A 6-year evaluation of a direct composite resin inlay/onlay system and glass ionomer cement–composite resin sandwich restorations

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The most undesirable characteristic of composite resin is its polymerization shrinkage. Two techniques developed to counter this problem are the composite inlay and the sandwich composite filling. The durability of 100 direct composite inlays and 34 closed and 16 open sandwich composite fillings made with a conventional glass ionomer cement were evaluated during a 6-year period in a group of low and high caries risk patients. Modified USPHS criteria were used. Six inlays (6%), 5 closed sandwich fillings (14.7%), and 12 open sandwich fillings (75%) needed replacement. Six other inlays and three closed sandwich fillings showed non-acceptable defects that could be repaired with composite resin. The direct composite inlays showed very good clinical durability, whereas the open sandwich filling with conventional glass ionomer cement as dentin replacement cannot be advocated as a class-II restoration. □ *Clinical study; composite resin; glass ionomer cement*

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First introduced in the late 1960s as a possible replacement for amalgam, composite resins presented several problems, especially wear. Improvements in physical and mechanical properties and patient expectations of tooth-colored restorations increased their use in class-II cavities during the late eighties. Although recently developed composite resins are superior to the earlier versions and some products have gained full acceptance for use in posterior teeth, there are still problems related to both the placement technique and characteristics of the material itself (1–3). Owing to insufficient wear resistance many composite resins are not yet suitable for large posterior restorations involving heavy occlusal contacts. But the most undesirable characteristic of the resin is still its polymerization shrinkage (3). The bonding strength of the composite resin to acid-etched enamel is satisfactory, but in parts of the cavity with little or no enamel, polymerization contraction forces of the resin surpasses the bonding strength to dentin, and marginal gaps develop (1, 4). This facilitates microleakage, which can cause secondary caries, pulpal irritation, postoperative sensitivity, and marginal discoloration (4, 5).

Several clinical techniques have been introduced during the last few years to counter the sealing problem in class-II cavities. Among these are the replacement of dentinal tissue with a glass ionomer cement base in the so-called sandwich fillings, the use of dentin bonding agents, and the placement of the composite in multilayer condensation techniques (6–8). Most of these methods and materials are very technique-sensitive, resulting in poor marginal qualities when the techniques are simplified (9, 10). Conclusive clinical proofs are still lacking.

Another way to counter the polymerization contraction problem is the use of composite inlays/onlays (11–13). Here the major part of the polymerization contraction of the restoration takes place before cementation, and possible gap formation is only due to shrinkage of the thin layer of resin cement.

The fact that the polymerization shrinkage of the bulk of the material occurs before bonding to tooth structure implies that marginal adaptation can be improved by minimizing stresses on the enamel and dentin cavity walls (14). In addition, post-curing of the composite inlay material ensures efficient conversion in the whole composite resin restoration, and slightly to moderately improved mechanical and physical properties have been reported (15–20). In vitro studies showed that microleakage for inlay restorations is less than for direct composite restorations (21, 22). However, others failed to show significant difference in leakage between multilayer direct composite filling techniques and a composite inlay (23). Several direct and/or indirect inlay/onlay composite resin systems have been introduced during the past years. They can be classified on the basis of the type of composite and method of curing (24, 25). Short-term studies of composite resin inlays showed that inlays cemented with a resin luting agent are highly effective (11, 26–28). No long-term clinical evaluations of composite inlays have been reported. The purpose of this study was to evaluate the durability of a direct composite inlay system, using a small filler particle composite resin and post-curing of the restoration in a light- and heat-curing oven. In the same patient group a few closed and open sandwich fillings were also placed and evaluated simultaneously.

Materials and methods

Experimental teeth

In 40 patients, 24 men and 16 women, with a mean age of 48 years (range, 27–70 years), a total of 100 direct composite inlays/onlays and 50 composite sandwich fillings were placed. The inlays were distributed as follows: 42 2-surface and 26 3-surface inlays in premolars, 12 2-surface and 2 3-surface inlays in molars, and 14 onlays in premolars and 4 in molars. Of the inlays 38 were placed in the upper arch and 62 in the lower arch. Here inlays/onlays are referred to as inlays. All teeth were in occlusion and had at least one proximal contact with an adjacent tooth.

