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# Clinical performance and marginal adaptation of class II direct and semidirect composite restorations over 3.5 years in vivo

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#### **KEYWORDS**

Posterior composite; Class II restorations; Direct-semidirect techniques; Clinical trial; Marginal adaptation **Summary** *Objective*. The study evaluated the clinical performance and marginal adaptation of direct and semi-direct class II composite restorations in a split-mouth design over 3.5 years.

Design. 44 upper posterior teeth in 11 adults with primary carious lesions were treated with 22 direct and 22 semi-direct restorations. Conventional cavities were prepared for both types of restorations. A fine fine hybrid composite (APH) and a multifunctional adhesive system (Prisma universal bond 3) were used for all restorations. The incremental '3-sited light curing' technique was applied to direct restorations. Semi-direct inlays were prefabricated on silicone casts and post-cured using light and heat. Clinical performance was evaluated using modified USPHS parameters, while marginal adaptation was judged on replicas, using SEM and a standardized evaluation technique.

Results. Clinical results after 3.5 years revealed a 100% retention rate with no fractures, sensitivity or recurrent caries for both types of restorations. SEM-evaluation of the occlusal margins showed at the tooth-restoration interface relatively low rates of marginal openings over the observation period (4-8%). Marginal restoration fractures ranged between 1 and 2%, marginal tooth fractures between 3 and 9%. Differences between the restorative techniques and after the different time observation periods were not statistically significant. Proportions of marginal fractures and openings at the restoration-luting composite interface were less than 10% after 3.5 years.

Conclusion. The results indicated no significant differences for direct and semi-direct fine hybrid composite restorations in medium size cavities in posterior teeth with respect to clinical performance and marginal adaptation over 3.5 years. © 2005 Elsevier Ltd. All rights reserved.

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## Introduction

Tooth colored adhesive restorations have become the treatment of choice for posterior teeth due to improved bio-mechanical properties esthetics.<sup>1-3</sup> However, some drawbacks are still inherent to direct composite restorations, such as polymerization stresses induced during and after their insertion.<sup>4-7</sup> Optimal occlusal and approximal anatomy and defect-free margins are also difficult to obtain routinely especially in large cavities and areas difficult to access. Indirect restoration techniques overcome most of these problems. Actually, indirect class II inlays showed better marginal adaptation than direct composite restorations in vitro, before or following mechanical and thermal fatigue tests, especially when placed in critical configurations such as large cavities and proximal margins extending close to or below the cementoenamel junction. 2,8-10 With the indirect treatment option, however, two appointment and the fabrication of temporary restorations are necessary; treatment fees are therefore higher, especially with ceramic workpieces. A variation and simplification of laboratory made inlays are chairside indirect restorations produced by the dentist. These so-called semi-direct techniques have been introduced and developed in 1980s with the aim to substitute large amalgams with composite inlays or onlays. 2,11,12 Considerable long term results could be obtained with these techniques. 13-15 Until now, however, data on the in vivo behaviour with emphasis on the micromorphological characteristics of the restoration margins of direct and semidirect composite restorations when used in similar conditions are scarce.

Therefore, the purpose of this clinical trial was to evaluate the performance and marginal adaptation of direct and indirect chair side class II composite restorations over a 3.5 year period in a split mouth study.

## Material and methods

The study was designed as a longitudinal prospective clinical trial in a private office. Eleven patients (seven females, four males), aged between 18 and 27 years with good oral hygiene and periodontal health gave their informed consent. The restorations were placed over a 1 year treatment period by one operator according to a split mouth design. Criteria for tooth selection were: presence of antagonists, normal proximal contacts and primary carious lesions of about the same extension in two

**Table 1** Distribution of class II restorations under evaluation.

Type of restoration	Total	Direct	Semi-direct
Number of restored teeth	44	22	22
Premolars	30	15	15
Molars	14	7	7
MO/OD premolars	12	8	4
MOD premolars	18	7	11
MO/OD molars	10	6	4
MOD molars	4	1	3

contra-lateral teeth of the same upper jaw. A total number of 44 upper bicuspids and first molars were treated with direct and semi-direct class II restorations using the same fine hybrid composite resin and bonding agent (APH, Prisma Universal Bond 3; DeTrey-Dentsply, Milford, DE, USA). Tables 1 and 2 give an overview of the restoration distribution and applied materials, respectively. To be included into the study, the occlusal cavity extension following preparation for direct and indirect restorations had to be smaller than 2/3 of the inter-cuspal distance, estimated using a calibrated periodontal probe as a ruler. All restoration procedures were performed under rubber dam.

