

A 3-year randomized clinical trial evaluating two different bonded posterior restorations: Amalgam versus resin composite

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ABSTRACT

Objective: To compare the performance and postoperative sensitivity of a posterior resin composite with that of bonded amalgam in 40 ($n = 20$) large sized cavities and to evaluate whether resin composite could be an alternative for bonded amalgam. **Materials and Methods:** This was a randomized clinical trial. Twenty patients in need of at least two posterior restorations were recruited. Authors randomly assigned one half of the restorations to receive bonded amalgam and the other half to composite restorations. Forty bonded amalgams ($n = 20$) and composites ($n = 20$) were evaluated for their performance on modified-US Public Health Service criteria and postoperative sensitivity using visual analogue scale (VAS) for 36-months. **Results:** Success rate of this study was 100%. First clinical alterations were rated as Bravo after 1 year in marginal discoloration, marginal adaptation, anatomical form, and surface roughness for both amalgam and composite. At the 3rd year, overall “Bravo” rated restorations were 12 for bonded amalgam and 13 for resin composites. There were no significant differences among the VAS scores of composites and bonded amalgams for all periods ($P > 0.05$) except for the comparisons at the 3rd year evaluation ($P < 0.05$). **Conclusions:** Within the limitation of this study, both resin composite and bonded amalgam were clinically acceptable. Postoperative sensitivity results tend to decrease more in composite restorations rather than amalgams. Therefore, it was concluded that posterior resin composite can be used even in large sized cavities.

Key words: Bonded amalgam, posterior restoration, postoperative sensitivity, resin composite

INTRODUCTION

Direct restorations have been commonly used to restore posterior teeth with large and deep cavities due to their equivalent clinical performance to indirect restorations, reduced chairside time, low cost and technique sensitivity.^[1,2] Amalgam and resin composites are two frequently used restorative materials that are considered suitable for direct restorations of posterior area. However, American Dental Association (ADA)^[3] limits the indications of resin composites to small and moderate sized cavities and United Nations Environment Programme^[4] suggests the phase-down use of amalgam due to environmental protection where there is no alternative and suitable restoration material is available. In some developing countries however, there is still ongoing use of amalgam despite of the shortcomings such as lack of adhesion, increased fracture rate in large cavities and debated toxic effects.^[5] Furthermore,

amalgam needs retentive cavities that reduce the strength of sound tooth. In order to reduce the need of mechanical retention, help to restore tooth integrity, increase fracture resistance and reduce sensitivity by sealing margins, a conservative technique has been introduced for bonding amalgam restorations.^[6]

Today increasing demand for aesthetic restorations among patients, the crucial concerns on mercury pollution and raised awareness on waste management

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of amalgam, has given rise to the development of composite restorations. Their more frequent utilization can also be observed in large cavities for their increased physical properties, ability to conserve tooth structure and easier adaptation techniques that allow placement of larger layers up to 4 mm.^[7,8] However, their long-term survival rate is still controversial because of the extended indications by clinicians for posterior teeth, which originally included only small and medium-sized restorations. In large cavities, the adhesive system preferred may affect the results of clinical success and postoperative sensitivity. In literature studies evaluating the clinical performance of etch-and-rinse adhesives show favorable results.^[9] What's more it was advised to use these systems especially in extended cavities where there is still large areas of enamel present.^[10] When postoperative sensitivity is of concern the sensitivity scores of etch-and-rinse adhesives were detected to be similar to that of self-etching primer systems.^[11]

While one can come across several studies that evaluate the clinical performance of direct posterior restorations in the literature there is still a dilemma of selecting suitable posterior restorative material as an amalgam substitute in large cavities. Therefore in this *in vivo* study, we aimed to evaluate the clinical success and postoperative sensitivity of both bonded amalgam and resin composite restorations after baseline (2 weeks), 6 months, 1 and 3 years. The null hypothesis was set to be proven that there is difference in the clinical performance of bonded amalgam and resin composite restorations.

