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ABSTRACT

The objective of this randomized control trial was to compare the five-year clinical performance of direct and indirect resin composite restorations replacing cusps. In 157 patients, 176 restorations were made to restore maxillary premolars with Class II cavities and one missing cusp. Ninety-two direct and 84 indirect resin composite restorations were placed by two operators, following a strict protocol. Treatment technique and operator were assigned randomly. Follow-up period was at least 4.5 yrs. Survival rates were determined with time to reparable failure and complete failure as endpoints. Kaplan-Meier five-year survival rates were 86.6% (SE 0.27%) for reparable failure and 87.2% (SE 0.27%) for complete failure. Differences between survival rates of direct and indirect restorations [89.9% (SE 0.34%) vs. 83.2% (SE 0.42%) for reparable failure and 91.2% (SE 0.32%) vs. 83.2% (SE 0.42%) for complete failure] were not statistically significant ($p = .23$ for reparable failure; $p = .15$ for complete failure). Mode of failure was predominantly adhesive. The results suggest that direct and indirect techniques provide comparable results over the long term (trial registration number: ISRCTN29200848).

KEY WORDS: clinical studies/trials, composite materials, prosthetic dentistry/prosthodontics, restorative dentistry, restorative materials, operative dentistry.

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Randomized Control Trial of Composite Cuspal Restorations: Five-year Results

INTRODUCTION

Cusp fracture of restored posterior teeth is frequently observed, with incidence rates varying from 21 (Fennis *et al.*, 2002) to 71 (Bader *et al.*, 2001) per 1,000 person-years at risk. Given the observation that 91% of fractures in vital teeth ended supragingivally, restoration is possible for the majority of teeth (Fennis *et al.*, 2002). For fractured premolars, the conventional treatment is a metal-ceramic crown with a five-year survival rate of 96% (Pjetursson *et al.*, 2007). Despite the favorable survival rate, a disadvantage of crowns is the required removal of a large part of the remaining cusp to create retention (Edelhoff and Sorensen, 2002).

It is expected that adhesive restorations do not require extensive mechanical retention, which may prevent complications like pulpal damage (Murray *et al.*, 2000). Regarding longevity, failure rates of 18% to 27% after 11 yrs were reported for large Class II composite restorations (Van Dijken, 2000). Furthermore, large resin composite restorations showed a higher survival rate after 12 yrs than did comparable amalgam restorations (Opdam *et al.*, 2010). Since long-term data on adhesive restorations replacing cusps are not available, it is often stated that resin composite is not appropriate as an occlusion-bearing restoration material. It is valuable to examine whether this assertion is true.

Resin composite restorations can be made with direct or indirect techniques. Direct restorations are preferred for reasons of minimal intervention (Tyas *et al.*, 2000). They are made in one treatment session at relatively low costs. Direct restorations are associated with polymerization shrinkage stress. In case of a cusp-replacing restoration, however, the configuration value is favorable (Feilzer *et al.*, 1987). Indirect restorations are advocated to overcome problems related to shrinkage (Reeves *et al.*, 1992). This should result in better marginal adaptation (Duquia *et al.*, 2006; Fruits *et al.*, 2006). Studies on *in vitro* microleakage between both techniques, however, were ambiguous (Kenyon *et al.*, 2007; Ferreira and Vieira, 2008). Advantages of the indirect technique include a higher degree of polymerization and the possibility for external surfaces to be shaped extra-orally. Conversely, an indirect technique requires a diverging cavity, resulting in loss of tooth tissue. Furthermore, a relatively weak cement is necessary that must adhere to the highly cured indirect restoration.

For both techniques, favorable and unfavorable characteristics were reported. While higher fracture resistance for direct (Sengun *et al.*, 2005) as well as indirect

resin composite restorations was reported (Aggarwal *et al.*, 2008), other studies revealed no significant differences (Kuijs *et al.*, 2006a; Coelho-De-Souza *et al.*, 2008; de Paula *et al.*, 2008). With regard to failure mode, catastrophic fractures were reported more frequently for direct restorations (de Paula *et al.*, 2008), although, clinically, no significant differences in survival rates of direct and indirect resin composite restorations were reported (Thordrup *et al.*, 2006; Mendonça *et al.*, 2010). For adhesive restorations replacing cusps, both direct and indirect techniques are adequate to restore morphology and function, but long-term data are not available (Kuijs *et al.*, 2006b).

