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2-year Clinical Evaluation of Alternative Treatments to Replacement of Defective Amalgam Restorations

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Clinical Relevance

Repair offers the most conservative and predictable results for the treatment of amalgam restorations with inadequate marginal adaptation and anatomic form.

SUMMARY

Objective: To investigate the effectiveness of alternative treatments for replacing defective amalgam restorations through a prospective longitudinal cohort clinical study. Methods: Forty-five patients aged 21 through 77 (mean=56) years with 113 defective amalgam restorations, which were independently diagnosed during treatment planning, participated in the study. These patients were assigned to 5 treatment groups: repair (n=20), sealing of defective margins (n=23), refurbishing (n=23), replacement (n=23) and no-treatment (n=24). The replacement and no-treatment groups served as comparison groups and received random assignment. Two clinicians examined the restorations (n=113) prior to and after the assigned treatment and at subsequent recalls, using a modified Ryge Criteria that included marginal adaptation, anatomy, contact, post-operative sensitivity and secondary caries. Results: At 1- and 2-year recalls, 79 (70%) and 74 (65%) restorations were examined. Kruskal-Wallis Test showed significant differences for marginal adaptation and anatomic form for both 1- and 2- year recall exams ($p<.05$). The repair and replacement groups had significant differences when compared to the no-treatment group. Conclusions: Defective restorations that have a Bravo rating for clinical characteristics other than marginal integrity and anatomical form do not need to be immediately replaced.

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DOI: 10.2341/05-112

INTRODUCTION

Despite advancements in resin-based composite (RBC) technology, amalgam restoration still is one of the restorative treatment options in several dental practices.[1-2] The relative initial low cost and long-term cost-effectiveness of this treatment modality in posterior restorations[3-4] accounts for its use in several dental practices.[1-2]

Although amalgam is not the main restorative material being replaced in general practice, it comprises

about 40% of the restorations being replaced with a median age of 12 to 15 years.[2,5-6] The most common reasons for replacement of amalgam restorations in general dental practice are the clinical diagnosis of recurrent or secondary caries[2,7-8] and fracture of restorations.[1,5,9] Secondary caries accounts for 41% of the replacements of amalgam restorations, while fracture of restorations is responsible for 22%.[2] The diagnosis of secondary caries is difficult, and it invariably leads to replacement of the entire restoration.[10-11] Secondary caries usually occurs at the gingival part of all types of restorations[12] and, when replaced consistently, results in extension of the cavity preparation as compared to the original size.

Total replacement is the most common treatment for amalgam restorations clinically diagnosed as defective. When replacement occurs, a significant amount of tooth structure is lost.[13] Recently, 3 treatment options versus total replacement were described.[14] These options may increase the longevity of the defective restoration and preserve tooth structure. The alternative options for treating defective amalgam restorations included repairing, sealing and refurbishing. 1) Repairing consisted of the removal of part of the restoration and any defective tissue adjacent to the defective area and restoration of the removed site. 2) Sealing included the application of a resin-based sealant in a small, defective site or deficient margin (up to .2 mm). 3) Refurbishing involved the removal of surface defects or excess from amalgam restorations with finishing burs. The longevity of these non-replacement strategies has not been established.

The aim of this longitudinal cohort study was to assess the longevity of a group of amalgam restorations that had been clinically diagnosed as defective, followed by repair, sealant or refurbishing treatment, rather than complete replacement. The authors hypothesized that the alternative treatments would not significantly improve clinical conditions of the existing restorations.

METHODS AND MATERIALS

Study Design

Forty-five patients aged 21 through 77 years (mean=56), with 113 defective amalgam restorations, participated in the study. The patients were routinely assigned for treatment at the Operative Dentistry Clinic, College of Dentistry, University of Florida. The restorations were assigned to 5 treatment groups: 1) repair (n=20), 2) sealing of defective margins with sealant (n=23), 3) refurbishing (n=23), 4) total replacement (n=23) and 5) no-treatment group (n=24). A subgroup of restorations (n=47) was randomly selected to serve as comparison groups and received random assignment to the replacement or no-treatment groups. The treatment assignment for the experimental groups was done according to the treatment needed, and it is described in the Study Methods section under Treatment Groups.