MATERIALS AND METHODS

This was a randomized clinical trial and the randomization of the restorations was obtained by flipping a coin to choose the first teeth to be restored by the resin composite. Twenty-five patients (aged 18–60) who took part in this study were selected among those who attended the Restorative Clinic of School of Dentistry within the first 3 months of 2010 that are only in need of at least two class II restorations (OD, MO or mesio-occluso-distal) in molars or premolars. To be included, the teeth to be restored had to: (1) Be asymptomatic (2) have occlusal and adjacent teeth in contact (3) have cavity sizes exceeding the one-third of the faciolingual distance between cusp tips. On the other hand the exclusion criteria were: (1) Patients with fewer than 20 teeth, (2) poor oral hygiene, (3) bruxism, (4) periodontitis, (5) a history of allergic reactions to any of the materials used.

Before participating to this clinical research, the patients were informed about the procedures and signed the consent form which explained the procedures that would be performed during the study. The study was conducted according to the ethical standards stated in the Helsinki Declaration and approved by the Institutional Review Board/Ethics Committee of Ege University.

Each patient received at least two restorations; one with etch-and-rinse adhesive system (XP Bond, Dentsply Caulk, Germany) and posterior resin composite (Quixfil, Dentsply Caulk, Germany) and the second with amalgambond bonding agent (Amalgambond, Parkell Inc., Edgewood NY, USA) and dispersed alloy amalgam (Cavex Holland BV, the Netherlands). Materials used in the study are summarized in Table 1. All restorations were placed by two dentists (H.T. and T.P.) who practiced the technique before they had placed the inaugural restoration. Fifty teeth (molars and premolars) were prepared and restored with bonded amalgam (25) or composite (25) restorations randomly, one of each being in the same patient. The included lesions were placed because of moderately large caries lesions [Figure 1]. One restoration for one appointment was addressed in order to have a reliable sensitivity test.

The operations were performed under local anesthesia if needed. The cavities were performed by using diamond burs under water cooling and the operating fields were isolated with cotton rolls and a suction device.

Resin composite restorations

Sectional contoured matrix system (Palodent, Dentsply Caulk, Germany) and wooden wedges (Sycamore, Premier Dental Products, Plymouth Meeting, PA, USA), were applied to the cavities which were to be conditioned with 34% phosphoric acid (Caulk 34% Tooth Conditioner Gel, Dentsply Caulk, Germany) at a later stage. It was given special emphasis to condition enamel for at least 15 s and dentin for 15 s or less, in order to prevent over demineralization. The etch-and-rinse adhesive, (XP Bond, Dentsply Caulk, Germany), was applied to the cavity walls and light-cured for 10 s with a polymerization light (Elipar Highlight, 3M Espe, Seefeld, Germany) at a minimum intensity of 750 mW/cm². Then, posterior resin composite (Quixfil, Dentsply Caulk, Germany) was inserted to the cavities in layers (4 mm) and light-cured for 20 s. Finishing and polishing of the restorations

Table 1: Properties and compositions of the materials used in the study

Materials	Type	Composition
DeTrey Conditioner, Dentsply Caulk, Germany	34% tooth conditioner gel	Water, 34% phosphoric acid, silicon dioxide, surfactants, blue colorant
XP Bond, Dentsply Caulk, Germany	Universal self-priming dental adhesive	TCB resin, PENTA, UDMA, TEGDMA, 2-HEMA, butylated benzenediol (stabilizer), ethyl-4-dimethylaminobenzoate, camphorquinone, functionalised amorphous silica, t-butanol
Quixfil, Dentsply Caulk, Germany	Posterior resin composite	UDMA, TEGDMA, di- and trimethacrylate resins, carboxylic acid modified dimethacrylate resin BHT, UV stabiliser Camphorquinone, ethyl-4-dimethylaminobenzoate, silanated strontium aluminum sodium fluoride, phosphate silicate glass
Enhance, Dentsply Caulk, Germany	Polishing system	Polymerized UDMA resin, aluminum oxide, silicon dioxide
Amalgambond Plus, Parkell, Farmingdale, USA	Self-cure bonding system	Activator: 10% citric acid + 3% ferric chloride Adhesive agent: 35% HEMA, water base: 4-META, MMA, HEMA catalyst: TBB HPA powder: PMMA
Cavex Non Gamma-2 Haarlem The Netherlands	Dispersed phase admix amalgam	Alloy powder: Silver 277.2 mg, tin 71.6 mg, copper 47.2 mg, zinc 4.0 mg Mercury 396 mg

