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## Clinical Research

# Longitudinal Results of a 10-year Clinical Trial of Repair of Amalgam Restorations

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### Clinical Relevance

Repair of amalgam restorations is a safe and effective treatment to increase the restorations' longevity with minimal intervention dentistry.

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### SUMMARY

**The aim of this prospective, blind, and randomized clinical trial was to assess the effectiveness of repair of localized clinical defects in amalgam restorations that were initially scheduled for replacement. A cohort of 20 patients with 40 (Class I and Class II) amalgam restorations that presented one or more clinical features that deviated from the ideal (Bravo or Charlie) according to US Public Health Service criteria, were randomly assigned to either the repair or the replacement group—A: repair, n = 19; and B: replacement, n = 21. Two examiners who had calibration expertise evaluated the restorations at baseline and 10 years after according to seven parameters: marginal occlusal adaptation, anatomic form, surface roughness, marginal staining, contact, secondary caries, and luster. After 10 years, 30 restorations (75%) were evaluated (Group A: n = 17; Group B: n = 13). Repaired and replaced amalgam restorations showed similar survival outcomes regarding marginal defects and secondary caries in patients with low and medium caries risk, and most of the restorations were considered clin-**

**ically acceptable after 10 years. Repair treatment increased the potential for tooth longevity, using a minimally interventional procedure. All restorations trend to downgrade over time.**

## INTRODUCTION

Amalgam has been the material of choice for stress-bearing dental restorations located in the posterior area. Despite the good long-term clinical results and relatively inexpensive cost,[1-3] this material does not fulfill the esthetic demand set by the public at large. Additionally, it does not provide adhesion to tooth structure.

Analyses of long-term restorations are an important factor for dentists, patients, and insurance companies. Amalgam presents limited longevity in the oral environment, which has been reported to be between 4.7 and 11.8 years of use.[4-6] Failures after this period have been associated with secondary caries, marginal deficiencies, degradation/wear, fracture, or loss of anatomic form.[5,7-16]

The replacement of failed restorations is the most common treatment in dentistry 10 years after initial placement, and long-term studies have shown that when failure takes place it typically happens within the first 24 months.[17]

Dentists frequently replace restorations that could be treated in a more conservative manner.[18,19] When a restoration is replaced, a significant amount of healthy tooth structure is removed and the preparation is subsequently enlarged. This negatively affects the longevity of the tooth.[20] Additionally, complete replacement of a restoration has the disadvantage of being more time consuming than a repair. There is also the added risk of converting the restoration to an indirect restoration or even the possibility of a major pulp-tissue injury.[5,21]

Repair rather than replacement of a failing restoration is part of minimally invasive dentistry, which seeks to ensure that healthy tooth structure is preserved. Early detection of carious lesions with minimal or no surgical interventions can lead to keeping teeth functional for life.[22,23]

Laboratory and clinical studies that compared replacement of defective restoration and restoration repair showed that repair was a simpler and less time-consuming procedure, thus improving the clinical properties of an otherwise defective amalgam restoration. The longevity of dental restorations increased considerably, and the repair was just as effective as a total restoration replacement, considering the minimal amount of intervention required and the lower cost involved. Repairing a restoration with a modified surgical approach that includes creating smaller tooth preparations and modifying the cavity-prep design could be, in many cases, the most conservative treatment option.[13,24-30]

Repair is an option for the treatment of defective amalgam restorations that present with localized defects. It involves the removal of the part of the restoration that is defective and any carious tissue adjacent and subjacent to the defective area and the remaining restoration of the prepared site.[25]

The aim of this prospective, blind, randomized cohort study was to assess the effectiveness of repairing localized clinical defects in amalgam restorations that were initially scheduled for restoration replacement.

The hypothesis was that the repair of amalgam restorations will improve their clinical conditions, increasing their longevity, similar to replacement of restorations.