Inlay/onlay

The composite resin material used for production of the inlays (Brilliant DI, Coltène AG, Altstätten, Switzerland) is a hybrid small-particle composite resin with an average particle size of 1 μm. The resin containing barium glass has a filler load of 78.5% by weight. All restorations were replacements of class-II amalgam fillings because of secondary caries, fracture, or esthetic reasons. After removal of amalgam and caries, box-shaped inlay cavities were prepared with slightly conical cavity walls. The cavosurface margins were not beveled. Forty-eight per cent of the restorations had a proximal box from which the gingival margin extended apically below the cementoenamel junction. After a rubber dam had been placed and the cavity had been cleaned with a surface active cavity cleanser (Tubulicid blue, Dental Therapeutics Ltd, Ektorp, Sweden), a glass ionomer cement base (GC lining, GC Ind. Corp., Tokyo, Japan) was placed to eliminate undercuts and deep parts of the cavities. A transparent matrix band was placed on the tooth, and reflective wedges (Luciwedges, Hawe Neos Dental, Gentilino, Switzerland) or wooden wedges were inserted to ensure gingival adaptation and provide tooth separation. An agar/alcohol separating solution provided with the inlay system was applied to the prepared tooth. The composite was applied in increments followed by 40 sec of visible light-curing (Luxor, ICI Dental, Macclesfield, Cheshire, England). The inlay was then removed from the cavity and postcured in the DI-500 light- and heat-curing oven (Coltène AG) for 7 min at 120°C. During that time the glass ionomer base was prevented from dehydration by a slightly wet cotton pellet. After the inlay had been removed from the oven, it was tried in the preparation to verify the fit. In a few cases the axial walls of the inlay were slightly relieved. Acid etching of the enamel cavity margins for 15–20 sec with 37% phosphoric acid was followed by thorough spraying with water for 20–25 sec and air drying. A dual-cured enamel bonding agent (Brilliant Duo Bond) was then applied and thinned with a gentle stream of com-

Table 1. Criteria for direct clinical evaluation

Category	Score (acceptable/unacceptable)		Criteria
Anatomic form	0		The restoration is contiguous with tooth anatomy.
	1		Slightly under- or over-contoured restoration; marginal ridges slightly undercontoured; contact slightly open (may be self-correcting); occlusal height reduced locally.
		2	Restoration is undercontoured, dentin or base exposed; contact is faulty, not self-correcting; occlusal height reduced; occlusion affected.
		3	Restoration is missing or traumatic occlusion; restoration causes pain in tooth or adjacent tissue.
Marginal adaptation	0		Restoration is contiguous with existing anatomical form; explorer does not catch.
	1		Explorer catches; no crevice is visible into which explorer will penetrate.
	2		Crevice at margin; enamel exposed.
		3	Obvious crevice at margin; dentin or base exposed.
		4	Restoration mobile, fractured, or missing
Color match	0		Very good color match; restoration almost invisible.
	1		Good color match.
	2		Slight mismatch in color, shade, or translucency.
		3	Obvious mismatch, outside the normal range.
		4	Gross mismatch.
Marginal discoloration			
	0		No discoloration evident.
	1		Slight staining; can be polished away.
	2		Obvious staining; cannot be polished away.
		3	Gross staining.
Surface roughness	0		Smooth surface.
	1		Slightly rough or pitted.
	2		Rough; cannot be refinished.
		3	Surface deeply pitted; irregular grooves.
Caries	0		No evidence of caries contiguous with the margin of the restoration.
		1	Caries evident contiguous with the margin of the restoration.

pressed air and not light-cured. After reapplication of the matrix band and the wedges, the dual-cure luting composite (Brilliant Duo Cement) was applied to the cavity and/or the inside of the inlay with a disposable brush. The inlays were quickly inserted with pressure, and bulk excess composite was removed. The dual-cure composite luting agent is identical to the restorative except that it has a lower filler load. Light-curing periods of 60 sec were used from occlusal and proximal sides. Occlusion and articulation were carefully checked after the cementing step. The inlays were then finished with fine-particle finishing diamonds, carbide finishing burs, polishing stones, and polishing strips (Soflex, 3M, St Paul, Minn., USA).