UDMA: Urethane dimethacrylate, TEGDMA: Triethyleneglycol dimethacrylate, BHT: Butylated hydroxyl toluene, HEMA: Hydroxyethyl methacrylate, MMA: Methyl methacrylate, PMMA: Polymethyl methacrylate, TBB: Tributylborane, HPA: High performance additive, UV: Ultraviolet, 4-META: Methacryloxyethyl trimellitate anhydride, TCB: Carboxylic acid modified dimethacrylate, PENTA: Phosphoric acid modified acrylate resin

**Figure 1:** The large sized cavities of this study

were accomplished with fine grit diamond burs, cups and points (Enhance, Dentsply Caulk, Germany).

Amalgam restorations

Cavities to be restored were limited with metal matrix bands (Hawe Tofflemire, Kerr) and wooden wedges (Sycamore, Premier Dental Products, Plymouth Meeting, PA, USA). The enamel margins and exposed dentinal walls were treated with amalgambond activator for 30 s and 10 s respectively. After washing and drying the surface, a thin layer of adhesive agent was brushed onto the activated surfaces followed by the application of base (two drops)/catalyst (one drop) mixture according to manufacturer's instructions. Amalgam had been triturated concurrently with the preparation of amalgambond resin mixture of base/catalyst, thus it has been condensed before the resin mixture dried.

Restorations were finished with fine green stones polished with cups and points after 24 h.

Clinical evaluations

All restorations were clinically evaluated according to Modified US Public Health Service (USPHS) - Ryge criteria for retention, marginal adaptation, anatomic form, surface texture and secondary caries [Table 2]. In addition to these assessments, postoperative sensitivity levels of each tooth were recorded using visual analogue scale (VAS) in order to transfer patients' subjective feedbacks into objective data. Two examiners who were not involved in the placement of the restorations evaluated the restorations after 2 weeks (baseline), 6 months, 1 and 3 years. In case of disagreement, the examiners reevaluated the restorations until they reached a consensus.

Postoperative sensitivity evaluation

Postoperative sensitivity evaluation was blindly conducted by a trained examiner after 2 weeks (baseline), 6 months, 1 and 3 years. At each visit, the sensitivity scores were recorded after the application of thermal (cold) stimuli. Thermal stimuli were assessed using a cotton applicator saturated with chloraethyl to the selected tooth. Patients' responses according to VAS have been accepted as the sensitivity value for each tooth and were marked on a VAS, with a 10-cm line labeled from no pain (0 cm) to intolerable pain (10 cm). Patients were tried to be examined at the exact scheduled appointment days of the study design. Any changes made in the date of the appointments have been accepted if the related

date was within minus or plus 1 month (10% of the annual appointment time) period.

Statistical analysis

Based on the Modified Ryge Criteria, we calculated the percentage of Alpha, Bravo, Charlie scores of enrolled bonded amalgam and resin composite restorations. Inter-examiner reliability was evaluated with Cohen's Kappa. Overall failure rate of this study was calculated according to the number of unacceptable restorations using the following formula:^[12]

$$\text{Failure percentage} = 100\% \times \frac{\left(\begin{array}{c} \text{previous failures} \\ + \text{new failure} \end{array} \right)}{\left(\begin{array}{c} \text{previous} \\ \text{failures} + \\ \text{currently recalled} \\ \text{restorations} \end{array} \right)}$$

In postoperative sensitivity, the differences between the subject responses were analyzed at baseline, 6 months, 1 and 3 years using the Friedman test followed by Wilcoxon. The significance was set at $P = 0.05$.