## METHODS AND MATERIALS

### Study Design

A cohort of 20 patients between the ages of 18 and 80 years (mean, 26.5 years), women (58%) and men (42%) with 40 (Class I and Class II) amalgam restorations that presented one or more clinical features that deviated from the ideal (Bravo or Charlie, according to modified US Public Health Service [USPHS] criteria) were recruited at the Operative Dentistry Clinic of the University of Chile Dental School. The protocol was approved by the school's Institutional Research Ethics Committee (project PRI-ODO-0207), and all patients signed an informed consent form and completed a registration form. The protocol of the study was registered under No. NCT02051179 (ClinicalTrials.gov).

*Inclusion Criteria*—Those included were 1) patients having at least one tooth with a localized marginally defective amalgam restoration(s) that was clinically determined to be suitable for repair, according to USPHS criteria; 2) patients with at least 20 teeth; 3) restorations in functional occlusion with at least one opposing natural tooth; 4) patients who were asymptomatic of postoperative sensitivity; 5) patients with occlusal and proximal contact areas; 6) patients older than 18 years; 7) patients who agreed and signed the informed consent form for participating in the study, and 8) patients with areas outside the restoration's failure that were in good condition.

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 | Dentin or base is exposed along the margin |
| 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 |
| Surface roughness | The surface of the restoration does not have any surface defects | The surface of the restoration has minimal surface defects | The surface of the restoration has severe surface defects |
| Marginal staining | There is no discoloration between the restorations and tooth | There is discoloration on less than half of the circumferential margin | There is discoloration on more than half of the circumferential margin |
| Contact | Normal | Light | None |
| Secondary caries | There is no clinical diagnosis of caries | — | There is clinical diagnosis of caries |
| Luster of restoration | The restoration surface is shiny and has an enamel-like, translucent surface | The restoration surface is dull and somewhat opaque | The restoration surface is distinctly dull and opaque and is esthetically displeasing |

*Exclusion Criteria*—Patients were excluded if they 1) had contraindications for regular dental treatment based on their medical history; 2) had special esthetic needs that could not be solved by repair treatments; 3) had xerostomia and/or were taking medication that significantly decreased salivary flow; 4) had a high risk for caries, or 5) had psychiatric or physical diseases that interfered with oral hygiene.

*Treatment Group Criteria*—Initially, 229 restorations (66 patients) were evaluated. Of those, 20 patients with 40 defective restorations were recruited and evaluated in accordance with the modified USPHS criteria. Restorations that were clinically diagnosed with secondary caries (Charlie) or undercontoured or overcontoured anatomic form defects and restorations with marginal defects (Bravo) were randomly assigned (Random Number Generator, Microsoft Excel 97) to either the repair or the replacement group. Diagnosis of active secondary caries was done according to Ekstrand's criteria.[31]

The groups were labeled A: repair, n=19 (Class I, n=8; Class II, n=11) and B: replacement, n=21 (Class I, n=9; Class II, n=12).

## Restoration Assessment and Outcome Measurements

The quality of the restorations was scored according to the modified USPHS criteria (Table 1).[32] Two examiners underwent calibration exercises (J.M. and E.F., Cohen κ interexaminer coefficient 0.74 at baseline and 0.87 at 10 years). The blinded examiners of the treatment assessed the restorations independently by direct visual and tactile examination (mouth mirror, No. 5, Hu Friedy Mfg Co Inc, Chicago, IL, USA, and explorer, No. 23, Hu Friedy) and indirectly by radiographic examination (bitewing) at baseline (immediately after treatment) and 10 years after treatment. The seven examined parameters were marginal occlusal adaptation, anatomic form, surface roughness, marginal staining, occlusal contact, secondary caries, and luster (Table 1). If any difference was recorded between the two examiners and if they did not reach an agreement, a third clinician (G.M.), who also underwent calibration exercises, made the final decision.

