



Evidence-based concepts and procedures for bonded inlays and onlays. Part III. A case series with long-term clinical results and follow-up

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Abstract

This third article in this series (Part III) aims to present new clinical results and long-term follow-up of resin composite inlays and onlays using the modern clinical concepts presented in the Part I and Part II articles. These revised protocols have contributed to eliminating the most frequent difficulties related to the preparation, isolation, impression taking, and cementation of tooth-colored inlays and onlays. This clinical report presents a series of 25 cases of indirect or semidirect inlays and onlays (intra- and extraoral techniques) made of microhybrid and nanohybrid composites with 6- to 21-year follow-ups. The restoration performance was assessed through clinical examination, intraoral radiographs, and clinical photographs. The overall clinical assessment aimed to confirm the absence (success) or presence (failure) of decay or restor-

ation fracture, while the restoration quality was judged on intraoral photographs. The restoration status with regard to margins, anatomy, and color was assessed using three quality scores (A = ideal, B = satisfactory, C = insufficient). Descriptive statistics were used to evaluate the possible impact of composite structure (microhybrid or nanohybrid) or observation time on restoration quality. Over this medium- to long-term observation period, no clinical failure was reported. Only a few restorations (mainly those made of conventional inhomogeneous nanohybrid) presented discrete marginal discoloration ($n = 4$) or occlusal anatomy change due to wear ($n = 7$). This first clinical survey with long-term follow-up supports the application of the aforementioned clinical concepts, which thus far have only been validated by *in vitro* studies.

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Introduction

The first and second parts of this article series^{1,2} described the indications, advantages, and detailed clinical procedures for the fabrication of tooth-colored inlays and onlays, applying revised, optimized clinical and biomechanical concepts. The most relevant improvements brought to the overall treatment approach were immediate, post-preparation dentin sealing (known as dual bonding [DB] or immediate dentin sealing [IDS]),³⁻⁵ filling of all undercuts by composite (cavity design optimization [CDO]),⁴ and a simultaneous coronal margin displacement in cases of deep cervical preparations (cervical margin relocation [CMR] or deep margin elevation [DME]).^{4,6} Together, these procedures limit unnecessary tooth preparation and tissue removal to create the required tapered geometry of indirect posterior restorations. Also, the immediately formed adhesive liner base protects the pulp-dentinal structures from any contamination or physicochemical disturbance during the temporary phase^{7,8} as well as stabilizing and improving the adhesive interface quality.⁹⁻¹¹ Furthermore, this overall updated clinical protocol allows for the safe use of non-cemented temporary restorations and facilitates restoration fabrication, thanks to a more even cavity design. Finally, the use of a highly filled, light-curing restorative material (instead of a dual-curing composite cement) eases the luting procedures through extended working time, while limiting interfacial wear around the occlusal margins.¹²⁻¹⁵ The aforementioned concepts, embracing the most recent material and technology developments, have fundamentally changed the authors' clinical approach and procedures for indirect partial posterior restorations (inlays and onlays). The suggested procedures also help the practitioner to eliminate the most frequent difficulties related to the preparation, isolation, impres-

sion taking, and cementation of tooth-colored inlays and onlays, while preventing complications such as discomfort during the interim phase and postoperative sensitivity.

There is very strong *in vitro* evidence to confirm the restoration quality of inlays and onlays placed following the aforementioned concepts, in particular regarding marginal and internal adaption rates that are comparable or superior to non-lined cavities.^{16,17} The aforementioned *in vitro* tests replicating moisture, thermal, and functional stresses are, to date, the best available predictors for the clinical performance of this new clinical approach, owing to the quality, quantity, and consistency of the results and evidence.¹⁸

This protocol has been widely used following the publication of several reports describing its detailed clinical application,^{4,6,19,20} although no randomized prospective clinical study has yet been published to confirm the true success or failure rates of restorations made using this specific technique. Therefore, this Part III of the article series presents a retrospective case series with long-term clinical follow-up as a first attempt to provide evidence regarding the clinical success of indirect composite restorations placed with contemporary clinical protocols.