#### Direct restorations

Direct restorations were realized according to the three-sited light-curing technique<sup>16,17</sup> with slight modifications, using a selective bonding technique.<sup>18</sup> Cavity preparations and finishing

Table 2   Restorative materials.							
	Туре	Brand name	Manufac- turer				
Restorative material	Fine-hybrid composite	A.PH	DeTrey- Dentsply				
Bonding	Unfilled	Prisma	DeTrey-				
agent	DMA-based bonding agent, low viscosity	Universal Bond 3	Dentsply				
Luting agent	Light and chemically (dual) cured fine hybrid composite	Dicor MGC luting cement	DeTrey- Dentsply				
Base material	Glass- ionomer cement	Baseline	DeTrey- Dentsply				

were performed with cylindrical and round diamond burs (Cerinlay No 3080.018 FG and 3025.018 FG; Intensiv; Viganello, Switzerland) to obtain a conventional cavity design with rounded internal and external edges (Fig. 1(A): Appendix A). All cavity margins were located in enamel. A calcium hydroxide liner (Dycal, DeTrey-Dentsply) was placed locally on dentinal areas close to the pulp while the remaining dentine was covered with a glassionomer cement (Baseline, DeTrey-Dentsply) as a base material. The margins were finished and bevelled using fine diamond burs (Composhape No FG4205L, Intensiv). Enamel margins were etched with a 37% orthophosporic acid gel for 30 s, rinsed with water spray for 30 s and dried with oil-free air. The bonding agent (Prisma Universal Bond 3) was applied and blown out to a thin layer. A transparent matrix band and light transmitting wedges were then seated. The cavity filling started with the proximal part, following the aforementioned incremental technique. Each layer, 1 mm thick or less, was light-cured for 40 s with a halogen lamp (Optilux 500; Demetron-Kerr, Orange, CA, USA) (irradiance  $\sim 750 \text{ mW/cm}^2$ ). Finally, the entire restoration surface was covered with a glycerine gel (Airblock, DeTrey-Dentsply) before a last 20 s irradiation. Proximal restoration margins were finished with abrasive discs and strips (Pop-on XT finishing and polishing discs and finishing strips; 3M-Espe, St Paul, MN, USA). Occlusal margins were finished with fine (40  $\mu$ m) and extrafine (15  $\mu$ m) flame and pear shape diamonds burs (Intensiv Nos 4205L, 4255; Nos 5205L, 5255) and silicone points (Brownies and Greenies; Shofu, Menlo Park, CA, USA) under abundant water spray. After rubber dam removal, the occlusion was carefully checked and, where necessary, corrected with fine diamond burs and polished again with silicone points (Fig. 1(B): Appendix A).

#### Semidirect restorations

Cavities were prepared as indicated for direct restorations. Undercuts, whenever present, were eliminated by applying the same glass-ionomer cement (Baseline) (Fig. 2(A): Appendix A). The cavity walls were finished to a slightly divergent shape without bevelling. All margins were located in enamel. Then, a polyvinyl siloxane impression (President light and heavy bodies, Coltène Whaledent; Altstätten, Switzerland) was taken, isolated with a special separating liquid (APH inlay system, Dentsply Caulk) and immediately poured with the low viscosity and fast setting hard silicone material (Mass model; DeTrey-Dentsply). On this

cast, after separation of the die using a blade, the inlay was shaped in 2-3 layers of the restoration material and each layer was light-cured for 40 s with the halogen lamp (Optilux 500). Following try in, marginal fit and approximal contacts were adjusted, where necessary and the inlay was proceeded to postcuring using light and heat (D.I.500, Coltène Whaledent) for 7 min at 120 °C. The tooth was prepared for insertion of the semidirect restoration by selective enamel etching with 37% phosphoric acid for 30 s, water spray for 30 s and air drying with oil free air. The inlays were roughened with a diamond bur and coated with a thin layer of bonding agent which was left uncured. The same bonding agent was applied to the entire cavity surface, without light-curing, and the dual cure luting composite (Dicor MGC luting cement; DeTrey-Dentsply) injected in the cavity with a syringe (Centrix; Hawe-Neos Bioggio, Switzerland). The composite inlay was then inserted with gentle pressure until complete seating. The cement excesses were removed interproximally with a probe and waxed dental floss and, occlusally, with a probe and a dry brush. Light-curing was performed for 40 s on each surface. All surfaces were covered with a glycerine gel and light cured for another 20 s. Finishing and polishing procedures were performed as previously described (Fig. 2(B): Appendix A).