The objective of this randomized control trial (RCT) was to compare the five-year clinical performance of direct and indirect resin composite restorations replacing cusps. The null hypothesis tested was that there was no difference in survival for direct and indirect restorations. Furthermore, failures were expected to be adhesive, without fracture of tooth substrate.

MATERIALS & METHODS

Patient Sample

This RCT was set in the university clinic of the Radboud University Nijmegen, The Netherlands (trial registration number ISRCTN29200848; Radboud University Nijmegen Ethics Committee approval 2001/166). Details of patient recruitment and follow-up are listed in the CONSORT flow diagram (Fig. 1, Appendix Table) (Boutron *et al.*, 2008). Between 2001 and 2007, 176 premolars in 157 patients (77 males, 80 females) were restored with 92 direct and 84 indirect resin composite restorations. In 138 patients, 1 restoration was made, with 2 in 19 patients. Mean patient age was 54.9 yrs (range, 35.0-81.0 yrs). The sample size was calculated based on an expected difference in survival of direct and indirect restorations of 15%, a power of 0.8, and a significance level of .05. Patients were referred by the university clinic or by general practitioners. Treatments were performed by two practitioners in a four-handed setting. After the referral was received and before the patient was assessed for eligibility, treatment technique and operator were assigned by blocked randomization (block size: 20), using a random permutation table (Fisher and Yates, 1974). Given the specific aspects of the 2 techniques, blinding of operators and patients was not possible. Written informed consent was obligatory for each patient.

Inclusion criteria were fracture of the buccal or palatal cusp of vital upper premolars along with a class II cavity or restoration in the same tooth. The remaining cusp had to be sound; preparation outlines in dentin and subgingival margins were allowed. Exclusion criteria were absence of an antagonist, presence of rest seats for a removable partial denture, and tooth mobility score 3 (Miller, 1950). Signs and symptoms of bruxism were not reasons for exclusion.

Cavity Preparation

All restoration material and carious tissue, if present, were removed. Pulp vitality was verified during preparation, after which local anesthesia was administered at the patient's request.

In case of negative pulp response, a radiograph was made to exclude apical periodontitis.

Restorative Procedures

For the direct technique, a contoured metal matrix (Hawe Tofflemire 1001C, Kerr, Orange, CA, USA) and wooden wedges were placed. Moisture was controlled by cotton rolls and a suction device. The cavity surface was etched for 20 sec with a 37% phosphoric acid etch gel (Superlux-Thixo Etch, DMG, Hamburg, Germany), rinsed for 20 sec, and gently air-dried. Dentin primer and bonding agent were applied according to the manufacturer's instructions (Clearfil SA primer and Clearfil PhotoBond, Kuraray, Osaka, Japan). The restoration was built up with a highly filled hybrid resin composite (70% vol, 86% wt filler load; AP-X, Kuraray), starting with the missing cusp. After this, placement of separation rings (Danville Materials, San Ramon, CA, USA) was possible. The Class II cavity was subsequently restored. Incremental composite layers of 2 mm maximum were applied. Each layer was light-cured for 40 sec with a halogen curing light with an intensity of 650 mW/mm².

For the indirect technique, a silicone impression of the cavity was taken (Provil, Heraeus Kulzer, Hanau, Germany) and poured in stone. A temporary restoration (Cooltemp, Dentsply Maillefer, Ballaigues, Switzerland) was cemented by a spot-etch technique. All indirect resin composite restorations (82% vol, 92% wt filler load; Estenia, Kuraray) were made by one dental technician according to the manufacturer's instructions. At placement, 2 wks after cavity preparation, the temporary restoration was removed, the cavity cleaned with pumice, and the indirect restoration inserted to check shape, fit, and color. The internal surface was sandblasted for 15 sec with 50 μ m Al₂O₃ with a pressure of 0.32 MPa (MicroEtcher, Danville Materials), acid-etched for 10 sec with a 37% phosphoric acid etch gel (Superlux-Thixo Etch, DMG), and treated with a silane coupling agent (Clearfil SE Bond primer mixed with Clearfil Porcelain Bond Activator, Kuraray). Moisture was controlled with cotton rolls and a suction device. The enamel was etched for 20 sec with the acid etch gel, rinsed for 20 sec, and gently air-dried. A self-etching primer (ED primer, Kuraray) was applied to enamel and dentin for 60 sec. The restoration was cemented with dual-cure resin composite cement (Panavia F, Kuraray). The cement was light-cured for 20 sec from the buccal, palatal, and occlusal surfaces. Excess cement was removed and oxygen blocker applied to the margins for 3 min.