RESULTS

At the beginning there were 25 patients recruited for this randomized *in vivo* study. However at the end

of 2 weeks only 20 patients were available for the recall appointment. We could not establish contact with those five patients who did not complete the study. The examiners evaluated deep and large sized 40 posterior restorations (20 amalgams and 20 resin composites) in 20 patients. Kappa score for inter-examiner agreement for all the evaluation criteria was 0.97.

The percentages of Alpha ratings for both bonded amalgams and resin composites at baseline, 6 months, 1 and 3 years have been shown in Table 3 [Figure 2a and b]. In this study, retention and secondary caries parameters of each restoration group was 100%. On the other evaluation criteria, clinically acceptable changes started to show up at 1-year recall. On this evaluation period, it was observed that an amalgam and four resin composites caused to marginal discoloration. In addition, two amalgams and two resin composites on marginal adaptation; three amalgams and one resin composite on anatomical form; five amalgams and seven resin composites on surface roughness criteria were rated as "Bravo." At the 3rd year, of all evaluation criteria, overall "Bravo" ratings were 26 for amalgam and 28 for resin composites [Figure 3]. Overall failure rate of this study was 0% (100% acceptance for 3 years) which shows that the quality of amalgams and resin composites complied with the requirements for

Table 2: Modified USPHS clinical criteria

	Score		
	Alfa	Bravo	Charlie
Retention	Completely retained	Not applicable	Partially or completely lost
Marginal adaptation	No crevice can be detected along margin by an explorer	Crevice can be detected along the margin but there is no exposure of dentin or base	Dentin or base exposed along margin
Anatomical form	Contour of the restoration follows tooth	Restoration is discontinuous with tooth, no exposure of dentin or base	Restoration has an overhang
Marginal discoloration	No staining between restoration and tooth	Superficial staining along the margin, no penetration to dentin	Penetration to dentin
Surface texture	Surface of the restoration does not have any defects	Surface of the restoration has minimal surface defects	Surface of the restoration has severe defects
Secondary caries	There is no clinical diagnosis of caries	Not applicable	There is clinical diagnosis of caries

USPHS: US Public Health Service

Table 3: Percentage of Alpha and Bravo ratings for amalgam (n=20) and composite (n=20) restorations

Scores	Amalgam								Composite							
	Baseline		6 months		1 year		3 years		Baseline		6 months		1 year		3 years	
	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B
Retention	100	0	100	0	100	0	100	0	100	0	100	0	100	0	100	0
Marginal adaptation	100	0	100	0	90	10	85	15	100	0	100	0	90	10	80	20
Anatomical form	100	0	100	0	85	15	50	50	100	0	100	0	95	5	75	25
Marginal discoloration	100	0	100	0	95	5	95	5	100	0	100	0	80	20	70	30
Surface texture	100	0	100	0	75	25	40	60	100	0	100	0	65	35	35	65
Secondary caries	100	0	100	0	100	0	100	0	100	0	100	0	100	0	100	0

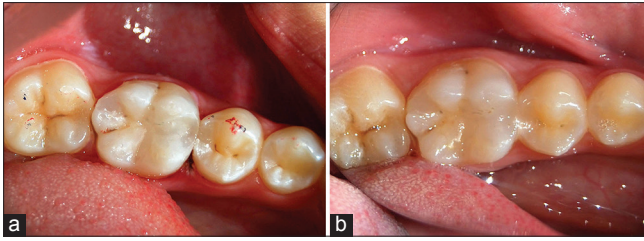


Figure 2: A resin composite restoration scored with Alpha in all evaluation criteria: At baseline (a) and at the end of the third year (b)

minimal standards of Acceptance Program Guideline by ADA.^[13]