Sandwich restorations

In addition, 50 composite fillings (Fulfil, De Trey/Dentsply, Konstanz, Germany) with a glass ionomer cement build-up (GC lining) were placed to compare the per-

Table 2. The 6-year evaluation scores of the test restorations (percentages). The evaluated variables, including non-acceptable scores, are given as cumulative frequencies. For the other variables, color match and marginal discoloration, all available scores at the 6-year recall are included

	Anatomic form			Marginal adaptation			Color match		Marginal discoloration		Surface roughness		Caries		
	Inlay	CS	OS	Inlay	CS	OS	Inlay	CS + OS	Inlay	CS + OS	Inlay	CS + OS	Inlay	CS	OS
n=	100	34	16	100	34	16	94	38	94	38	96	38	100	34	16
0	64.0	52.9	25.0	60.0	41.2	6.3	19.2	10.5	80.9	68.4	70.8	47.4	98	94.1	87.5
1	28.0	35.3	0.0	30.0	41.2	18.8	66.0	57.9	17.0	31.6	22.9	28.9	2	5.9	12.5
2	2.0	5.9	62.5	2.0	5.9	0.0	14.9	31.6	2.1	0.0	4.2	15.8			
3	6.0	5.9	12.5	2.0	5.9	62.5	0.0	0.0	0.0	0.0	2.1	7.9			
4				6.0	5.9	12.5	0.0	0.0							

CS = closed sandwich; OS = open sandwich.

formances of the composite inlays and direct composite fillings. Fulfil contains barium glass filler particles loaded to 78% by weight. The mean diameter of the glass is 3 μm. Two types of these so-called sandwich fillings were placed. In 16 of the fillings, all premolars, the glass ionomer base was placed in such a manner that the cement covered all the exposed dentin and extended to the periphery of the proximal box, to form the cervical seal (open sandwich), and in 34 fillings, 20 premolars and 14 molars, the cement was placed such that it covered all the exposed dentin but did not extend to the periphery of the cavity (closed sandwich). The glass ionomer cement was placed in a thickness of at least 1–2 mm, to form the cervical seal. The closed sandwich fillings were 18 2-surface and 16 3-surface restorations, and for the open sandwich fillings the numbers were 4 and 12, respectively. Enamel margins were etched for 15–20 sec, rinsed with water for 20–25 sec, and air-dried. A layer of enamel bonding agent (DeTrey/Dentsply) was applied before the composite resin was placed and cured in increments not exceeding 2 mm in thickness. Forty-second curing periods were used for each increment except for the first increments in the deepest parts of the proximal boxes, for which a 60-sec cure was applied. All restorations were placed by the author.

Evaluation

The restorations were evaluated 1–2 weeks after placement (base line) and every half year thereafter for 6 years. Each restoration was evaluated for the following characteristics: anatomic form, marginal adaptation, color matching, marginal staining, surface texture, and secondary caries. Criteria for evaluating the quality of the restorations, shown in Table 1, are a slight modification of the USPHS criteria as used in earlier studies (29, 30). Roentgenograms were taken for assessment of proximal marginal integrity and presence of recurrent caries. Color slides were taken for reference purposes at some of the evaluations. In addition to the clinical evaluations, alginate impressions were taken at base line, the 6-year evaluation, and some of the other recalls and poured in Velmix die stone. Occlusal wear was examined at ×15 magnification using a stereomicroscope (Nikon SMZ 1, Japan) to evaluate the occlusal surface for evidence of heavy localized wear and the enamel/inlay border for step formation and/or ditching.