Material and methods

Sixteen patients were included in this retrospective clinical survey. The patients had between one and three teeth being treated with composite inlays and onlays; a total of 25 restorations were placed between 1994 and 2009 with follow-up periods ranging from 6 to 21 years (Table 1). The restorations were placed by two experienced operators under rubber dam isolation and following the specific adhesive protocol described below (Fig 1). The patients did not undergo



Fig 1. 14- and 21-year follow-up of two direct composite inlays (semidirect extraoral technique) with the CMR and CDO concepts.





Table 1 Case series data and clinical findings (cases presented according to year of placement)

Patient no.	Restoration no.	Restorations	Product (composite type*)
1	1	Onlay SDIO 15 MOD	Tetric (MH) ¹
2	2	Inlay SDEO 26 MOD	Tetric (MH) ¹
3	3	Inlay SDEO 14 OD	Tetric (MH) ¹
3	4	Inlay SDEO 15 MO	Tetric (MH) ¹
4	5	Inlay SDEO 16 MOD	Miris (MH) ²
4	6	Inlay SDEO 15 MOD	Miris (MH) ²
5	7	Inlay IND 24 OD	Belleglass (MH) ³
5	8	Inlay IND 25 MOD	Belleglass (MH) ³
6	9	Onlay SDEO 36 MODV	Belleglass (MH) ³
5	10	Inlay IND 26 MOD	Tetric (MH) ¹
6	11	Overlay IND 36	Belleglass (MH) ³
7	12	Inlay SDEO 25 MOD	TPH (MH) ⁴
7	13	Overlay SDIO	Miris (MH) ²
4	14	Onlay SDIO 36 MOV	Miris (MH) ²
9	15	Onlay SDEO 15MODV	Miris (MH) ²
10	16	Inlay SDIO 16 MOD	Miris (MH) ²
11	17	Overlay SDIO 46 ODV	Miris 2 (INH) ²
12	18	Overlay SDIO 25	Miris 2 (INH) ²
13	19	Onlay SDIO 46 MODL	Miris 2 (INH) ²
14	20	Onlay IND 27 MODV	Miris 2 (INH) ²
14	21	Inlay IND MOD 26 MOD	Miris 2 (INH) ²
14	22	Inlay IND MOD 25 MOD	Miris 2 (INH) ²
15	23	Onlay SDIO 26 ODV	Miris 2 (INH) ²
16	24	Onlay IND 16 MODV	Miris 2 (INH) ²
16	25	Onlay IND 17 MODP	Miris 2 (INH) ²

¹ = Ivoclar Vivadent, ² = Coltene Whaledent, ³ = Kerr, ⁴ = Dentsply
 MH = microhybrid composite; INH = inhomogeneous microhybrid; SD = semidirect (chairside procedure);
 IO = intraoral; EO = extraoral; IND = indirect; IDS = immediate dentin sealing; CDO = cavity design optimization;
 CMR = cervical margin relocation
 Scores: A = ideal, B = satisfactory, C = insufficient

any specific selection process other than being part of a recall system, including yearly or biyearly clinical and radiographic examination, and otherwise not presenting any severe, active carious and parafunctional pathologies.

The treatment rationale applied to all the restorations relied on distinctive basic procedures: the immediate, postpreparation placement of an adhesive base liner in the form of a dentin coating using a thick layer of dentin bonding agent, preferably a filled