In this study, postoperative sensitivity of the restorations was examined according to patients' responses to cold stimuli using VAS. There were higher number of amalgam restorations exhibiting increased sensitivity at the control periods compared to baseline; however, these increased levels did not present statistical significance ($P > 0.05$) [Table 4]. For resin composites, postoperative sensitivity tended to decrease generally and variations obtained were significant for all time intervals ($P < 0.05$) [Table 4]. Wilcoxon signed ranks test indicated that there were no significant differences among the VAS scores of resin composites and amalgams for all time periods except for the comparisons at the 3rd year evaluation ($P < 0.05$) [Table 5].

DISCUSSION

In our study, the clinical success of bonded amalgam and direct resin composite restorations in deep and large sized cavities was evaluated for 3 years. Judging from the results, survival rate was 100% for both of the restoration types and they were found to be successful.

The type of direct restoration material affects the clinical performance and longevity. Restorations of the small sized cavities with amalgams or resin composites present excellent clinical results due to less amount of material used, reduced cavity margins, easier control of the oral conditions and less chair side time spent. On the other hand, restoration of large sized cavities could include some limitations and challenges when either amalgam or composite were chosen as a direct restoration material. Failure rate of the restorations with four or more surfaces is 4 times greater than that of the single surface restorations due to tooth fractures and secondary caries.^[14] As reported in previously published data, secondary caries is the main reason



Figure 3: At the end of 3 years, marginal discoloration around the restoration and chipping of the material at palatal area were observed in resin composite of the second premolar. At amalgam restoration besides, failures of anatomical form and surface texture were detected

for failure of both resin composites and amalgam restorations.^[15-18] Additionally it was affirmed that evaluation of caries adjacent to composite was faster than amalgam because composite increases the risk for bacterial growth, however in our study, we did not observe any tooth fracture and secondary caries for both types of restorations. Studies concluded that more extensive restorations showed reduced clinical performance, especially the survival rates decrease as the size of restorations increase.^[6,19,20] This decline is more noticeable in resin composites than amalgams. In a study,^[20] it was reported that after 5 years 14.2 of large amalgam restorations and 19.8% of large composite restorations had to be replaced. In another study,^[15] survival rates of large sized cavities were found to be 89.5% for amalgam and 74.3% for composite. Similarly there are several studies showing that amalgam restorations show higher results on longevity, in both small and large cavity size.^[21,22] Conversely, in the present study the survival rate of resin composite was found to be 100% after 3 years of follow-up period. Even though, we did not observe any bulk fracture, chipping was available in one resin restoration of this study. This finding of the present study is in accordance with the conclusion that resin composite can serve adequately even in large sized cavities when they were properly bonded to tooth structure.^[23] Therefore, resin composites can undoubtedly be considered as a strong candidate to be used as a substitute for amalgam. Nevertheless, 3 years of evaluation period may not be long enough to make inferences on restorations' inadequacies. The results should be confirmed by the scores that will be obtained from the following recall appointments.

Table 4: Variations and significance of the subject responses within each treatment group

Test groups	Variations of VAS scores											
	Baseline - 6 months				Baseline - 12 months				Baseline - 36 months			
	Negative ranks	Positive ranks	Ties	Significancy	Negative ranks	Positive ranks	Ties	Significancy	Negative ranks	Positive ranks	Ties	Significancy
Amalgam	5	1	14	$P>0.05$	7	5	8	$P>0.05$	5	7	8	$P>0.05$
Resin composite	7	0	13	$P<0.05$	9	1	10	$P<0.05$	10	0	10	$P<0.05$

VAS: Visual analogue scale

Table 5: Statistical significances for materials and evaluation periods used in the study