Inclusion Criteria:

1) Patients who had defective amalgam restorations that could be corrected with repair, sealant or refurbishing of the margins; 2) with no contra-indications for dental treatment; 3) who were older than 18 years of age and 4) who could read English. At baseline, the defective restorations needed to score Bravo (USPHS-Public Health System, Ryge criteria, Table 1)[15] in either marginal adaptation or anatomic form.

Table 1: *Ryge USPHS Clinical Criteria*

Clinical Characteristic	**Alpha**	**Bravo**	**Charlie**
Marginal adaptation	Explorer does not catch or has 1-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 follow the contours of the tooth.	The general contour of the restoration does not follow the contour of the tooth.	The restoration has an overhang.
Contact	Normal.	Light.	None.
Post-operative	No sensitivity when an air syringe is activated for 2 seconds 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 seconds 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 an air syringe is activated for 2 seconds at a distance of half an inch from the restoration, with the facial surface of the proximal tooth covered with gauze and does not cease when the stimulus is removed.
Secondary caries	There is no clinical diagnosis of caries.	---	There is clinical diagnosis of caries.

Exclusion Criteria:

1) Patients with contraindications for regular dental treatment due to medical history; 2) patients with xerostomia, 3) those taking medications that are proven to significantly reduce regular salivary flow or 4) patients with defective restorations that scored Charlie (unacceptable or failed, USPHS, Ryge criteria).

Methods

The study was approved by the Institutional Review Board (IRB) at the University of Florida before the study was initiated. Patients received treatment of the restorations by third- and fourth-year dental students under faculty supervision. Patients approved and signed the informed consent form approved by the IRB.

The USPHS/Ryge criteria (Table 1) was used to evaluate the clinical quality of the restorations. Two independent clinicians recorded the restoration at its initial stage, immediately after the treatment and at 1- and 2-year recall exams. The importance of calibration among examiners was emphasized. A calibration exercise revealed that the inter-examiner agreement ratio was 92%. If there was disagreement between the evaluators, a third evaluator was called to examine the restoration for a final decision. Clinical failure of the restoration or treatment was determined by the criteria outlined in Table 1 under Charlie.

Treatment Groups

Repair:

The amalgam at the defective site was partially removed with a carbide bur to allow for a proper diagnosis and evaluation of the extent of the defect. Provided the defect was limited and localized, any defective tooth tissue was then removed. The amalgam surface was roughened with a diamond bur, and the resultant preparation was restored with a dispersed-phased amalgam restorative material (Original D; Wykle Research Inc, Carson City, NV, USA).

Sealant:

Restorations with a crevice or "ditch" at the cavosurface margin received a resin-based sealant (Delton, Dentsply Caulk, Milford, DE, USA) after acid etching with 35% phosphoric acid for 15 seconds. The sealant was polymerized with a light-curing unit (Optilux 401, Demetron, Division of Kerr Corporation, Danbury, CT, USA). Rubber dam isolation was used for this procedure.

Refurbishing:

Defective areas that had excess amalgam were removed with carbide burs (12 or 30 blades, Brasseler USA, Dental Rotary Instruments, Savannah, GA, USA). On occlusal and buccal/lingual surfaces, silicone impregnated rubber points (Brownie, Greenie and Supergreenie, Shofu Inc, Kyoto 605 Japan) were used for polishing.

Assignment for Replacement or No-treatment Groups:

Forty-seven of the 113 defective restorations described previously were randomly assigned to either replacement (n=23) or no-treatment (n=24) groups.

Replacement:

The defective restoration was completely removed. After cavity preparation was completed, the tooth was restored with a dispersed-phased amalgam restorative material (Original D; Wykle Research Inc).

No-treatment:

The restorations were examined visually and no treatment was done to the defective area.

Outcome Measurements

Rating of the Clinical Condition:

Eight clinical characteristics using the USPHS/Ryge criteria were evaluated, when applicable: 1) occlusal marginal adaptation, 2) proximal marginal adaptation, 3) anatomic form: occlusal, 4) anatomic form: proximal, 5) occlusal contact, 6) proximal contact, 7) secondary caries and 8) post-operative sensitivity. They were assigned a score of Alpha, Bravo or Charlie according to the USPHS/Ryge criteria (Table 1).

Timeline:

1) All restorations received a score for each clinical condition at the pre-operative evaluation.
2) The restorations were then assigned to the treatment groups.
3) All restorations were re-evaluated for a post-treatment score, except those in the no-treatment group.

The score of the pre-operative treatment was used as baseline for analysis of the longitudinal data.

