



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

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