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

## Treatment Groups

*A: Repair*—The clinicians (P.V. and C.M.) used carbide burs (330-010 Komet, Brasseler GmbH Co, Lemgo, Germany) to explore the defective margin, carious lesion, or anatomic form of the restorations. Part of the restorative material adjacent to the defect was removed as an exploratory procedure, thus allowing a proper evaluation and subsequent diagnosis of the extent of the defect. Provided that the defect was limited and localized, the clinician then removed any defective tooth tissue. Mechanical retention was used inside the existing amalgam restoration. Rubber dam isolation was used for this procedure. Repair of the restorations was carried out with a dispersed-phase amalgam (Original D, Wyckle Research Inc, Carson City, NV, USA).

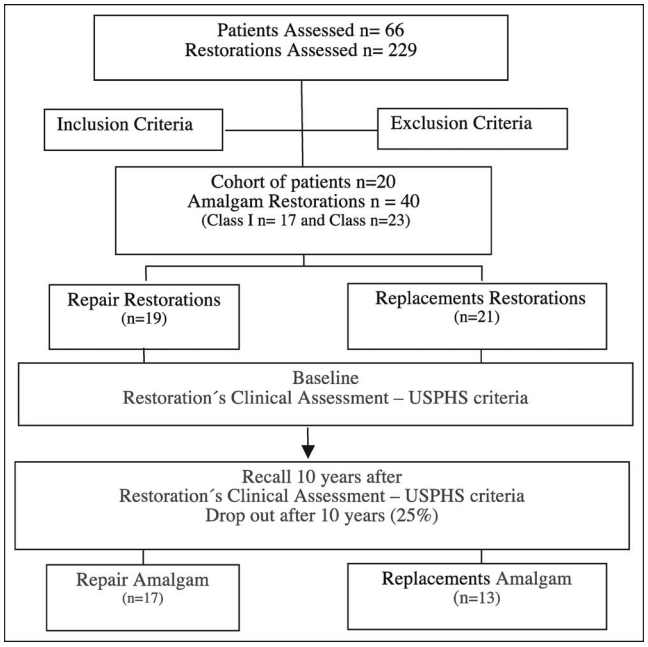


Figure 1. *Flow diagram of restorations, separated by group.*

*B: Replacement*—The clinicians completely removed and replaced the defective restorations. The removal of soft tooth tissue infected with caries was done using carbide high-speed burs under full water irrigation. After completing the cavity preparations, the tooth was restored with a new amalgam (Original D, Wyckle Research). Bonding agents and/or liners underneath the amalgam restorations were not used in this trial. Rubber dam isolation was used for all restorative treatments.

Patients were recalled four and 10 years after the restorations were placed for clinical assessment by the same examiners, who applied the same criteria used at baseline. Failed restorations were removed from the study and treated according to their diagnosed needs (Figure 1).

### Statistical Analysis

The ordinal dependent variable was changed at the level of the modified USPHS criteria from the baseline value. The assigned score of each restoration reflected the worst result for any of the parameters. The results of each group in terms of degradation or upgrade were analyzed by the nonparametric Friedman range test to compare the preoperative and postoperative conditions. Additionally, the performance of all groups was contrasted using the Mann-Whitney test to determine the differences between the upgrade and downgrade of the restorations' quality. The statistical significance was set at 95%, $\alpha$=0.05 and $\beta$=0.20; SPSS version 15.0 (SPSS Inc, Chicago, IL, USA) was used for statistical analysis.

## RESULTS

Of the 40 restorations evaluated at baseline, 30 were returned for the 10-year recall (75%), group A: n = 17 and group B: n = 13. At the 10-year recall, two restorations were withdrawn from the study due to orthodontic reasons (metallic band covered the restorations), and patients who did not return for the recall were dropped (restorations withdrawn/dropped out = 2.5% per year).

In the marginal adaptation parameter, at baseline 31.58% of the repair group presented a Charlie value, as did 42.9% of the replacement group; neither group showed any Charlie after the initial intervention at the 10-year exam. Marginal adaptation at baseline presented 15.79% Alpha value for the repair group and 9.5% for the replacement group and after 10 years the Alpha value increased to 23.53% and 53.8%, respectively, (Figures 2a-3a).