Two subsequent evaluations of the clinical characteristics of the restorations were performed at 1- and 2-year recall.

Grading Change of the Clinical Condition Outcome:

For each time interval (1-year recall, 2-year recall), each restoration that received a clinical rating of Alpha, Bravo or Charlie could result in 4 different outcomes: the final evaluation was either 1 (upgrade from Bravo to Alpha), 0 (no change), –1 (downgrade from Alpha to Bravo or from Bravo to Charlie) or -2 (downgrade from Alpha to Charlie).

Statistical Analysis

Data management and analysis were done using the SPSS 12.1 Program (SPSS Inc, Chicago, IL, USA). The ordinal dependent variable was "change in level" of the Ryge criteria. Kruskal-Wallis Test was used to assess

the change of each clinical criteria (baseline and 1-year, baseline and 2-year recall) across all the treatment groups at α=.05. Following significant findings, non-parametric pairwise comparisons were used to test for specific differences between each treatment and the no-treatment group.

RESULTS

Seventy-nine (70%) of the 113 restorations were examined at the 1-year recall exam and 74 (65%) of the 113 restorations were examined at the 2-year recall exam.

Initial Change in Baseline Scores Before and After Treatments:

A statistically significant improvement was seen immediately after treatment for all alternative groups when compared to the no treatment group for marginal adaptation and anatomic form characteristics.

Change of Clinical Characteristic from Baseline to 1 Year and from Baseline to 2 Years: (baseline minus 1-year results and baseline minus 2-year results)

When marginal adaptation and anatomic form were compared among the different treatments, no difference was found between the refurbishing and no-treatment groups. However, a significant statistical difference was found between the no-treatment and remaining treatment groups (sealant, repair and replacement groups) (Tables 2 and 3).

1) The sealant group presented a significant difference in marginal adaptation after 1 year only when compared to the no-treatment group.
2) The repair and replacement groups had statistically significant differences in marginal adaptation and anatomic form when compared to the no-treatment group after 1- and 2-years.

The refurbishing and sealant groups presented statistically significant downgrading on marginal adaptation and anatomic form when compared to the replacement group and the repair group at both 1- and 2-year recalls.

The refurbishing and sealant groups differed statistically on marginal adaptation at the 1-year recall only, with the refurbishing group presenting more deterioration than the sealant group.

Results Comparing the Stability of Treatment Groups After 1- and 2-year Recalls: (Tables 4 through 7)

The outcome of the no-treatment, refurbishing and sealant groups were not significantly different at 1- and 2-year recall exams.

The no-treatment group was significantly more likely to receive a downgraded rating when compared to the repair and replacement groups for marginal adaptation at 1- and 2-year recalls and anatomic form at 2-year recall exam.

The refurbishing group was significantly more likely to receive a downgraded rating on marginal adaptation when compared to the repair group, at 1-year recall and when compared to the replacement group at 2-year recall.

The sealant group was significantly more likely to receive a downgraded rating on marginal adaptation and anatomic form when compared to the repair and replacement groups.

The repair group showed no significantly different outcome when compared to the replacement group.

DISCUSSION

The clinical diagnosis of secondary caries has been the most common indication for replacement of amalgam restorations in general dental practice.[2,7-8] However, as indicated by Pimenta and others,[16] the presence of a marginal defect at the amalgam restoration is insufficient evidence to determine the presence of secondary

Table 2: *Changes in Upgrade and Downgrade of the Different Treatment Options When Compared to No Treatment Group for Marginal Adaptation: Occlusal at Each Recall Session*

Time (years)	n	Treatment of Upgrade	Frequency of No Change (1)	Frequency of Downgrade (0)	Frequency of Downgrade (-1)	Frequency of (-2)	*p*-value
0-1	17	**No treatment**	3 (17.5%)	11 (65%)	3 (17.5%)	0 (0%)	N/A
	13	Repair	4 (31%)	6 (46%)	3 (23%)	0 (0%)	**.003***
	15	Sealant	11 (73%)	3 (20%)	1 (7%)	0 (0%)	**.004***
	13	Refurbishment	2 (15%)	10 (78%)	1 (7%)	0 (0%)	p>.05
	17	Replacement	12 (71%)	5 (29%)	0 (0%)	0 (0%)	**.003***
0-2	17	**No treatment**	2 (12%)	9 (53%)	5 (29%)	1 (6%)	N/A
	10	Repair	4 (40%)	6 (60%)	0 (0%)	0 (0%)	**.035***
	16	Sealant	5 (31%)	8 (50%)	3 (19%)	0 (0%)	*p*>.05
	13	Refurbishment	2 (15%)	8 (62%)	3 (23%)	0 (0%)	*p*>.05
	15	Replacement	10 (67%)	4 (27%)	1 (6%)	0 (0%)	**.002***