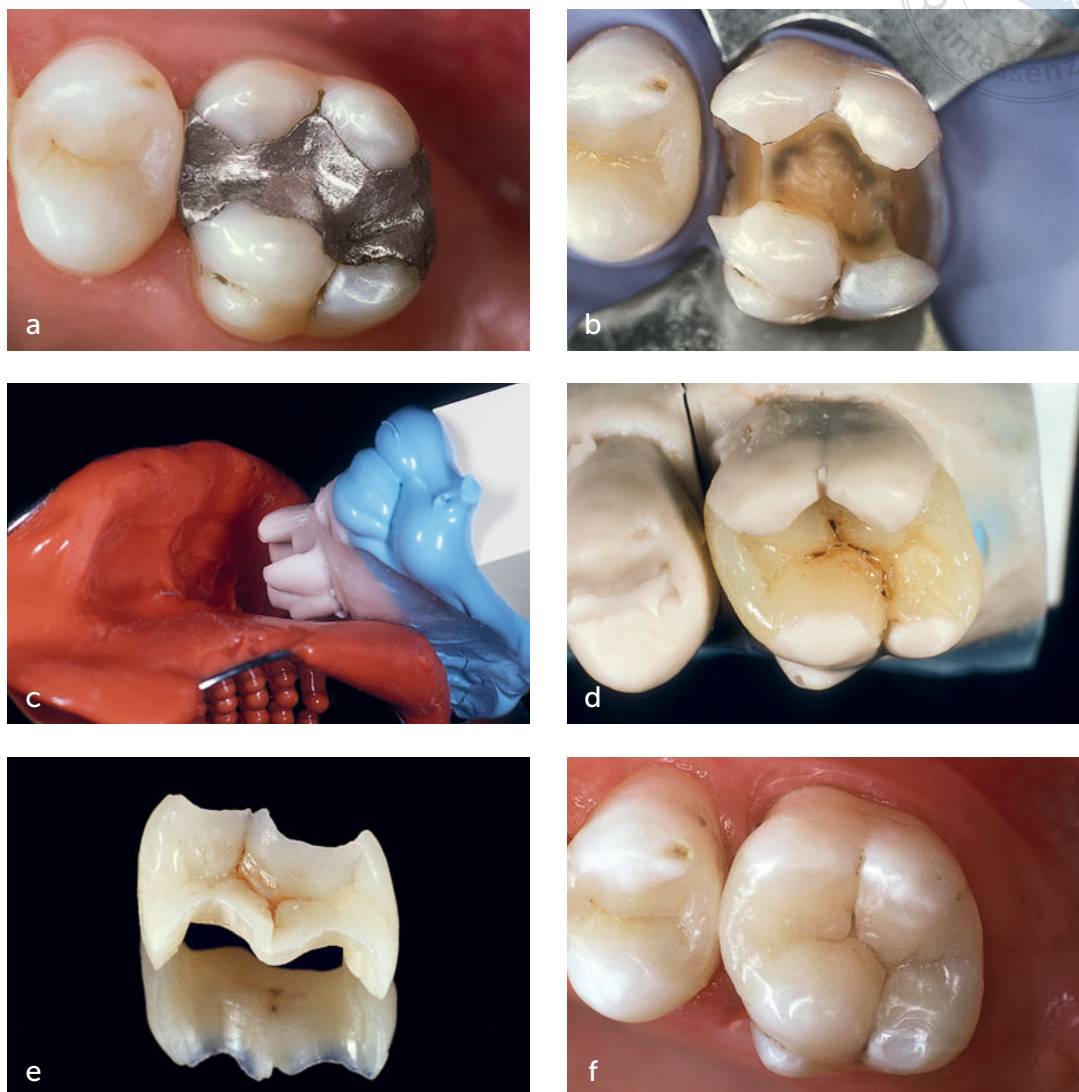
Adhesive preparation			Placement year	Follow-up in years	Restoration quality		
IDS	CDO	CMR			Margins	Anatomy	Color
✓	-	-	1994	15	A	A	A
✓	✓	-	1995	19	A	A	A
✓	✓	✓	1996	21	A	A	A
✓	✓	✓	1996	21	A	A	A
✓	-	-	1999	17	A	A	A
✓	-	-	1999	17	A	A	A
✓	✓	✓	1999	17	B	A	A
✓	✓	-	1999	17	B	A	A
✓	✓	✓	1999	18	A	A	A
✓	✓	-	2000	16	B	A	A
✓	✓	-	2000	16	A	A	A
✓	✓	-	2001	13	A	A	A
✓	✓	-	2001	13	A	A	A
✓	✓	-	2003	13	A	A	A
✓	✓	-	2003	14	A	A	A
✓	✓	-	2003	13	A	A	A
			2005	11	B	B	A
✓	✓	-	2005	11	A	B	A
✓	✓	✓	2005	9	A	B	A
✓	✓	✓	2005	14	B	B	A
✓	✓	✓	2005	14	B	B	A
✓	✓	✓	2005	14	B	B	A
✓	✓	-	2005	11	A	B	A
✓	✓	✓	2009	6	A	A	A
✓	✓	✓	2009	6	A	A	A