The anatomic form presented at baseline was given a Charlie value in 26.3% of the repair group, and 9.5% in the replacement group; after treatment, no restorations were assessed as Charlie during the 10 years of observation. The Alpha value of the repair group increased from 15.8% at baseline to 23.5% after 10 years (Figures 2a, 3b), whereas the replacement group changed from 19.0% to 53.8% (Figure 3). All restorations from both groups were clinically acceptable after 10 years, according to the Friedman range test, which showed a parallel level of quality during the study period (Figures 2a, 2b and 3c).

The roughness parameter in the repair group began with an Alpha value of 47.4% at baseline, increased one year after intervention to 57.9%, and slowly decreased to 35.3% at the 10-year recall. The group's Charlie value was 0% at baseline and increased to 5.9% after 10 years; whereas, at baseline the replacement group showed an Alpha value of 28.6% and finished the study with 46.2% after 10 years. The Charlie value originally represented 19% and 0% of the replacement group at baseline and after 10 years, respectively (Figures 2a, 2b and 3d).

Marginal staining in both groups increased for the Alpha value after treatment, from 78.9% to 94.7% of repair and from 52.4 to 95.2% of replacement after the first year. Whereas repair showed a Charlie value at the third (5.9%) and fourth years (18.8%),

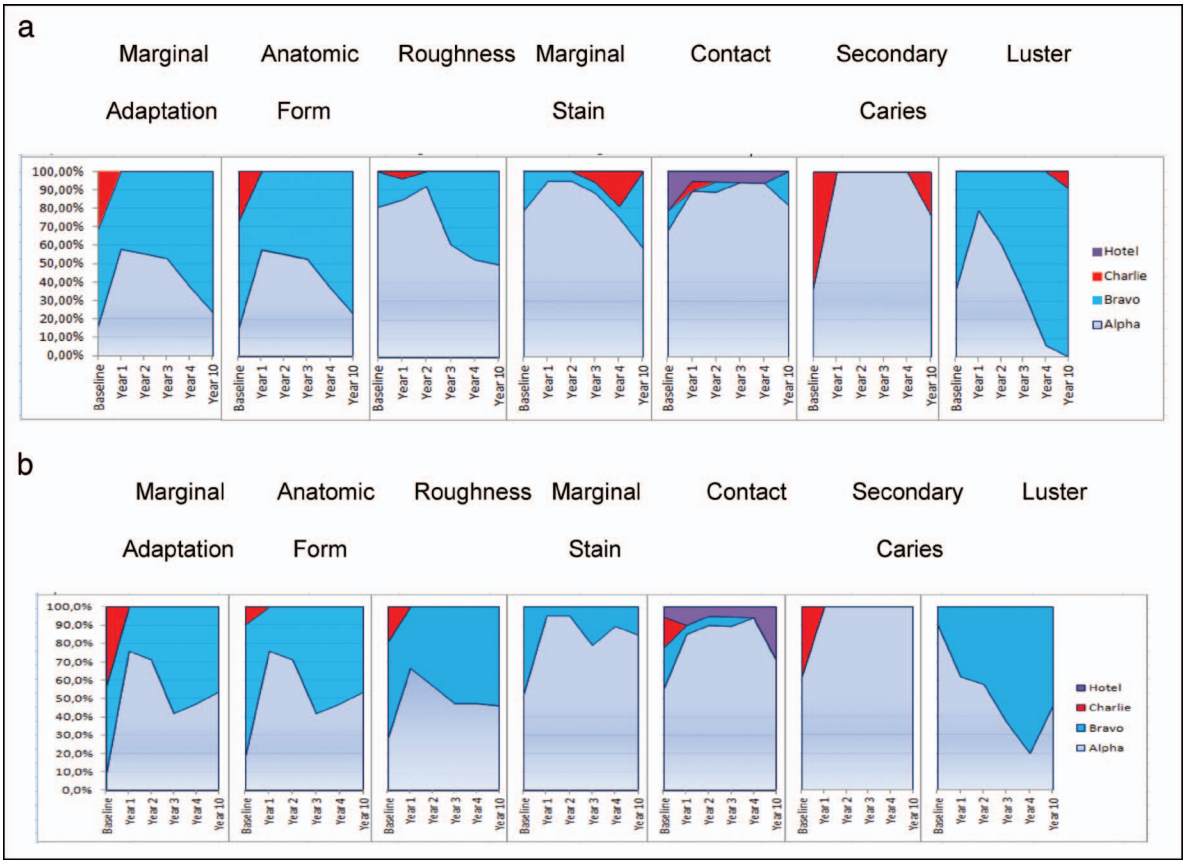


Figure 2. *(a) The area of the graph represents the different quality levels of the repaired restorations, expressed in percentages, separated by parameters and years of observation from baseline to 10 years. (b) The area of the graph represents the different quality level of the replacement restorations, expressed in percentages, separated by parameters and years of observation from baseline to 10 years.*

