A Randomized Clinical Trial of Cusp-Replacing Resin Composite Restorations: Efficiency and Short-Term Effectiveness

Ruud H. Kuijs, DDS, PhD[a]/Willem M. M. Fennis, DDS, PhD[b]/Cees M. Kreulen, DDS, PhD[c]/
F. Joost M. Roeters, DDS, PhD[d]/Nico H. J. Creugers, DDS, PhD[e]/Rob C. W. Burgersdijk, DDS, PhD[f]

Purpose: This study aimed to assess the efficacy and short-term effectiveness of the morphology and function of direct and indirect cusp-replacing resin composite restorations. ***Materials and Methods:*** In 94 patients, 106 cusp-replacing restorations for maxillary premolars were fabricated to restore Class II caries lesions with 1 cusp missing. Fifty-four direct (Clearfil AP-X) and 52 indirect (Estenia) resin composite restorations were placed following a strict protocol. The treatment technique and operator were assigned randomly. Treatment time was recorded for all restorations. One-month postoperative evaluation included assessment of postoperative sensitivity and presence of occlusal and proximal contacts. ***Results:*** Treatment time for the indirect technique (68 ± 17 min) was longer than for the direct technique (45 ± 13 min). Regression analysis revealed that the restorative method, operator, and location of the preparation outline had a statistically significant effect on the total treatment time. Occlusal contacts were observed in 94% of the direct restorations and in 98% of the indirect restorations (chi-square, $P > .05$). Mesial proximal contacts were present in 98% of the direct and in 97% of the indirect restorations (chi-square, $P > .05$). Distal contacts were present in 100% of the restorations for both techniques. Postoperative sensitivity within 1 week posttreatment was reported for 11% of the direct restorations and for 13% of the indirect restorations, but decreased to 4% and 6%, respectively, after 1 month (chi-square, $P > .05$). ***Conclusion:*** The results of this study suggest that in the short term, both direct and indirect adhesive techniques are adequate to restore the morphology and function of premolars presenting with Class II caries lesions and a missing cusp. *Int J Prosthodont 2006;19:349–354.*

[a]*Assistant Professor, Department of Preventive and Curative Dentistry, Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands.*
[b]*Assistant Professor, Department of Oral Function and Prosthetic Dentistry, Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands.*
[c]*Associate Professor, Department of Oral Function and Prosthetic Dentistry, Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands.*
[d]*Associate Professor, Department of Preventive and Curative Dentistry, Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands.*
[e]*Professor and Chair, Department of Oral Function and Prosthetic Dentistry, Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands.*
[f]*Professor, Department of Preventive and Curative Dentistry, Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands.*

Correspondence to: *Dr Ruud Kuijs, Department of Preventive and Curative Dentistry, Radboud University Nijmegen Medical Centre, PO Box 9101, 6500 HB Nijmegen, The Netherlands. Fax: +31 24 3540265. E-mail: R.Kuijs@dent.umcn.nl*

Cusp fracture of teeth with amalgam restorations is frequently seen in dental practice.[1] In an epidemiologic study, cusp fracture was observed in 14% of patients aged over 45 years.[2] Another study reported that 10% of Class II amalgam restorations were replaced because of fracture of the tooth.[3] For complete cusp fracture, incidence rates of 20.5[4] and 71[5] per 1,000 persons have been published. Consequently, in an average Dutch dental practice with about 2,500 regular attending clients, a case of cusp fracture in the posterior region will present about once per week.

The traditional treatment of cusp fractures in premolars is to restore the tooth with a metal-ceramic crown or a cusp-covering amalgam restoration. However, these techniques require removal of a large part of the remaining cusp to create retention and resistance for the restoration. Use of adhesive techniques to restore the fractured cusp will save sound tooth tissue. Further, because there is a reduced need for

Table 1 No. of Premolars in the Sample for Several Variables

Restorative technique	Operator		Fractured cusp		No. of restored surfaces	
	1	2	Buccal	Palatal	3	4
Direct	29	25	28	26	4	50
Indirect	26	26	31	21	8	44
Total	55	51	59	47	12	94

preparation, complications like pulpal damage may be prevented.[6] Adhesive resin composite restorations in Class II caries lesions perform satisfactorily according to many clinical studies. A recent review reported mean annual failure rates of 2.2% for direct resin composite restorations and 2.9% for composite inlay restorations.[7] In a study of large Class II restorations, failure rates were reported of 17.7% for indirectly made and 27.3% for directly made resin composite restorations after 11 years.[8] For cusp-replacing adhesively bonded restorations, no data are available on clinical performance and longevity.