one, on its own for thin restorations (dual bonding [DB]/immediate dentin sealing [IDS])³⁻⁵ or usually combined with a restorative or flowable composite layer leveling all cavity irregularities and undercuts (altogether known as cavity design optimiza-

tion [CDO]),⁴ and, when necessary, the simultaneous coronal relocation of deep cervical margins (cervical margin relocation [CMR]).^{4,6} Overall, the resulting preparations present an ideal geometry with slight divergence of all cavity walls and supragingival



Fig 2 Clinical workflow for semi-direct extraoral technique (chairside method). This case appears as no. 4 in Table 1, with a 19-year follow-up. (a) Preoperative view showing a large amalgam to be replaced. (b) Preparation with CDO performed with a multicomponent adhesive and flowable composite. (c) Chairside model fabricated using hard, dual-viscosity silicone materials (Mach-2 and Blu-Mousse, Parkell); a condensation silicone or alginate is used for the impression. (d) The restoration is built up in composite using a dentin shade of adequate chroma, effect shade, and enamel shade. (e) Completed restoration using a microhybrid resin composite. (f) Post-adhesive cementation.



margins. After tooth preparation following the aforementioned procedures, the composite inlays or onlays were produced using one of three methods:

1. The semidirect extraoral technique (Fig 2), which makes use of a dual-viscosity, hard, A-silicone model (ie, Mach-2 and Blu-Mousse, Parkell) on which the restoration is fabricated. The impression is preferably done with an alginate or a soft-consistency C-silicone (ie, Speedex Medium; Coltène Whaledent). The restoration fabrication starts with the dentin core and is then completed proximally

and occlusally using a few more enamel increments, as needed.

2. The semidirect intraoral technique (Fig 3) which allows for the build-up of the restoration directly on the tooth following effective, physical cavity isolation from the IDS layer and composite base, using, for instance, a thin layer of liquid latex (Rubber Sep; Kerr). After application, the isolation material is gently dried until it becomes transparent. A full-contoured matrix (ie, Lucifix; Kerr) is then placed around the tooth to allow for the placement and polymerization of the com-



Fig 3 Restoration fabrication method for semidirect intraoral technique (chairside method). This case appears as no. 18 in Table 1, with a 9-year follow-up. (a) Preoperative view showing large amalgams to be replaced on teeth 36 and 37. (b) Preparation with CDO and CMR performed with a multicomponent adhesive and flowable composite. Tooth 37 is restored with a direct technique. (c) The cavity is then isolated with a latex varnish (Rubber Sep; Kerr), which allows work on the tooth as a laboratory die. (d) The restoration is built up directly on the tooth using a normal posterior matrix. (e) Restoration fabricated with dentin and enamel composite shades, ready for cementation. (f) Post-adhesive cementation.

posite in just a few layers (usually one or two enamel increments for the proximal and buccolingual walls, one dentin increment for the central volume, and a final occlusal enamel layer). After completion of its overall anatomy, the restoration can be taken out of the mouth for the final adjustments of margins and proximal contacts. Due to the potential difficulty of removing the restoration, only onlays with a minimal cavity divergence of 10 degrees were produced with this technique. As the restoration might remain locked into the cavity due

to composite polymerization contraction, this technique is contraindicated for deep mesiodistal cavities.

3. The indirect technique (Fig 4) for which restorations were produced in the laboratory, directly on isolated stone dies with the same combination and sequence of dentin and enamel increments as described for the semidirect extraoral technique, with either a restorative or laboratory composite.