replacement did not present any Charlie values at the 10-year follow-up visit. In general, both groups showed a similar performance during all study periods, as per the Friedman test (Figures 2a, 2b and 3e). At the end of the study, 58.8% of the restorations in the repair group had an Alpha value compared with 84.6% of those in the replacement group.

The contact parameter of the repair group showed an Alpha value in 68.4% of the restorations and finished the study with 81.8%; whereas, the replacement group began with 55.6% of the restorations having an Alpha value and increased to 71.4% after 10 years. The overall value showed a reduction in the repair group from 21.1% at baseline to 0% at the end of the study; whereas, in the replacement group, it increased from 5.6% to 28.6% (Figures 2a, 2b, and 3f).

The secondary caries parameter showed a reduction in the repair group from 15.8% of Charlie value to 5.9% at the end of the study; whereas, the reduction in the replacement group was from 38.1% at baseline to 0% at the end. Neither group showed a Charlie case after the intervention and during the four years (Figures 2a, 2b, and 3g).

Finally, luster decreased in both groups: from 36.8% at baseline to 0% at the 10-year follow-up for the repair group and from 90.5% to 46.2% after 10 years for the replacement group. The Charlie value increased from 0% at baseline to 9.1% after 10 years for the repair group; whereas, the replacement group did not show any case of a Charlie value during the entire study period (Figures 2a, 2b, and 3g).

When comparing the restoration quality between the baseline and the 10-year follow-up, the groups showed statistically significant differences in the parameter anatomic form only, favoring the replacement group (Table 2).

## DISCUSSION

Increased lifespan in humans to more than 80 years of age in numerous developed countries means that more individuals are reaching old age. From an oral-