Both direct and indirect restorations were finished with fine-grit diamonds, polishing discs, strips, and rubbers.

Evaluation Procedure

Patients were invited for a check-up once a year. They were instructed to contact the operators if an event occurred concerning their restoration. Performance of the restorations was evaluated by clinical examination. Failure was recorded on the basis of predefined criteria and considered as:

Figure 1. CONSORT flow diagram detailing patient recruitment and follow-up at 5 yrs.

- (1) reparable – interventions such as polishing after chipping of fragments of resin composite and re-cementation of dislodged indirect restorations; or
- (2) complete – problems such as caries or tooth fracture and dislodged direct or re-cemented indirect restorations.

Reparable and complete failures were categorized in 2 levels. First, restoration level included (1) dislodgement and

- (2) cohesive failure. Second, tooth level included (3) post-operative sensitivity, (4) caries, (5) endodontic treatment, (6) tooth fracture, and (7) extraction.

Statistical Analysis

‘Time to reparable’ and ‘time to complete failure’ were the primary outcomes of interest. Restorations not showing failure after five-year follow-up were censored. Data for drop-out patients

*Due to loss of adjacent tooth. Censored for Kaplan Meier survival analyses

**One tooth was extracted for periodontal reasons. Censored for Kaplan Meier survival analyses

Figure 2. Life cycle of adhesive restorations replacing cusps during the follow-up period.

were censored at the last date on which information on the restoration was available. Reasons for drop-out were traced. Kaplan-Meier five-year survival probabilities, standard errors, and 95% confidence intervals (CI) were calculated and discriminated according to restoration technique. Differences in survival were analyzed with the log rank test. Furthermore, frequency distributions were constructed for failure categories at restoration and tooth level as secondary outcome. Analyses were performed with SPSS version 20 (IBM SPSS Statistics, Chicago, IL, USA). Independence of multiple restorations in one patient was checked with R-package prodlm (R Development Core Team, 2012).

RESULTS

Mean follow-up time was 5.6 yrs (SD, 0.9 yrs; range, 4.5-8.8 yrs) for the direct technique and 6.0 yrs (SD, 1.3 yrs; range, 4.5-8.5 yrs) for the indirect technique. During the follow-up period, 17 patients (12 direct and 6 indirect restorations) were lost to follow-up (10.2%) (Fig. 1). These drop-out patients could not be contacted or were unable to participate, mostly for travel reasons. The life cycle of the restorations is presented according to Van Heumen *et al.* (2009) (Fig. 2). Failures occurred at a mean follow-up of 35.4 mos (SD, 20.9 mos) for the direct technique and 37.4 mos (SD, 14.4 mos) for the indirect technique. Twenty-three

restorations (8 direct, 15 indirect) failed because of complications at the restoration level, subsequent restorative treatment, or complications at the tooth level. Four failures were considered reparable. Three indirect restorations were re-cemented but failed again within 1 wk to 7 mos.

Survival curves of direct and indirect restorations are shown in Fig. 3. The pooled Kaplan-Meier five-year survival rates were 86.6% (SE 0.27%) for reparable failure and 87.2% (SE 0.27%) for complete failure. The estimated median survival time was 106 mos (SE, 3.3 mos) for reparable failure. Inclusion of repaired restorations did not increase median survival time. Although five-year survival rates were higher for direct than for indirect restorations [89.9% (SE 0.34%) vs. 83.2% (SE 0.42%) for reparable failure, and 91.2% (SE 0.32%) vs. 83.2% (SE 0.42%) for complete failure], differences were not significant (log rank tests: reparable failure $p = .23$, 95% CI = -5.1 to 18.5%; complete failure $p = .15$, 95% CI = -3.6 to 19.6%). Use of the R-package prodlm revealed identical results and confirmed independence of the data.