Potential caries activity

To evaluate the secondary caries risk around the restorations, a prediction of the caries risk of each patient, expressed as the potential caries activity, was made. The caries prediction procedure has been used and described earlier (29, 30). The individual caries risk is estimated from the net effect of the patient's oral hygiene, intake of fermentable carbohydrates, salivary microbial counts, salivary flow rate, and buffer value. These factors were regarded as negative factors when certain values were exceeded. Oral hygiene was defined as a negative factor when a plaque score or gingival bleeding was observed on more than 30% of the tooth surfaces. Intake of fermentable carbohydrates with a mean of six times a day or more registered during 4 days was regarded as negative. The presence of more than 2.5×10^5 colony-forming units (CFU)/ml saliva of *Streptococcus mutans* or 10^5 CFU/ml saliva of lactobacilli was regarded as a negative factor, as was a buffer value of 5.5 or lower and a flow rate of 0.7 ml/min or less. For each individual a maximum of six negative factors could thus be obtained.

Statistical analysis

The small sample size of composite fillings in this clinical trial and the fact that the three experimental restorations evaluated were not placed in such a manner that an intra-individual comparison is possible prohibit estimation of statistical significance, and the evaluated characteristics of the test restorations are therefore described by descriptive statistics, using frequency distribution of the scores.

Results

All patients except one, who could only return at the 2- and 5-year recalls, were examined at all recalls during the 6-year evaluation period. Two teeth with composite inlays were extracted for periodontal reasons after 5 years. Table 2 shows the scores of the 6-year evaluations using the modified USPHS criteria, expressed as frequencies of restorations available at the 6-year recalls or as cumulative frequencies for the factors, which included non-acceptable restorations. The color match, marginal discoloration, and surface roughness scores for the four open sandwich restorations at the 6-year recall were equal with and therefore given combined with the scores for the closed sandwich fillings. The cumulative relative frequencies (percentages) of the non-acceptable restorations during the 6-year period are given in Fig. 1 and Table 3. The acceptable inlays showed only slight changes in the scores for the evaluated criteria during the study. The numbers of restorations with unchanged or, in a few cases, better scores at the end of the study compared to the baseline registrations are shown in Table 4. The better scores were in most cases caused by operative corrections and in other cases possibly by drift of the evaluator.

Twelve inlays (12%), 8 closed sandwich fillings (23.5%), and 12 open sandwich fillings (75%) were registered as non-acceptable during the evaluation period (Tables 2 and 3). Of these restorations 6 inlays (6%), 5 closed sandwich fillings (14.7%), and all 12 open sandwich fillings (75%) needed replacement, whereas the other restorations with smaller defects could easily be repaired with composite resin. The inlays were replaced because of partial fracture (4%) or total loss (2%), whereas the repaired inlays showed small occlusal defects (2%) or smaller chip fractures (2%) and superficially secondary caries (2%). The five failed closed sandwich fillings were replaced because of isthmus and cusp fracture (5.9%) and secondary caries (8.8%), whereas the repaired fillings consisted of occlusal pores or small chip fractures (8.8%). All the failed open sandwich fillings showed progressive loss of glass ionomer cement, resulting in cervical gap formation, which was combined in two fillings with a composite fracture (12.5%) and in two other fillings with secondary caries (12.5%). The potential caries risk evaluation of the individual patients, expressed as number of negative factors, showed that 18 patients (45%) had 3 or more negative factors and were considered high caries risk patients (30). The secondary caries registered occurred in high caries risk patients except in one, who had progressive loss of cement in an open sandwich.

Post-operative sensitivity to masticatory forces was registered for two open-sandwich and three closed-sandwich fillings during the first weeks after placement. One composite inlay patient complained about a lower degree of sensitivity to masticatory forces for