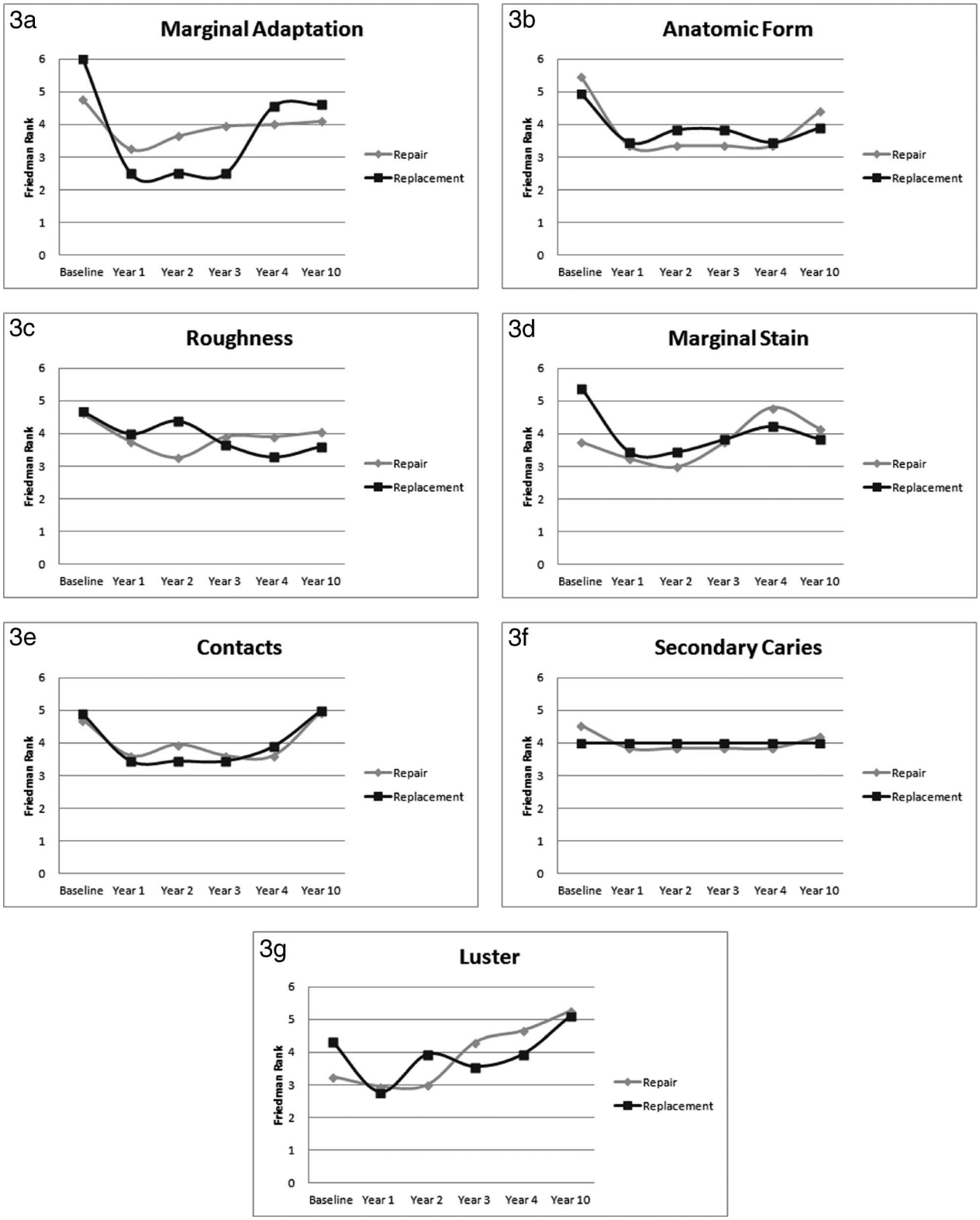


Figure 3. *(a) Marginal adaptation parameter, separated by group and year, indicates the distribution of the restoration quality, according to the Friedman Range Test. (b) Anatomic form, separated by group and year, indicates the distribution of the restoration quality, according to the Friedman Range Test. (c) Roughness, separated by group and year, indicates the distribution of the restoration quality, according to the Friedman Range Test. (d) Marginal stains, separated by group and year, indicates the distribution of the restoration quality, according to the Friedman Range Test. (e) The contact, separated by group and year, indicates the distribution of the restoration quality, according to the Friedman Range Test. (f) Secondary caries was separated by group and year. This figure indicates the distribution of the restoration quality, according to the Friedman Range Test. (g) Luster, separated by group and year, indicates the distribution of the restoration quality, according to the Friedman Range Test.*

health perspective, the increase in human longevity implies the need for prolonged tooth preservation.[33] Given the mechanisms and biological foundation of changes affecting teeth, it is necessary to apply novel dental therapies and adequate protective measures[34] to increase tooth longevity in the aging adult.