The use of an adhesive technique to restore teeth with fractured cusps requires that existing restorative procedures be adopted and specific protocols be developed with regard to restoration material and cavity configuration. In vitro research suggests that resin composite might be a suitable material for fabrication of cusp-replacing restorations in premolars.[9,10] Fracture strengths of cusp-replacing resin composite restorations are comparable to the fracture strengths of ceramics and amalgam restorations.[11–13] Cavity preparation for adhesive restorations uses a minimally invasive approach. Studies done on this subject suggest that resistance forms like shoulder preparation or cuspal coverage are not required for the treatment of a premolar with an existing amalgam cavity preparation and a fractured cusp. However, when the tooth-restoration interface was a flat surface, fracture resistance was significantly lower because of shear stresses.[11] In addition, the filling technique did not influence stress as a result of polymerization shrinkage.[14] Laboratory data indicated that direct and indirect restorative techniques resulted in comparable fracture loads and failure modes.[10] It has also been stated that direct resin composite restorations are preferred to indirect restorations because of the minimal intervention[15] and better adhesive strength.[16,17] Nevertheless, indirect techniques are advocated to overcome problems related to shrinkage[18] and because they depend less on the operator's clinical skills to achieve the required anatomic shape.

Based on preparation and restoration designs tested in vitro, 2 cusp-replacing resin composite restoration techniques for maxillary premolars were chosen for testing in this clinical study.[9–11,14] The aim was to compare the efficiency and short-term effectiveness of these techniques regarding function and morphology, defined as: treatment time required, postoperative sensitivity, presence of occlusal and proximal contacts, and patient satisfaction with the color of the restoration. The hypothesis was that the indirect technique requires more clinical treatment time but leads to less postoperative sensitivity and is more adequate for restoring occlusal and proximal contacts than the direct restoration.

Materials and Methods

Patient Sample

Between December 2001 and June 2004 a total of 106 premolars with a fractured cusp in 94 patients (mean age 54, range 35 to 79 years; 45 men, 49 women) were included. Patients were recruited from the Nijmegen Dental Faculty or referred by general practitioners in the region. Inclusion criteria were fracture of the buccal or palatal cusp or re-restoration of vital maxillary premolars with an existing cusp-replacing restoration. Patients had to be in healthy general condition. Teeth with periodontal problems were excluded only if the Miller score for mobility exceeded 3.[19] Patients with a habit of bruxism were not excluded. Exclusion criteria were absence of an antagonist and presence of occlusal stops for removable partial dentures. The remaining cusp had to be sound; preparation outlines in the dentin were allowed. Of the selected group of 106 teeth, 54 were restored using a direct resin composite technique and 52 were restored using an indirect resin composite technique. Eighty-nine percent of the restorations were 4-surface restorations (MODP or MODB); the other 11% were 3-surface restorations (MOB, DOB, MOP, or DOP) (Table 1). Eighty-five percent of the buccal and palatal cervical outlines of the preparations were above gingival level, 67% for the distal outline, and 82% for the mesial outline.

All treatments were performed by 2 practitioners at the clinic of the dental faculty. The operators were experienced in making direct resin composite restorations, although in the beginning, they had limited experience in making indirect resin composite restorations. The treatment technique and operator were assigned randomly (Table 1) using random numbers. For calibration reasons, the first 20 patients were treated by one operator treating with the second operator assisting or vice versa.

The study protocol was screened and approved for ethical acceptability by the Committee on Experimental Research on Man of the Radboud University Nijmegen Medical Centre, and all patients provided informed consent.

Cavity Preparation

All present restoration materials and carious tissue were removed. For both techniques the cavities were finished with a 45-degree bevel for the ascending walls and the cervical margin if enamel was present. Dentin margins were finished with a butt joint. The preparation of the indirect technique was carefully assessed and if necessary adjusted to prevent undercuts. During preparation, tooth vitality was checked by asking the patient whether the preparation area was sensitive. If the patient preferred to have local anesthesia this was administered after a vital response of the pulp during preparation. In case of a negative r esponse, a radiograph was taken to check for periapical deviations.