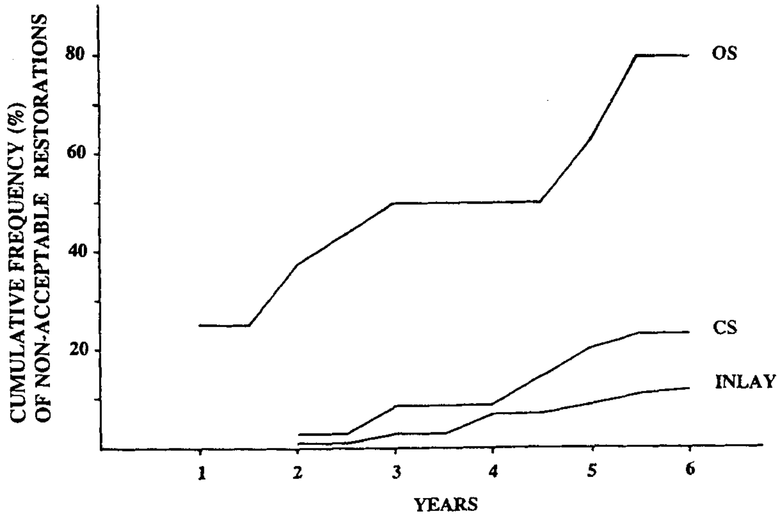

Fig. 1. Cumulative relative frequencies (percentages) of non-acceptable restorations during the 6-year period. OS = open sandwich; CS = closed sandwich (for description, see Materials and methods).

Table 3. Non-acceptable restorations (percentage) replaced in case of large defects or repaired with composite resin in case of smaller defects

	No.	Replaced	Repaired
Direct composite inlay	100	6.0	6.0
Closed sandwich fillings	34	14.7	8.8
Open sandwich fillings	16	75.0	0.0

2 years. The wear of the inlays, assessed by examination of stone replicas of the 6-year recalls at ×15 magnification, using a stereomicroscope (Nikon SMZ 1), generally showed only very small, mostly not clinically registered, wear steps between the enamel and the inlay material, indicating that the wear of the inlay material and the luting material is rather equal and that the wear of the inlay material was not a clinical problem during the period of evaluation. SEM observations of marginal adaptation of the inlays are evaluated in another ongoing study. All the fractures observed in the inlay and closed sandwich filling group were found in patients with severe parafunctional habits (bruxism).

Discussion

The composite inlay technique is an attempt to overcome some of the disadvantages of the direct composite filling. The major reason is to reduce polymerization shrinkage with subsequent secondary caries risk and postoperative sensitivity by improving marginal adaptation (25). Shrinkage of the inlay

Table 4. Frequency of restorations showing unchanged and, in a few cases, better scores at the 6-year recalls compared with the base-line scores (percentage). Inlays are compared with both composite sandwich fillings

	Anatomic form	Marginal adaptation	Color match	Marginal discoloration	Surface roughness
Inlay	70	68	82	84	74
Sandwich fillings	48	32	48	68	56

occurs before cementing, and the only clinical important shrinkage will occur in the thin cement layer. Feilzer et al. (31, 32) suggested that the C-factor in the thin cement layers will be extremely large and that the contraction equals the polymerization shrinkage in light-cured systems. Peutzfeld & Asmussen (33), on the other hand, showed in vitro that the increased wall-to-wall polymerization did not seem to be a problem.

Reinhardt & Smolka (34) showed superior marginal adaptation of inlays in occlusal cavities, and in two other clinical studies (13, 35) a very good adaptation of composite inlays was seen after 6 months and 1 year, respectively. The latter investigators estimated the longevity to be 3–5 years. In this study 90% of the inlays showed an acceptable marginal adaptation after 6 years. Even after 6 years almost no clinical signs of ditching were observed. Ditching of the resin luting agent has been reported in a 3-year evaluation of ceramic inlays (29). The luting agent used here is a dilution of the inlay composite resin, which has almost the same abrasion resistance as the inlay itself. The ceramic inlay, on the other hand, has a better wear resistance than the luting resin. The resin will therefore wear, especially occlusally, much faster then the ceramic material. Earlier suggestions that the resin luting agent is the weakest link in the adhesively luted tooth colored inlay was not confirmed in this study.

Only slight marginal discoloration was seen, and secondary caries was only found around 2% of the inlays even though almost half of the patients were considered to be high caries risk patients. In an earlier longitudinal 6-year follow-up of anterior composite fillings, in a group of patients with lower caries risk, a higher secondary caries activity was found (30). The patients in these two studies received the same type of dental care and individually adapted prophylaxis. The low secondary caries frequency around the inlays, which has also been shown in other clinical 2-year follow-up studies (28, 36), can be due for a large part to the good marginal adaptation of the inlays.