**Statistically significant different at α=.05.*

Table 3: *Changes in Upgrade and Downgrade of the Different Treatment Options When Compared to the No Treatment Group for Anatomic Form Occlusal at Each Recall Session*

Time (years)	n	Treatment	Frequency of Upgrade (1)	Frequency of No Change (0)	Frequency of Downgrade (-1)	Frequency of of Downgrade (-2)	p-value
0-1	17	**No treatment**	1 (6%)	12 (70%)	4 (24%)	0 (0%)	N/A
	13	Repair	7 (54%)	6 (46%)	0 (0%)	0 (0%)	**.008***
	15	Sealant	3 (20%)	11 (73%)	1 (7%)	0 (0%)	*p*>.05
	13	Refurbishment	0 (0%)	12 (92%)	1 (8%)	0 (0%)	*p*>.05
	17	Replacement	11 (65%)	6 (35%)	0 (0%)	0 (0%)	**.007***
0-2	17	**No treatment**	1 (6%)	11 (65%)	3 (17.5%)	2 (12.5%)	N/A
	10	Repair	4 (40%)	6 (60%)	0 (0%)	0 (0%)	**.015***
	16	Sealant	3 (19%)	10 (62%)	3 (19%)	0 (0%)	*p*>.05
	13	Refurbishment	0 (0%)	12 (92%)	1 (8%)	0 (0%)	*p*>.05
	15	Replacement	10 (67%)	5 (33%)	0 (0%)	0 (0%)	**.00001***

**Statistically significant different at α=.05.*

Table 4: *Intergroup Comparison of Changes from Baseline to 1-year Recall Exam for Marginal Adaptation: Occlusal*

	No Treatment	Repair	Sealant	Refurbishing	Replacement
No Treatment	N/A				
Repair	***p*=.003***	N/A			
Sealant	***p*=.004***	***p*=.028***	N/A		
Refurbishing	*p*>.05	***p*=.02***	***p*=.006***	N/A	
Replacement	***p*=.001***	*p*>.05	*p*>.05	***p*=.003***	N/A

**Statistically significant different at α=.05*

Table 5: *Intergroup Comparison of Changes from Baseline to 1-year Recall Exam for Anatomic Form: Occlusal*

	No Treatment	Repair	Sealant	Refurbishing	Replacement
No Treatment	N/A				
Repair	*p*>.05	N/A			
Sealant	*p*>.05	***p*=.053***	N/A		
Refurbishing	*p*>.05	***p*=.002***	*p*>.05	N/A	
Replacement	***p*=.007***	*p*>.05	***p*=.001***	***p*=.0001***	N/A

**Statistically significant different at α=.05*

caries. This fact has a greater impact in light of another study in which the inter-observer variations in replacement decisions and diagnosis of caries and crevices was remarkable.[17-19]

When the presence of active caries cannot truly be ascertained, dentists still elect to replace defective amalgam restorations over repairing them.[20] Repair is mostly considered only when there is either loss of part of the restoration or marginal ditching.[20] Previous studies have shown an increase in loss of tooth structure when defective amalgam restorations with crevice margins are replaced.[12-13,21] These studies showed that, unless the clinicians diagnosed frank caries, they treated good and bad cavity margins alike; that is, they replaced the restoration and "freshened up" the cavity margins irrespective of their quality.[12,13,21] Therefore, alternative treatments to the replacement of restorations may constitute a mechanism for the preservation of tooth structure. In this study, the treatments used proved to be conservative treatment options for defective restorations.