The distribution of failure categories is shown in Fig. 4. For direct restorations, fracture of the remaining cusp and cohesive restoration failure were the main problems [37.5% ($n = 3$) and 25% ($n = 2$), respectively]. For indirect restorations, dislodgement and dislodgement plus cohesive failure were the main

Figure 3. Restoration survival probability as a function of time for direct ($n = 92$) and indirect ($n = 84$) adhesive restorations replacing cusps.

Figure 4. Failure categories (n) for the direct and indirect techniques.

causes for failure [26.7% ($n = 4$) and 20% ($n = 3$), respectively]. After loss of an adjacent tooth, one tooth with an indirect restoration served as abutment for an adhesive bridge. Another tooth with an indirect restoration was extracted for periodontal reasons. These 2 teeth were censored for the Kaplan-Meier survival analysis.

DISCUSSION

To our knowledge, no long-term RCT results on adhesive restorations replacing cusps have yet been published. Not excluding

patients with signs and symptoms of bruxism, the five-year survival rate of the present study is comparable with that for extensive Class II restorations (Van Dijken, 2000; Opdam *et al.*, 2010) but lower than that for metal-ceramic crowns (Pjetursson *et al.*, 2007). Certainly a direct comparison of those figures cannot be made. The attractive features of adhesive restorations are the minimally invasive approach and the possibility of repair. However, the differences between survival rates for reparable and completely failed restorations in this study were small. It can therefore be questioned whether repair is an advantage for prolonging the longevity of adhesive restorations replacing cusps.

A limitation of the applied RCT study design was the inclusion of patients following strict criteria. Based on an incidence study (Fennis *et al.*, 2002), we estimated an inclusion period of 6 mos. In reality, inclusion of patients was more difficult; it took more than 5 yrs to reach the sample size. To ensure control of treatment protocols during the operative period, only two operators were involved, in a university setting. As a consequence, it may be difficult to infer the results of this trial to general practice.

The mode of failure was predominantly adhesive: 7 out of 15 failed indirect restorations dislodged. When fracture of the remaining cusp was considered a failure of the vertical interface, half of the failed direct restorations were adhesive as well. Adhesive failure may be prevented by coverage of the remaining cusp, particularly with thin cusps that are prone to fracture. *In vitro* research revealed that cuspal coverage leads to higher strength (Fennis *et al.*, 2004; Magne *et al.*, 2012). Cuspal coverage, however, requires substantial tissue removal (Edelhoff and Sorensen, 2002) and leads to a higher risk of catastrophic failure (Fennis *et al.*, 2004). To prevent catastrophic failure, fibers can be applied in the restoration, but the benefits of this technique need to be confirmed clinically (Fennis *et al.*, 2005; Magne *et al.*, 2009). For these reasons, we are reluctant to lower sound cusps for adhesive restorations.

Apart from cohesive restoration failure, subsequent restorative treatment that apparently was not associated with the functioning of the restoration was the second most common reason for failure. These treatments were provided by the patient's dentist, and the background for the treatment decisions was not clear. Since it cannot be determined whether those interventions were due to a flaw in the restoration, these were considered failed. Based on the same considerations, 1 of the 2 extractions was classified as a restoration failure; the other was censored for periodontal reasons. One direct restoration was replaced due to post-operative sensitivity and was considered failed. The replacement was included as a new direct restoration and has been in function for 6 yrs since.

The baseline clinical evaluation provided comparable results for direct and indirect restorations replacing cusps (Kuijs *et al.*, 2006b). Apparently, the extra-oral shaping and optimized curing regime of the indirect restoration do not lead to improved performance. After 5 yrs, survival rates were higher for direct than for indirect restorations, although differences were not significant. The longer treatment time (Kuijs *et al.*, 2006b) and higher costs for the indirect restoration argue in favor of the direct technique. Since minimal cavity preparation was applied, the

non-significant difference in survival rates can hardly be due to additional removal of tooth substance for indirect restorations. Rather, we suspect that adhesive failure of the restoration is more likely within the cement than at the direct bonding interface, although previous studies show ambiguous results (Sengun *et al.*, 2005; Aggarwal *et al.*, 2008).

With the direct and indirect technique of applying composites for the restoration of premolars with a Class II cavity and a missing cusp, an overall five-year survival of 87% (95% CI = 81 to 93%) was obtained. No significant difference between the two techniques was observed.

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