## Clinical follow-up

All restorations were evaluated clinically according to selected modified USPHS criteria<sup>19,20</sup> at baseline (14 days), 9 months and 3.5 years following insertion, by visual inspection using magnification loupes (4.5×; Carl Zeiss GmbH, Jena, Germany). Parameters assessed clinically were: post-operative sensitivity, restoration and cavosurface integrity with respect to fractures and cracks and presence of secondary caries. In addition to the clinical records used for the study, patients were recalled for regular dental check-ups once a year, including bite-wing radiographs.

#### SEM-evaluation of the marginal adaptation

Using a standardized replica technique<sup>21,22</sup> the restoration margins were analyzed semi-quantitatively in a SEM (XL 20, Philips, NL-5600 Eidhoven, NL) at 200× magnification. Replicas were taken 2 weeks after placement, after 9 months and after 3.5 years. The interproximal area was not considered in this analysis since the applied impression technique and the interproximal oro/facial extension of

the restorations did not allow for appropriate observation. The following quality parameters were assigned to the margins: excellent margin (EM), underfilled margin (UF), overfilled margin (OF), marginal opening (MO), marginal tooth fracture (MTF) and marginal restoration fracture (MRF). Occlusal margins free of imperfection together with areas showing overhangs or underfilled margins (but without gaps) represent the overall rate of continuous margin (CM). <sup>19,22,23</sup> Overhangs and underfilled marginal parts associated with discontinuity appeared as marginal openings. Likewise, marginal openings, marginal tooth and restoration fractures together were rated as discontinuous margins (DCM). <sup>19,23</sup>

The results were expressed as percentages of the total observable marginal length for each parameter. For technical reasons, the interface luting material-composite inlays was evaluated only following 3.5 years of clinical service. At baseline and at the 9 month recall, this part of the adhesive interface was not clearly distinguishable in the SEM.

## Statistical analysis

Statistical analysis was based on Mann-Whitney U, Friedmann and Wilcoxon-Wilcox tests. All tests were carried out at 95% confidence level.<sup>24</sup>

#### Results

## Clinical evaluation

Clinical results after 3.5 years revealed a 100% retention rate for direct and semi-direct

restorations, with all restorations available for all recall appointments. Clinically, the inlays performed satisfactorily up to 3.5 years, with no sensitivity, fractures or recurrent caries reported. Post operative sensitivity between 1 and 4 weeks had been reported for one direct and two indirect restorations. Wear facets were observed on only one indirect restoration.

#### **SEM results**

Results of the SEM-evaluation are presented in Table 3 and Figs. 1 and 2. Ratings for continuous margins at the tooth restoration interface ranged between 89 and 96% over the whole observation period. Proportions of marginal opening (from 4 to 8%), marginal tooth fractures (3-9%) and marginal restoration fractures (1-2%) therefore, remained low over this study duration. Differences between the two restorative options and the various observation periods regarding the aforementioned parameters were not statistically significant (p>0.05, Mann-Whitney U, Friedmann, Wilcoxon-Wilcox tests).

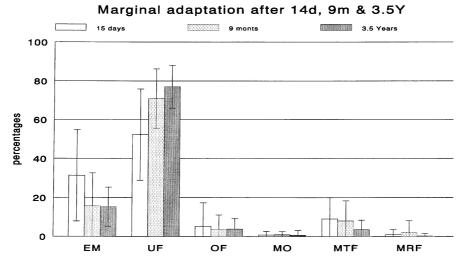
At baseline, proportions of underfilled margins were significantly higher in direct restorations than in indirect restorations (52% versus 22.4%; p < 0.05, Mann-Whitney U tests). Then, proportions of underfilled margins for both direct and indirect restorations increased significantly to proportions of about 77% (p < 0.05 Friedmann, Wilcoxon-Wilcox tests), as sign of clinical wear. For the same reason, insignificant decreases in marginal tooth and restoration fractures and marginal openings were observed.

The luting composite restoration interface at the 3.5 year evaluation showed above 99% of excellent adaptation.

**Table 3** Results of the marginal adaptation of direct and semi-direct restorations, at baseline (2 weeks) and 9 months and 3.5 years after placement (percentages ± SD standard deviation).