The composites used with the aforementioned fabrication procedures were either

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Fig 4 Clinical workflow for indirect technique. This case appears as nos. 20 to 22 in Table 1, with a 14-year follow-up. (a) Preoperative view showing large amalgams to be replaced. (b) Preparations with CDO and CMR performed with a multicomponent adhesive and flowable composite. (c) Laboratory made composite restorations on the hard stone model. (d) Trial of the restorations fabricated with a nanohybrid (inhomogenous type). (e) Post-adhesive cementation.



microhybrid – Tetric (Ivoclar Vivadent), Belleglass (Kerr), Miris (Coltène Whaledent), and TPH (Dentsply) or nanohybrid (Miris 2; Coltène Whaledent) resin composites. The Belleglass system was the only laboratory composite system that involved a special dual-polymerization method (light- and heat-curing initiation) and nitrogen pressure for complete resin conversion using a specific curing oven.

Apart from the Belleglass system, all other composites were polymerized, first using a conventional halogen light-curing unit (470 nm at > 750mW/cm², each increment

being cured for a minimum of 20 s), followed by a heat (110°C) and light postcuring treatment in a specific oven (DI-500; Coltène Whaledent). A highly filled, light-curing restorative material was used as a luting agent (usually the same enamel as the one used to fabricate the surface of the restoration for semidirect restorations); otherwise, a translucent shade of a microhybrid resin composite was used (ie, Tetric Transparent). The viscosity of the luting material was reduced by sonic/ultrasonic energy using a specific application tip (with plastic insert) – SONICflex cem (KaVo) or Sonocem Tip



(EMS), and/or material heating (55°C) (ie, Calset; AdDent) to ease the complete restoration insertion.

The evaluation was performed on radiographs for the presence or absence of proximal decays, clinical examination for the presence of occlusal decays or fractures, and intraoral photographs for the other quality parameters. Three parameters (margin, anatomy, and color match) were used to assess the restoration quality after any given observation period, with three possible scores: A = ideal, B = satisfactory, and C = insufficient. For instance, for the margin parameter, a B score meant a discrete, partial discoloration and/or irregularity, while a C score meant noticeable, extended discoloration or irregularity. In the case of recurrent decay, restoration fracture or a C score, the restoration would be considered a failure, which would necessitate retreatment. Otherwise, any restoration showing no decay or fracture and with an A or B score was deemed a success, with possible minor interventions necessary (such as repolishing or, in a worst case scenario, localized repair). This clinical assessment method is similar to the modified United States Public Health Service (USPHS) ranking method.²⁰⁻²² The quality assessment was crosschecked by both operators. Due to data heterogeneity and the limited number of cases, no specific statistical test/s other than clinical, technical, and qualitative descriptions could be carried out. The results are presented in Table 1.

Results

Table 1 details the technical and clinical characteristics and quality of the 25 restorations, surveyed according to the aforementioned criteria, following periods of service from 6 to 21 years. Three cases had a follow-up observation period of < 10 years, 19 cases of between 10 and 20 years, and

two cases of > 20 years. Figure 5 presents the clinical overview of all the restorations, with pre- and postoperative views (at treatment completion and at the specific evaluation period); a radiograph after the final evaluation period completes this documentation.

None of the restorations observed showed recurrent decay or fractures; no restored tooth surveyed underwent any pulpal complication or required any endodontic treatment. Among the 16 semidirect and indirect restorations fabricated with microhybrid resin composites (Tetric, Belleglass, Miris, and TPH), only three restorations presented a slight marginal discoloration and degradation (B score); all the other restorations were considered optimal (A score) for the three evaluated parameters (margin, anatomy, and color match). Among the nine semidirect or indirect restorations fabricated with an inhomogeneous nanohybrid (Miris 2), four restorations presented a slight marginal discoloration and degradation, and seven presented discrete anatomical surface change. The analysis (shown in Tables 2 and 3; distribution of scores A and B) did not suggest any impact of the follow-up time on the restoration quality, except for a slightly better clinical behavior of classical microhybrids (Tetric, Belleglass, TPH) compared with the nanohybrid (Miris 2). No other discriminative judgments could be made with the limited number of cases reviewed.