Direct Technique Restorative Procedure

Prior to the actual restorative procedure, a contoured tofflemire metal matrix (Hawe Neos 1001C) and wooden wedges were placed. Moisture was controlled using cotton rolls and a suction device. The cavity surface was etched for 20 seconds with a 37% phosphoric acid etch-gel (Superlux-Thixo Etch, DMG). The preparation was then thoroughly rinsed for at least 10 seconds and gently air dried. A dentin primer and bonding agent were applied according to the manufacturer's instructions (Clearfil SA primer and Clearfil PhotoBond, Kuraray). A heavily filled (70% vol, 86% wt) hybrid resin composite (AP-X, Kuraray) was used as the restorative material. The restoration was built up in layers with a maximum thickness of 2 mm using an injection technique. Each layer was light cured for 40 seconds with a halogen curing light. Intensity was 650 mW/mm^2 as measured before and after the experiment using a curing radiometer. First, the missing cusp was built up and mesial and distal separation rings were placed (Danville), after which the mesial and distal boxes and the step were restored. The wedges, rings, and matrix were removed immediately after restoration.

Indirect Technique Restorative Procedure

After the preparation was finished, a full-arch silicone impression (Provil, Heraeus Kulzer) was taken. A temporary filling was made (Cooltemp, Maillefer) and fixed using spot-etch technique. In the laboratory, the indirect composite restoration (Estenia, filler load of 82% vol, 92% wt, Kuraray) was modeled according to the manufacturer's instructions. All restorations were made by the same technician. Two weeks later, the temporary filling was removed and the restoration was inserted to check the anatomic form, marginal fit, and color. The restoration was sent back to the laboratory if the color was not correct or if the marginal fit could not be adjusted. If anatomic form, marginal fit, and color were correct, the internal surface was sandblasted for 15 seconds with 50-µm aluminum oxide, acid-etched for 10 seconds using a 37% phosphoric acid-etch gel, and treated with a silane coupling agent (SE primer with Porcelain Bond Activator, Kuraray). Moisture was controlled using cotton rolls and a suction device. The enamel of the preparation was acid etched for 10 seconds with 37% phosphoric acid-etch gel, rinsed, and gently air dried. A dentin primer (ED primer, Kuraray) was applied for 60 seconds to the whole preparation surface. The restoration was cemented with a dual-cure resin composite cement (Panavia F, Kuraray). The cement was light cured for 20 seconds from the buccal, palatal, and occlusal directions. Excess cement was removed and an oxygen blocker was applied on the margins for 3 minutes.

Finishing

Both the direct and indirect restorations were finished with polishing disks and strips for the proximal and buccal or palatal surfaces. The occlusal surfaces were finished with fine-grit diamond burs. Finally, occlusion, articulation, and proximal contacts were assessed.

Evaluation Procedure

Before treatment, patients were interviewed regarding sensitivity of the tooth before and after cusp fracture. The treatment times required for the different stages of the treatment procedure were recorded. The laboratory time needed to fabricate the indirect restoration was not recorded.

Restorations were evaluated 1 month posttreatment, via an interview and a visual inspection. Patients were asked whether they had experienced sensitivity within 1 week and after 1 month (yes or no), for how long (min), and under what circumstances (cold/warm, while biting, or spontaneously). Static and dynamic occlusion were assessed as the presence or absence of contacts using 12-µm-thick occlusion paper. Proximal contacts were assessed as present or absent using waxed dental floss (Johnson & Johnson). The contact was scored as "absent" if there was no resistance against the floss and as "not applicable" if there was a diastema or if the contact surface was not involved in the restoration. The operator who had not done the treatment performed the corresponding evaluations. Patient satisfaction with the color of the restoration was recorded through a nonanonymous interview. Patients were asked to give a score on a 10-point scale, with a score of 10 meaning "very satisfied."

Table 2 Mean Treatment Times (Min) (SD) for the Different Steps of the Restorative Procedures

Procedure	Restorative technique		*P*
	Direct	Indirect	
Total	45 (13)	68 (17)	.000*
Preparation	10 (8)	10 (4)	.470**
Matrix	4 (3)		
Restoration	14 (4)		.120**
Fitting		8 (5)	
Cementing		12 (6)	
Finishing	18 (6)	14 (6)	.006**
Impression		13 (5)	
Temporary		12 (5)	

*1-tailed, **2-tailed.