Moreover, dentistry has recognized the problem of the restorations' replacement, with more than 400 papers having been published during the past few years. The papers are related to the repair of restorations,[35] and many laboratory and clinical studies have shown that repairing amalgam restorations is possible and successful.[17,25,36-40]

This is the first prospective study that compared repair and replacement of localized restoration defects, and it was observed that both groups presented a similar level of quality after 10 years with the exception of the anatomic form parameter. This is easily explained, because repair included only a partial correction area of the restorations, and it is not possible to recover the total anatomy.

In general, restorations of both groups showed significant improvement during the first year after treatment in all parameters and began a slow and continued reduction of quality during all the study periods, as other research has shown.[4,17,25,41] Most of the restorations were assessed as clinically acceptable (Alpha or Bravo) after 10 years, and only a small percentage of restorations showed a Charlie value at the end of the study.

Parameters like marginal adaptation, roughness, and contact showed similar performance in both groups (no restoration with a Charlie score after 10 years), but marginal staining, secondary caries, and luster tend to result in more of a Charlie value in the repair group than the replacement group, although the differences were not statistically significant. Early downgrade was observed in the marginal staining parameter of the repair group (24.7% scored a Charlie during the third and fourth years), compared with no Charlie in the replacement group. The roughness of the repair group also scored a Charlie in the first year (5.3%), compared with no Charlie in the replacement group, but neither were statistically significant. This performance agrees with Gordan and others,[17] whom after seven years of amalgam repair observation noticed that there were no significant differences between study groups other than deterioration that had begun after the first two years.

In general, most of the Class I and Class II restorations in the repair group, downgraded to a Bravo after a period of three to four years, had a lower Charlie score at the end of the study in marginal adaptation, roughness, and luster. A revised analysis is necessary to determine whether it is possible to repair the restoration again and increase longevity of the restoration with a minimally invasive additional treatment to recover the Alpha score; however, the Bravo score did not represent a high risk of immediate restoration failure.[17]

For this study, limited and localized defects were considered as presence of secondary caries, undercontoured or overcontoured anatomic form, and marginal failures of occlusal, proximal, and cervical areas, clinically and radiographically detected. The accesses for repairing cervical and proximal defects included an occlusal approach in order to obtain complete visibility of the defect, given that the patients were mostly young adults; however, this practice could be different in the case of elderly patients, where probably, given gingival recession, the access to the cervical wall could be made by buccal or lingual faces or directly by the cervical area in some patients who had wide interproximal spaces.

The proposed hypothesis was confirmed: the Class I and Class II amalgam restorations showed similar results to the restorations that were repaired. By 10 years of observing the clinical characteristics, performance had increased with minimal intervention. Thus, the results provide evidence for clinicians to have a safe alternative to repair restorations that present with localized defects in marginal areas, including gaps with exposed dentin, loss of anatomic form, altered contact, or secondary caries. This observation will save time and healthy tooth tissue, lessen the need for anesthesia, and lower patients' stress as compared with the typical patient stress of traditional full restoration replacement Additionally, the results of this study support the idea that restoration repair could increase the longevity of restorations for least 10 additional years. The present study did not show any teeth or amalgam fracture or pulp injury during a 10-year period; those findings agree with previous reports that the strength of the repaired restoration was acceptable with no evidence of fracturing at the repaired interface.[42-44]

This increase in longevity and the fact that no additional treatment was required in the majority of the teeth studied for the repaired restoration group strengthens the hypothesis that restorations are able to function well without full replacement. However, the reasons for restoration downgrades

Table 2: *Comparison of the Seven Parameters, Between Baseline and 10 Years After, Between Groups by Mann-Whitney Test*

| | Marginal Adaptation | Anatomic Form | Roughness | Marginal Staining | Contact | Secondary Caries | Luster |
|---|---|---|---|---|---|---|---|
| *p* value | 0.52 | 0.001* | 0.056 | 0.105 | 0.353 | 0.458 | 0.458 |

were not identified and the variables related to individual characteristics of the restorations were not evaluated (ie, flexion of the tooth cusp, problems related with deep carious lesions, size or design of the restoration, malocclusion, and bruxism). Those variables need to be further explored in order to get a representative statistical analysis for the downgrade scores.