Resin composite	Amalgam			
	Baseline	6 th month	12 th month ^c	36 th month ^d
Baseline ^a	$P>0.05$			
6 th month ^b		$P>0.05$		
12 th month ^b			$P>0.05$	
36 th month ^b				$P<0.05$

Different letters indicate statistical significances within each material. Comparisons of the materials according to evaluation periods were presented with P values

Since traditional amalgam restorations did not strengthen tooth structure, fracture was observed often. Therefore, some researchers advocated the use of bonding agents with amalgams declaring that this advantageous procedure reduces early microleakage, fracture, postoperative sensitivity and conserves tooth structure.^[24,25] Indeed, we did not observe any failure due to tooth fracture for bonded amalgams. However, we had only one amalgam with small marginal fracture with no exposed base and dentin [Figure 4]. Thus we could repair the restoration easily without the need for replacement of whole restoration. Amalgambond used in this study is a multi-step total etch system that contains 4-meta, a specific monomer. This system is a self-cure adhesive system, which does not need any light curing procedure to set. Amalgam needs to be placed as soon as the bonding agent is applied and condensed in the unset bonding agent. Amalgam particles and the resin sets together forming a locked intermingled impermeable surface.^[26] This merged structure may increase the fracture resistance at tooth/restoration unit.

Based on the current developments in material technology, resin composites have started to be used broadly in larger restorations also. In this situation, occlusal wear, polymerization shrinkage, technical complexity of sealing ability, secondary caries risk, failure in determining the margins of the restoration and adaptation of the preferred matrix system are the concerns that still exist. Despite of these concerns, we did not detect any of these mentioned problems except for matrix adaptation. In order to achieve tighter



Figure 4: Marginal fracture with no exposed base and dentin in amalgam was rated with Bravo score

proximal contacts in resin composite restorations, dental material manufacturers and researchers advocate using of sectional matrix systems. However, we observed some difficulties in the placement of sectional matrix to cavity lines of large sized cavities resulting in overhang and grooves at gingival area of some restorations.

In the postoperative sensitivity criteria, we found gradual increase in sensitivity levels for bonded amalgam restorations through the end of the investigation period. On the other hand, the sensitivity levels of resin composite restorations decreased throughout the time. These fluctuations observed in sensitivity results were not statistically significant. Furthermore, at the end of the 36th month, sensitivity levels of resin composites were statistically lower than that of the amalgam restorations. Even though both of the restorations were adhesively bonded with etch-and-rinse technique, formulations of etchants, compositions of adhesives and the number of application steps were different from each other. XP bond used in the resin composites was a one-bottle system with improved ability to diffuse through dentin. When compared to amalgam bond, it has fewer number of application steps, it is less technique sensitive and polymerized with light in 20 s. On the

contrary, etchant of amalgambond plus contained citric acid and ferric chloride and its priming solvent was acetone. The adhesive systems that contain acetone in their primers require much more attention to form a primed dentin because of their material sensitivity. Therefore, the difference between the postoperative sensitivity of the materials might be attributed to the chemical structure, complex and multi-step procedure of amalgam bond. Furthermore, it was stated that multi-step bonding systems caused gaps in the interface between resin and dentin. These gaps could cause microleakage and postoperative sensitivity.^[27] Besides, base-free application might be the reason of elevated postoperative sensitivity of the amalgam restorations due to increased thermal conductivity of the bulk metallic alloys. Therefore, amalgam should be used cautiously when there is risk of postoperative sensitivity.

At the end of 3 years, both bonded amalgam and resin composite were found to be clinically acceptable according to modified USPHS criteria. However, first Bravo ratings for both types of restorations were recorded after 1 year. These minor changes in the quality of the restorations did not need replacement. In postoperative sensitivity criteria, resin composites presented lower sensitivity levels than amalgams after 3 years. Within the limitations of this study, it can be concluded that resin composite can be an alternative for bonded amalgam restorations and can be used with utmost assurance even in large size cavities.

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Conflicts of interest

There are no conflicts of interest.

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