Statistical Analysis

To analyze the effect of the restoration method, operator, number of restored surfaces, and location of the preparation outline on the total treatment time, stepwise backward regression analysis was performed. Since the distribution of the treatment time was positively skewed, Ln (treatment time) was used as the independent variable. To analyze the differences in treatment time for the separate steps of the treatment, 2-tailed *t* tests were performed. For the total treatment time, a 1-tailed *t* test was performed, because the total treatment time for the indirect technique was expected to be longer than for the direct technique. The presence of a learning curve was analyzed by splitting the records into 2 consecutive cohorts and a 2-tailed *t* test was performed on Ln-transformed treatment times. Chi-square test was used to analyze differences in postoperative sensitivity between the 2 treatment options. Spearman correlation was applied to sensitivity before and after treatment. Chi-square test was used to analyze differences in patients' satisfaction regarding color of the restoration. For all statistical analyses a significance level of .05 was used. All analyses were performed with SPSS version 10.

Results

Treatment Time

The mean total clinical treatment time for the indirect technique (68 ± 17 min) was significantly longer than for the direct technique (45 ± 13 min) ($P < .001$) (Table 2). The time needed for preparation was comparable for both techniques ($P = .47$), and finishing took less time for the indirect restorations ($P = .006$). When the combined time for placing the matrix and making the direct restoration (18 ± 5 min) was compared with the combined time for fitting and cementing of the indirect restoration (20 ± 7 min), no significant difference was found ($P = .12$). Treatment times needed for the impression and temporary filling were 13 ± 5 min and 12 ± 5 min, respectively. Regression analysis revealed that the restoration method had the largest effect on treatment time, followed by the operator and the location of the distal preparation outline. The indirect technique took 49% more time than the direct technique ($P = .0001$), operator 2 needed 20% more time than operator 1 ($P = .002$), and restoration of a cavity with a distal outline below the gingival level took 14% more time than a supragingival outline ($P = .02$). Cavity size, fractured cusp (buccal or palatal), and the outline location of the mesial and buccal or palatal side had no significant influence.

For the direct technique, all treatment phases demonstrated a learning curve. The total treatment time decreased from 51 to 39 minutes ($P = .0001$). For the indirect technique, only the preparation time decreased ($P = .001$). The total treatment time decreased from 73 to 63 minutes, but this was not significant ($P = .08$).

Outcome Evaluations

Occlusal contacts were present in 94% of the direct and 98% of the indirect restorations (chi-square, $P > .05$). Mesial proximal contacts were present in 98% of the cases for the direct technique and 97% of the indirect technique cases (chi-square, $P > .05$). Distal proximal contacts were present in 100% of the restorations for both techniques (Table 3). Postoperative sensitivity within 1 week posttreatment was reported for 11% of the direct restorations and 13% of the indirect restorations, but decreased to 4% and 6%, respectively, after 1 month (chi-square, $P > .05$) (Table 4). Sensitivity was minimal and no intervention was required. Sensitivity just before treatment was correlated with sensitivity during the first days after treatment ($r = 0.207$, $P = .04$).

The score for patient satisfaction regarding color was 8.5 for the direct technique and 8.8 for the indirect technique. This difference was not significant ($P > .05$).

Discussion

Based on our incidence study,[4] it was expected that a patient with a premolar with a cusp fracture would present daily to a clinician in the region of Nijmegen. Thus, our projection was that it would have taken 3 months to recruit the 94 patients for this study. Unfortunately, it took 2.5 years to recruit these patients, and this long intake period might have influenced the internal validity of the study. However, the decision to use only 2 operators insured proper control of the treatment protocols, so this was unlikely to affect the results.

