DENTAL MATERIALS 30 (2014) 824–838

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# One-year evaluation of two hybrid composites placed in a randomized-controlled clinical trial

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ARTICLE INFO

*Article history:*
Received 24 October 2013
Received in revised form
29 April 2014
Accepted 19 May 2014

*Keywords:*
Randomized controlled clinical trial
Resin composite
Total etch
Class I restorations
Class II restorations
Longevity

ABSTRACT

*Objective.* The aim of this prospective randomized-controlled clinical trial is to assess the long-term performance of two direct composite resins in posterior teeth. This study provides a survey of the one-year results.

*Materials and methods.* A total of 1805 restorations were placed by students in stress-bearing Class I/II cavities (including cuspal-coverage) in molars and premolars in 456 patients. Clinical evaluation was performed at baseline and after one year using modified USPHS criteria. The restorations in each patient were performed either with Ceram X/Prime&Bond NT or Tetric Ceram/Optibond Solo Plus.

*Results.* After one year 528 fillings with Ceram X and 580 with Tetric Ceram were available for evaluation of substance loss, contact point, color match, marginal staining, marginal adaptation, secondary caries and radiographic examination (if necessary). This represents a recall rate of 61.18% (279 patients). The failure rate per material was 5.3% in the Ceram X group and 6.1% in the Tetric Ceram group. Most of the failures were associated with marginal adaptation/integrity of the filling. A significant influence on the occurrence of a failure was observed for the number of treated teeth per patient, the age of the patient, the mesio-distal extension of the restoration and the tooth position. Gender, material, a previous root canal treatment, the bucco-lingual extension of the filling or cuspal-coverage did not significantly influence the failure rate. Patients attending the first recall were significantly older and had more fillings than patients not attending.

*Conclusions.* In a group of Class I/II restorations (including cuspal-coverage), there was no significant difference in failure rates between ormocer-based and bis-GMA-based restorative systems after one year. A previous root canal treatment had no negative influence on the failure rate. A longer observation period is indicated to get clear evidence of the long-term performance of these composite resin systems.



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http://dx.doi.org/10.1016/j.dental.2014.05.006
0109-5641/

## 1. Introduction

Amalgam, which was the filling material of choice for direct posterior restorations for more than 100 years, is increasingly being replaced in favor of composite restorations. This tendency can be explained by growing concern in populations over possible mercury intoxication from amalgam and the rising demand for tooth-colored restorations [1–6]. Furthermore, composite filling materials, in contrast to amalgam, meet the criteria to allow for the use of "minimal invasive technique" in dentistry and to maintain a maximum of tooth tissue [7].

The patient demand for white filling materials is rising, and furthermore, composite materials such as packable resin-based composites and "bulk-fill" materials are being promoted as an alternative to amalgam in respect to their handling procedures [8–10].

The longevity of a dental restoration is influenced by material-, dentist- and patient-related factors. Patient-related factors include oral hygiene amongst others (dietary habits, preventive measures, compliance in recall, oral environment and systemic diseases, tooth-related factors, cooperation and parafunctional habits) [6]. There are numerous studies in which dental students have served partly or solely as a patient population [3,5,11–14].

As a matter of fact, the performance of restorations in dental students can greatly vary from that of socially deprived patients. The different dental awareness of oral hygiene and caries prevention is a possible reason [15]. In 1997, Roulet stated that "trial patients are very carefully selected, especially for good compliance" [1]. In recently published recommendations for conducting clinical trials, the authors call for study groups that represent a cross-section of the population [15]. According to Opdam et al., cross-sectional studies represent more daily practice, but they do not offer data on survival or failure rates [16]. Controlled longitudinal clinical studies do provide this information [6]. In most conducted clinical trials, the restorations are performed by experienced university dentists on selected patients, who are motivated to maintain good oral hygiene. Practice-settings can differ from that in controlled, clinical trials. Typically, university dentists dedicate more time to the placement of a composite filling compared with practice-settings. [16,17].

Several clinical trials published during the last several years only provide so-called short-term results (0–5 years) [6,18,19]. Long-term clinical trials are clearly needed, particularly when considering that failures in restorations should be subdivided into early (after weeks or months) and late failures (after several years of clinical function) [6,15]. Failures during the treatment procedures can be held primarily responsible for the early failures, whereas late failures are a result of tooth and/or restoration fracture, secondary caries and wear [6].

Furthermore, long-term data are necessary to evaluate the long-term costs of a restorative treatment. The longevity of a restoration can be regarded as an indicator of the success of a treatment procedure [20].

The failure rate among 17 clinical studies between 1996 and 2002 varied greatly from 0% to 45%. Studies lasting longer than 10 years had the highest failure rates. It could be demonstrated that short-term studies provided more favorable results, in addition to having smaller study populations [18].

According to van Dijken and Lindberg, the longevity of a restoration is predominantly dependent on the dentist's qualification and the stress the oral cavity is exposed to [21].

The shortcomings of all of these studies (small study population, short-term results, selection of the study population in favor of oral hygiene) served as a basis for this present study.

The aim of this study is to assess the long-term performance of two direct composite resins for posterior restorations placed in a randomized-controlled clinical trial (over 10 years). This feasibility study demonstrates if treatment of a high number of participants is feasible in the routine clinical student course. This study also examines if the failure rate of these composites will differ more than 10% after 10 years of clinical service using modified US Public Health Service (USPHS) scoring system [22]. This study provides the results after one year of clinical service.

## 2. Materials and methods

### 2.1. *Study design, patient selection and description of the study population*

The null hypothesis reflects that no difference will be determined between the restorations of Class I/II (including cuspal coverage) after an observation period of 10 years using two different composite materials (Table 1).

The primary outcome of this study is the clinical service of restorations of Class I/II defects (occurrence of failure: yes/no). The following is recorded: restoration failure; if dentin or base was exposed; if contact point was missing (present periodontal inflammation); color and/or translucency beyond the normal range of tooth colors; marginal staining penetration in the direction of the pulp; marginal gap exhibiting the enamel–dentin junction; fractured, loose filling that is missing partly or completely and presence of caries (associated with the filling). This outcome is being assessed every year until 10 years after baseline (time of filling placement).

The study population was recruited from patients of the Bernhard Gottlieb University Clinic of Dentistry during one year. Each patient, who has been in need of a direct posterior restoration, was offered participation in the study. As a benefit for the patients, the composite fillings were free of charge. The patients committed to attending the annual recall by participating in the study.

To maintain a high recall rate, the patients were offered one free composite restoration in posterior teeth (in case of replacement) for every successfully attended recall. The patients can quit the study at every time without giving any reason.

Prior to the restorative treatment, each patient provided written, informed consent to participate in the study.

The patients had to meet the following *inclusion* criteria:

(1) At least one permanent (pre-) molar in the posterior teeth with a natural antagonist (even third molar).
(2) Patient's age was over 18 years at the time of filling placement.