Pallesen & Qvist (36) found replacement frequencies of 3.6% and 2.1% for composite fillings and indirect composite inlays, respectively, after 2 years. The replacement rates in this study are slightly higher, but the same relation between fillings and inlays was found. Although the small number of composite fillings included in this study does not permit estimation of statistical significance, it is clearly shown that the inlay is the restoration with the clinically longest durability, followed by the closed sandwich filling in second place. The high failure rate in the open sandwich composite filling group confirms the findings of two earlier studies (37, 38) concluding that this type of filling cannot be advocated in general as a class-II restoration. Several reasons for its failure can be mentioned. In the open sandwich the cement is initially very susceptible to early moisture contamination, which can increase dissolution. Moreover, the exposure to longer acid clearance times in the proximal space compared with, for example, buccal fillings, will cause a higher erosion rate of the surface material. The lining cement used, in most cases mixed at a low powder to liquid ratio, lacks strength. The cement will be stressed continuously by the masticatory forces, which are transferred via the composite filling. This stress probably results first in crack formation at the composite cement interface and later in fractures of the cement. The use of the newer resin-modified glass ionomer cements, which have greater tensile strength and are less moisture-sensitive, can possibly result in better longevity of the open sandwich restoration. These kinds of sandwich restoration are now under investigation in our clinic.

The use of two different composite resins for the inlays and the direct fillings may partially explain the differences in quality of the restoration techniques. However, the direct filling composite Fulfil, showing a higher failure rate than the inlays in this study, is one of the few composite resins that was found clinically acceptable by the ADA criteria, a guarantee for the materials properties. The extra-oral post-curing of the composite inlay was introduced to enhance the physical and mechanical properties of the composite resin. The heat cure also improves the marginal adaptation, probably by means of relaxation of residual material stress (39, 40). De Gee et al. (41) showed that application of the DI-500 oven significantly improved the wear resistance of 11 composites studied, resulting in 20%–60% improvement after the first 5 days. However, when the wear rates were followed up over longer periods, the difference from non-heat-treated samples appeared to decrease with time. Wendt & Leinfelder (39) found no difference in wear resistance between non-heat- and heat-treated inlays after a 3-year evaluation. Wear of the inlays in this study, evaluated clinically with the USPHS system and microscopically on the 6-year stone replica models, showed that the long-time wear is low in most patients and clinically acceptable. In some patients with severe bruxism local occlusal defects were registered. This is in accordance with findings in other studies showing that most of the wear of composite restorations occur during the first 6 to 12 months and diminishes during the following years.

Cusp fractures, one of the main reasons for initial failures of class-II amalgam fillings (42), were registered for one closed sandwich filling in this study. The tooth fracture mechanism in the direct filling technique is in most cases related to fatigue caused by the outward flexure and return of the cusp from the stressed deformation state to its original state. Lopes et al. (14) showed that composite inlays recover from tooth stiffness even in large MOD preparations to an extent not significantly different from that of the non-restored tooth up to occlusal forces of more than 100 N. Instead of tooth fracture, material fatigue of the composite restorations will lead to traditional isthmus fractures and cohesive chip fractures.

The inlay system investigated did not include a dentin bonding agent at the start of this study. During the past years studies have shown that treatment with an effective dentin bonding agent increased the retention of composite fillings and inlays (36, 43, 44). Today's dentin bonding agents are more effective than the earliest versions, and the use of dentin adhesives in combination with composite inlays might be advisable (7, 43). The agent might be more effective than in direct composite fillings, due to lesser shrinkage stress of the inlay system, which is only produced in the luting agent layer. Haller et al. (45) showed in vitro that the use of effective dentin bonding agents in combination with post-cured composite inlays gave the greatest number of restorations without marginal leakage.

In conclusion, the composite inlay technique showed good durability, and the technique offers several advantages over presently used restorative techniques.

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