Table 3 Presence of Proximal and Occlusal Contacts

	Restorative technique	
	Direct	Indirect
Proximal contacts (%)		
Mesial	98	97
Distal	100	100
Diastema (n)		
Mesial	2	5
Distal	2	3
Occlusal contacts (%)		
Static	94	98
Dynamic	83	96

Table 4 Pretreatment and Posttreatment Sensitivity (% of Patients)

	Restorative technique	
	Direct	Indirect
Pretreatment		
Before fracture	15	12
By intake	13	13
Posttreatment		
Within 1 wk	11	13
After 1 mo	4	6

From previous studies and clinical experience we assumed that resin composite using a direct technique is suitable to restore a fractured cusp of a maxillary premolar. The indirect restoration technique was included in the study because it was expected that this technique facilitates proper functional morphology, since the restoration is made extraorally. In this study, both techniques gave satisfactory results and met functional standards such as proper proximal contacts and good occlusion. There are several features that can help clinicians create a well-designed direct restoration. The use of a contoured metal matrix for the direct technique helps obtain a good contour, and the placement of separation rings results in tight proximal contacts.[20] Whereas in the past transparent matrices were advocated to transmit light, metal matrices have been proven to work equally as well.[21–23] An advantage of a metal matrix is the easier insertion when a proximal contact is still present. The use of separation rings prevents excess material at the margins and therefore reduces the time needed to finish the proximal contact areas.

In this study, rubber dam was not used. Clinical studies have shown that the use of rubber dam compared with proper isolation with cotton rolls does not have an effect on the long-term survival of restorations.[24,25]

It was hypothesized that the indirect technique would require more treatment time than the direct technique. Preparation time was comparable for both techniques, while the finishing procedure of the direct restoration took a little longer than that of the indirect restoration. However, adhesive cementation of the indirect restoration is a complex procedure that required almost as much time as fabrication of the restoration with the direct technique. A careful fitting and cementing procedure was important because the present type of preparation provides little macromechanical retention and resistance form. The longer time required for the indirect technique is caused by the time needed to make the impression and temporary restoration. The time needed to make the impression (13 ± 5 min) would have been longer with more preparation outlines below the gingival level. In this study, 6 of 52 restorations were sent back to the laboratory because of improper fit or color. The time needed for this extra session was not taken into account. The time required for the laboratory procedure was estimated at 90 minutes per restoration. Because both operators had limited experience with the indirect technique at the beginning of the clinical study, there was a learning curve, which resulted in a decreasing time needed for the treatment. Such an effect was seen only for the preparation procedure. This might be because the other phases, like impression taking and fitting of the restoration, are routine procedures that are comparable to the procedures used when making a full crown. For the direct technique, a learning curve for the time needed to accomplish the procedures was seen for all phases of treatment. This might be because the direct technique requires specific skills that even experienced operators continue learning.

One could expect that patients treated with the direct restoration would experience more postoperative sensitivity than patients treated with the indirect technique as a result of the stresses caused by polymerization shrinkage. However, for both techniques only 5% of the patients experienced postoperative sensitivity. It is possible that the previous restoration of the premolars caused sufficient deposition of reactionary dentin. For both techniques, preparation trauma was minimal and appeared to be well accepted by the pulp. Even with the indirect technique, when 1 cusp of a premolar is fractured and the existing restoration is removed, undercuts seldom remain. Thus, additional preparation can be minimal even for the indirect restorations. Furthermore, polymerization shrinkage of the direct restoration apparently had no effect on the postoperative sensitivity. This may be because of the favorable C-factor of the preparation geometry.[26] The direct restorations were made with Clearfil AP-X because of its strength and good handling properties. Clearfil AP-X is a heavily filled hybrid resin composite

with a barium-glass filler, which is less abrasive than current filler particles. Because of these fillers, the material is rather opaque and cannot be polished to a high gloss. Nevertheless, these restorations met the esthetic wishes of the patients. The indirect restorations were made with Estenia, which is also a heavily filled material with high esthetic performance. The material is designed to be used in indirect applications.

If a cost-effectiveness analysis is to be made, more details on production costs should be recorded. For example, patients had to visit the clinic twice to receive an indirect restoration. The longer treatment time and the higher production costs for the indirect technique argue in favor of the direct restoration. Effectiveness, of course, is determined primarily by the long-term clinical performance of the restorations, and differences between the techniques in this respect will influence the outcome of the analyses. Higher costs for the indirect technique are acceptable if the long-term survival rate is superior to that of the direct technique. The long-term performance of both restoration techniques will be reported in the future.

Conclusions

The direct and indirect cusp-replacing resin composite restorations provided comparable results for the adequate restoration of occlusal and proximal contacts, postoperative sensitivity, and color. Since the indirect technique requires additional (laboratory) costs and more treatment time, the direct technique is considered to be more cost effective in the short term.

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