Recall period	CM (%)	EM (%)	UF (%)	OF (%)	DCM (%)	MO (%)	MTF (%)	MRF (%)
Direct restorations: interface tooth-restoration								
2 Weeks	89.2 (12.5)	31.4 (23.4)	52.3 (23.5)	0.7 (1.9)	10.8 (11.5)	5.3 (12.0)	9.0 (11.0)	0.9 (2.7)
9 Months	89.5 (12.2)	15.7 (16.8)	70.2 (15.4)	0.8 (1.7)	11.5 (11.7)	3.6 (7.4)	8.0 (10.3)	2.1 (6.0)
3.5 Years	95.9 (4.8)	15.3 (10.0)	77.0 (11.1)	0.6 (2.5)	4.1 (4.8)	3.8 (5.5)	3.4 (5.0)	0.3 (1.1)
Indirect restorations: interface tooth-restoration								
2 Weeks	90.6 (19.4)	59.8 (27.8)	22.4 (19.7)	1.1 (3.3)	9.4 (7.4)	8.3 (12.7)	3.2 (6.0)	1.1 (4.9)
9 Months	91.6 (9.0)	27.1 (25.4)	58.5 (23.7)	1.7 (4.3)	8.4 (8.9)	6.0 (8.7)	5.1 (7.7)	1.7 (4.5)
3.5 Years	96.2 (6.8)	14.4 (11.1)	76.6 (10.0)	1.2 (4.6)	3.8 (6.7)	5.0 (7.1)	2.7 (5.3)	0.0 (0.0)
Indirect restorations: interface luting composite-restoration								
3.5 Years	99.4 (2.0)	99.4 (2.0)	(0.0)	-	0.6	0.4	-	0.2 (0.6)

CM, continuous margin; EM, excellent margin; UF, underfilled margin; OF, overfilled margin; DCM, discontinuous margin; MO, marginal opening; MTF, marginal tooth fracture; MRF, marginal restoration fracture.



**Figure 1** Results of the marginal adaptation of direct restorations (percentages  $\pm$  SD).

## **Discussion**

## Restorative techniques

In direct composite restorations, initial contraction stress and post-cure polymerisation following placement, stresses the restoration bond to the cavity walls and margins. If adhesion is maintained, deformation of the tooth structure, the adhesive layer and restorative materials will occur. In unfavorable cavity configurations and with large composite volumes, polymerisation forces might develop too fast and reach values superior to the existing bond. As a result, adhesive or cohesive failures will develop close to or within the adhesive interface. 25-27 Incremental filling

techniques are attempts to overcome the development of these damaging polymerisation shrinkage stresses and maintain a satisfactory restoration adaptation, 16,17,28 mainly by optimising the configuration factor and reducing the thickness of each separate increment.<sup>25,27</sup> This multi-incremental restorative approach helps releasing stresses by favouring flow at the free surfaces and to obtain a more uniform light-curing energy distribution within the increments. 27,29 Using indirect techniques is another effective mean to limit polymerisation stresses by reducing the volume of composite to be cured in-situ to the sole cementing gap, improving restoration adaptation and seal. 11,12,30-33 Composite inlay techniques include also secondary cure of the restorative

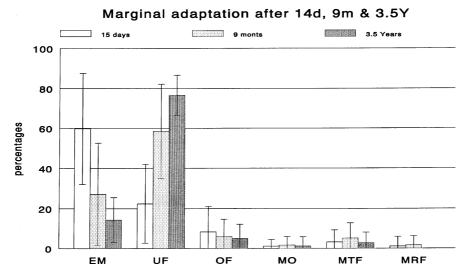


Figure 2 Results of the marginal adaptation of inlays, at the restoration-luting cement interface (percentages ± SD).

material to improve its conversion rate. This allows the initial polymerization contraction and the following post cure stress to occur before insertion. <sup>4,6</sup> Both aforementioned restorative techniques can therefore be considered appropriate for medium-size class II cavities, the indirect or semi-direct approach being theoretically more effective in maintaining low stress levels.

## Clinical follow-up

In the present study, no restoration failed or showed evidence of further failure, such as recurrent decay or fracture. Both direct and indirect restorations showed as well a good wear resistance. Clinically, secondary cure of the fine hybrid composite material provided no evidence of superiority with respect to wear resistance over direct polymerisation in situ, as evaluated using modified USPHS criteria. The absence of fractures and clinically detectable marginal degradation may be attributed on one hand to the medium size of the primary restorations evaluated in this study; such a configuration is more favourable than the one of secondary restorations replacing large and undermining amalgams. 34,35 The present excellent findings might be attributed as well to the clinical experience of the single operator and the strict respect of clinical procedures and usual rules for oral health maintenance. Beside the cavity extent and dimensions, the absence of existing structural defects such as fissures and wear facets, patient abnormal oral habits including parafunctions, and the ability to isolate the operative site with rubber dam represent further favourable conditions to the long term restoration interfacial integrity and clinical success. 36,37

