scores in all groups at the 10-year examination, according to Friedman Rank ($p=0.516$) although in the replacement group, a small but insignificant increase was observed for the Bravo scores. It is possible that in the replacement group, all dental tissue was exposed during the cavity preparation, whereas in the sealant group, no tissue exposure took place because the restorations were not removed.

The marginal adaptation is one of the most important and one of the weakest areas in a restoration. It is accepted that the chipping of restoration margins is a premature sign of deterioration during clinical service, which tends to be limited to a small part of the restoration (frequently a short segment of the cavosurface margin). Overall, the restorations had similar scores after 10 years of service, in most of the studied parameters in the three groups. The only exception was in marginal staining. These findings refute the initial hypothesis and suggest that the appropriate treatment for amalgam marginal defects remains is an open question, and additional research is needed to develop a minimal invasive technique to solve it, because unnecessary replacement of amalgam restorations not only represents a significant oral health care expense but also, most importantly, lead to loss of healthy tooth tissue [3,10,23,40].

The survival of amalgam restorations at the beginning of the study was 21.8 years, its represents an important issue because, restorations of sealed and untreated groups presented close to 32 years of longevity at the end of the study. The Kaplan Meier analysis was not possible to made due to low number of failures, but the comparison of the dichotomous survival proportion showed that was not significant differences between sealed and untreated groups, (Mantel Cox long rank test), and there was a low hazard ratio, (Mantel Haenszel test). Highlighting the fact that cohort having amalgam restorations with occlusal marginal defects (lower than 1 mm) having survival for many years (Fig. 5).

Most of the restorations of the present study were judged as Bravo score at 10th year, indicating that control groups presented similar performance than sealed restorations, this fact is important to analyze, because it could be considered a consequence of the measurement instrument applied during each check-up, because USPHS criteria presented a big amplitude of Bravo criteria, (from 200 um to 3 mm or more before to change to Charlie criteria in marginal gaps) and it is not able to detect little changes, that probably could be better identified using other criteria as the proposed by Hickel et al. [39].

Despite having low amount of restorations with Charlie value, they appear after the second year in secondary caries and marginal staining parameters, this fact is according with Gordan et al. [22] observation, while marginal adaptation was belatedly as shown Opdam et al. [40].

The present study is the first one of 10-years sealing performance and was used white sealant, which prevented the blind evaluation of the sealant group. However, the exam of the restorations was blinded for the other two groups.

Post-hoc power test exhibited low level of binary sensitive between sealed and replaced groups at tenth year, it is related to the sample size estimation, it was based on previous studies of amalgam longevity, but nevertheless since sealing treatment was not studied before, we learned that were needed more than 98 restorations per group to detect statistical changes. Effect side applied to the beneficial of the sealing was null at tenth year for all studied parameter, with the exception of marginal staining. Additionally, if the sample size is analyzed under equivalence testing, it is observed that both treatments are equivalent [44].

The low failure rate of the present study could be related with the high educational level of patients (most of them professional), with timely access to health care, without bruxism and complete dental formula.

In summary, the application of dental sealant has proven to be successful in dentistry [23,42–45,46]. Dental sealants were introduced more than 50 years ago to prevent dental caries in pits and fissures of occlusal tooth surfaces. Sealants prevent the accumulation of bacteria in pits and fissures that can lead to dental caries. The main outcome of the present study was all three studied groups showed equivalent performance after ten years, when they

are sealed, replaced or untreated, with the exception of marginal staining parameter, therefore, current state of the sealed occlusal amalgam gaps, lower than 1 mm, without any intervention during ten years, under the parameters of this study, could be probably considered an over treatment.

5. Conclusion

The results of this clinical study revealed that most occlusal amalgam restorations with marginal gaps showed similar long-term results than the restorations were sealed, replaced, or not treated over a 10-year period.

Sealing the marginal defects of amalgam restorations is a conservative treatment that increases initially the quality of marginal adaptation parameter but at ten years they were similar to replacement and untreated groups.

Clinical relevance

Based on the results of this study, amalgam restorations with sealed marginal defects produce similar outcome of restorations that are replaced or left untreated after 10-years, with the exception of marginal staining parameter, in patients with low (20%) and medium (80%) caries risk.

Conflict of interest

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

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