In vitro studies suggested that sealed margins of defective amalgam restorations performed better than restorations that were not sealed.[22-23] Similarly, clinical studies showed positive results for amalgam restoration margins that received sealant immediately after restoration.[24-25] Restorations that received sealant presented superior clinical performance and marginal integrity compared to restorations that did not receive sealant. The sealant retention rate was

Table 6: *Intergroup Comparison of Changes from Baseline to 2-year Recall Exam for Marginal Adaptation: Occlusal*

	No Treatment	Repair	Sealant	Refurbishing	Replacement
No Treatment	N/A				
Repair	***p*=.035***	N/A			
Sealant	*p*>.05	***p*=.005***	N/A		
Refurbishing	*p*>.05	***p*=.029***	*p*>.05	N/A	
Replacement	***p*=.0002***	*p*>.05	***p*=.05***	*p*=.009*	N/A

**Statistically significant different at α=.05*

Table 7: *Intergroup Comparison of Changes from Baseline to 2-year Recall Exam for Anatomic Form: Occlusal*

	No Treatment	Repair	Sealant	Refurbishing	Replacement
No Treatment	N/A				
Repair	***p*=.015***	N/A			
Sealant	*p*>.05	***p*=.001***	N/A		
Refurbishing	*p*>.05	***p*=.012***	*p*>.05	N/A	
Replacement	***p*=.0001***	*p*>.05	***p*=.004***	***p*=.0001***	N/A

**Statistically significant different at α=.05*

82.5%, with a cumulative failure rate for the restoration of 2% after 9 years.[25] The current study placed sealant over existing restorations, and the retention rate of sealant was lower than for the study mentioned above. One possible explanation for the differences in retention rate would be that the sealants could have better retention when placed over freshly placed amalgam restorations. In this study, some of the ditched margins also had corrosion products that could preclude proper mechanical bonding of the sealant into the existing amalgam.[26] Nevertheless, all restorations that received sealants did not show signs of significant degradation in this study (they maintained the Bravo rating).

Refurbishing is mostly considered when there is either poor anatomic form or marginal ditching.[20] However, to date, no clinical study has been performed to evaluate the outcome of refurbishing defective restorations. Although refurbishing seems logical, the practice in this area has not been documented and the available knowledge is anecdotal. The refurbishing of a defective margin can strengthen the restoration by removing areas of excess or submargination. In the case of amalgam restorations that may have suffered expansion, proper contour of the restorations can be established by removing the excess area through polishing the restorations. In this way, the longevity of the restorations could also be increased. In addition, plaque retention at these sites could be reduced with proper contour and polishing of the margins of the restorations, which may reflect the overall health of the tooth and adjacent dental structures. The current study showed that the majority of downgrading in the refurbishing group was related to marginal adaptation. Most of the refurbished restorations maintained their original properties for the other clinical criteria.

Studies dealing with the repair of resin-based materials and amalgam restorations have been published.[27-31] However, this approach is not routinely considered in the treatment planning of defective restorations, and the entire restoration is often replaced. The repair of a defective restoration is a conservative treatment option that was shown to be effective in this study. Although none of the repaired restorations presented failure due to fracture in this study, previous studies suggest that use of a resin bonding system, such as Panavia F, prior to receiving amalgam repair, significantly enhances the bond strength results when compared to no treatment of the amalgam surface.[32] The final outcome of the current study after 1 and 2 years did not show any difference between the repair and replacement groups, which is a positive result toward preservation of tooth structure.

The positive impact on the replacement group was mostly seen in the first year recall, when this group presented the lowest percentage of downgrade. However, in the second year, it was concluded that this group behaved similarly to the repair group, and no significant difference could be observed in the final outcome. Conversely, the negative effects of restoration removal through replacement have been demonstrated in numerous studies where a significant amount of healthy tooth structure was lost.[12-13, 21]

A previous clinical trial studying the efficacy of occlusal amalgam restorations showed that marginal integrity and inadequate anatomical form were the main forms of deterioration for amalgam restorative

material.[33] Similarly, in this study, significant deterioration was found on marginal adaptation and anatomic form. Other important aspects, such as secondary caries, fracture, occlusal wear and post-operative sensitivity, were not significant for any of the groups during the 2-year observation period.

CONCLUSIONS

This study indicated that defective restorations that have a Bravo rating for clinical characteristics other than marginal integrity and anatomical form do not need to be replaced immediately.

If the defective restoration has a Bravo rating for marginal adaptation or anatomic form, the restoration may subsequently need to be treated to avoid further deterioration of the restoration and/or adjacent tooth structure. Repair or replacement would offer the most predictable results for the treatment of restorations with those problems. Repair would be the most conservative treatment option.

Acknowledgements

This research was supported by the University of Florida—DSR research grant #01042678 and, in part, by grant #DE13412 from NIDCR/NIH.

(Received 20 July 2005)

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