Clinical studies have found that the annual failure rate of direct posterior composite restorations over several years (3-25 years) in classes I and II cavities is even slightly inferior to that of amalgam (2,2 and 3,3% median annual failure rate, respectively).<sup>38</sup> Regarding composite inlays, the analysis of several clinical studies has shown higher variations in the treatment success, but with a median annual failure slightly inferior to direct restorations (2,0 median annual failure rate).<sup>38</sup> Main reasons for failure of both direct and indirect methods reported in clinical studies were restoration and tooth fractures, secondary caries and pulpal complications. 14,15,39-48 None of these complications was observed in the present study. Differences in restoration quality assessment, materials tested, patient sampling and clinician ability, are variables in clinical trials contributing to large success rate deviations, leading sometimes to apparently conflicting conclusions. This points out the need for more accurate evaluation methods, such as the SEM evaluation of restoration margins which was used in the present study to implement the useful but less discriminative information provided by clinical observation. In addition, it was shown that the presence of defective margins in posterior composite restorations was correlated to higher failures rates. <sup>49</sup> This points out the relevance of marginal quality evaluation by precise means.

## Marginal adaptation evaluation

Dietschi and Holz<sup>23</sup> evaluated with scanning electron microscopy class I and II direct restorations made of different types of posterior composites following 2 years of clinical service, using a similar evaluation protocol. Proportions of discontinuous margins varied between 3 and 15% of the evaluable marginal length for the four tested materials; these values lie within the same ranges as to the present study. Another similar study reported data following 1 and 4 years of clinical service for class II fine hybrid composite restorations with interproximal areas in dentin and extended multisurface cavities; 50,51 mean proportions of continuous margins were over 90% initially, but dropped to around 65% after 4 years. These values were lower than the present study data, which could be attributed to the following reasons: longer clinical service time, large variety in cavity size, retreatment of classical undermining and extended amalgam restorations and interproximal margins frequently located in dentin.

With respect to the inlay restoration margins, clinical studies reported good quality of the marginal adaptation after short and long term service in vivo. 14,15,30,50,52 Wiedmer, Krejci and Lutz 13 found only 12% of marginal gap formation following 5 years, with inlays completely surrounded by enamel. These findings are in agreement with the present study, where mean proportions of margins free of gaps and marginal fractures were around 90% over the 3.5 year observation period at both luting cement-tooth and -restoration interfaces.

Only few studies compared intra-individually resin composite inlays to direct composite restorations. These clinical assessments showed overall no important differences between the techniques, as confirmed by the present investigation. These findings, however, are in

contrast to those of van Dijken et al.<sup>15</sup> who concluded after a 11 year clinical observation, that the major benefit of an inlay/onlay system was the improvement of marginal adaptation. The larger restoration size as well as other unfavourable patient's related conditions such as bruxism and high carie risk are certainly accounting for the superior performance of inlays/onlays in this particular study.

In the present study, marginal wear assessed as underfilled margins, was initially slightly higher for direct restorations, probably due to more aggressive finishing procedures. <sup>54</sup> Underfilled margins significantly increased over time to almost equivalent mean proportions for both direct and indirect restorations. Wear of the luting agent (ditching) known as a weakness of ceramic inlays was minimal here, with values within the same range as reported in previous studies. <sup>55,56</sup>

At the 9 month and 3.5 year evaluation, no significant difference in marginal adaptation was revealed between the two restorative methods. This suggests that a composite inlay has no clear advantage over a direct composite restoration for a medium size cavity, when a meticulous clinical protocol is applied. Due to the need for increased removal of sound tooth structure, the indirect approach should not be selected for convenience but only in the context of extensive single or serial restorations, when a large cavity volume and unfavourable configuration contra-indicates a direct technique. <sup>3,37,57</sup>

#### **Conclusions**

- Following 3.5 years of clinical service under similar conditions, the retention rate of 44 direct and semi-direct (inlay) fine hybrid composite restorations in two and three surface medium size class II cavities was 100%.
- According to modified USPHS parameters, the overall clinical performance of both restorative types was excellent, with no fractures, sensitivity or recurrent caries reported.
- 3. The micromorphological evaluation of restoration margins using SEM revealed low mean rates of discontinuous margins over the whole observation period, with statistically insignificant differences in marginal adaptation. This suggests that indirect or semidirect techniques should be selected mainly for extensive restorations.
- 4. The present findings further emphasize the relevance of clinical dental material testing

under maximally standardized conditions and meticulous evaluation of the restoration quality.

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# Supplementary material

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.jdent.2004.11.009

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