Selecting criteria for making the decision to repair is one of most important problems to solve in treatment planning. It is necessary to clarify that a repair in the present study was indicated when the defects were localized and the other part of the restorations remained in acceptable clinical condition (Alpha or Bravo); it is considered to have been carried out with minimal intervention and implies the addition of new restorative material, with cavity preparation, in patients with standard oral health and low or medium caries risk. Like any other restorative treatment plan, the need for periodic monitoring, presence of marginal gaps with or without exposed dentin or ditching with or without marginal staining, diagnosed localized secondary caries, and wear of the restorations were the main indications of repair in the present study.[35] Most defects in restorations involve the cervical area; therefore, the early determination of the extension of the exploratory procedure is a key for the clinical decision to repair or to replace the restorations. It is not possible to indicate repair when secondary caries is not totally accessible with a minimally involved carious lesion or if it affects the restoration's resistance to typical functional forces, because deep involvement will undermine the carious lesion. Also, when restorations present with bulk defects they do not benefit from the alternative treatments. Those restorations are typically treated successfully if a complete replacement is done. Other contraindications must be considered when patients are reluctant to have a restoration repaired and would prefer to have a replacement due to prior history of a failed repair.[35]

New marginal carious lesions in teeth represent the greatest reason for failure. Caries represents an infection, which cannot be treated only by replacing or repairing the restoration. Practitioners must consider teaching the patient how to make changes in the biofilm with better oral hygiene practices. The restorative treatment is only a symptomatic treatment for secondary caries; the patient response, in addition to the quality of the restoration evaluation, must be considered with this factor.[45]

This alternative treatment represents an additional option to address many of the increasing number of restorations each year that require treatment due to deterioration. Repair instead of replacement of localized defective restorations significantly improved their morphology and function. The restorations showed some deterioration over time; however, they retained their acquired properties satisfactorily during the observation period in similar conditions other than replacement.[17,29,42,46] It is necessary to consider that repairing a restoration could serve to reduce the dimension of the repaired cavity, because it improves repair strength, and additionally it has been observed that rounded undercuts slightly reduce the repair strength values.[39]

A previous retrospective study by Smales and Hawthorne[47] compared the long-term survival rate of repaired vs replaced amalgam restorations, with no significant survival differences between both groups at year 5; however, higher failure rates of the repaired amalgam were seen after 10 years (only 37.2% of the restorations survived). In the present study, repair and replacement restorations did not show significant survival differences, when analyzing only the Alpha value, remained at an Alpha value for about five years, depending on the parameter, but later, restorations remained clinically acceptable because most of them retained a Bravo value at the end of the study period. Smales' study presented several differences with the current research; for example, the clinical criteria for repair indication and assessment criteria of the restoration was declared as a clinical judgment of the dentist, whereas the present study used calibrated clinicians and USPHS criteria. Additionally, the present study did not include data related to bulk amalgam fractures or cusp fractures. Another difference is that Smales' study[47] was carried out retrospectively in private practice and the present investigation was prospectively conducted in a university environment.

This study agreed with other studies when it suggested repairing restorations instead of replace-

ment as it revealed broad clinical success when based on proper indications.[17,48]

This cohort includes data of restorations previously reported [25,27,29,30,46] and patients subsequently recruited. In a study by Fernandez et al.[49] data of resin composites restorations was reported with similar methodology. It is important to remark that, besides the difference in the material, the patient cohort was also different.

## CONCLUSION

The present study supported the concept that a Class I or Class II amalgam restoration showed improvement and similar results when they were diagnosed with a localized marginal defect, a secondary carious lesion, wear, or an anatomic form defect and then treated by a repair or replacement restoration in patients with a low or medium caries risk, thus keeping the restorations clinically acceptable after 10 years. Repairing the restoration with minimal intervention dentistry procedures increased the longevity of the original restoration and the tooth itself. It is worth noting that all restorations trend to downgrade over time.

### Conflict of Interest

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

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