Discussion and conclusions

The revised protocol presented in the Part I and II articles in this series has been used widely due to its endorsement by numerous clinicians following published case reports detailing its clinical application.^{4,6,19,20} There is, however, as yet no published clinical data evaluating the impact of this technique on the success rate and longevity of bonded inlays and onlays, apart from a 1-year study



Fig 5 Clinical overview of the case series. The left column shows restorations at $t = 0$, the middle and right columns show the radiographic and clinical findings at the indicated follow-up periods (see Table 1 for detailed clinical data and assessments). Case nos. 7, 8, and 10 are presented at 6 years in the left column, instead of $t = 0$.





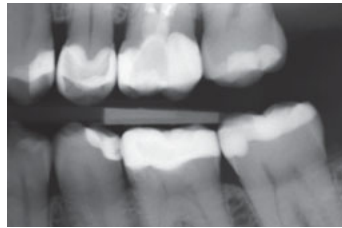
Case 11



16Y



Case 12



13Y



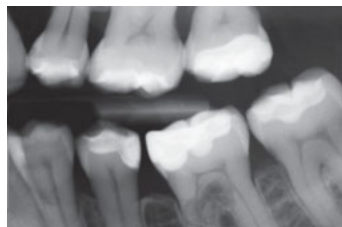
Case 13



13Y



Case 14



13Y



Case 15



14Y



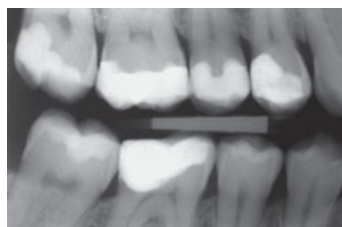
Case 16



13Y



Case 17



13Y



Fig 5 cont.



investigating the periodontal status of restorations placed with the CMR technique,²³ which showed a slight increase in bleeding on probing (BoP) as the only adverse effect.. This is partly due to the fact that well-structured, randomized, prospective studies are extremely demanding, and also because the many confounding factors of *in vivo* trials impact their discriminative power (the effort needed to evaluate only procedural

changes may thus not be justified). Therefore, owing to the quality, quantity, and consistency of the results and evidence¹⁶⁻¹⁸ of rigorous *in vitro* trials (and combinations of them), these trials are often the most adequate performance predictors for new restorative protocols while ultimate confirmation is awaited from clinical studies.

This case series demonstrated the high success rate of composite inlays and onlays

Composite	Margin quality			Anatomy			Color		
	A	B	Total	A	B	Total	A	B	Total
Belleglass (MH)	2	2	4	4		4	4		4
Miris (MH)	6		6	6		6	6		6
Miris 2 (INH)	5	4	9	2	7	9	9		9
TPH (MH)	1		1	1		1	1		1
Tetric (MH)	4	1	5	5		5	5		5
Total	18	7	25	18	7	25	25	0	25

Table 2 Summary of restoration quality assessment per product (the number for each score indicates the number of samples per designated product)

NB: Note that no restoration exhibited a C score.

Follow-up in years	Margin quality			Anatomy			Color		
	A	B	Total	A	B	Total	A	B	Total
6	2		2	2		2	2		2
9	1		1		1	1	1		1
11	3	1	4	1	3	4	4		4
13	3		3	3		3	3		3
14	1	3	4	1	3	4	4		4
15	1		1	1		1	1		1
16	1	1	2	2		2	2		2
17	1	2	3	3		3	3		3
18	1		1	1		1	1		1
19	1		1	1		1	1		1
21	2		2	2		2	2		2
Total	17	7	24	17	7	24	24	0	24

Table 3 Summary of restoration quality assessment according to follow-up time (the number for each score indicates the number of samples per follow-up period)

NB: Note that no restoration exhibited a C score.

made with either semidirect or indirect techniques following extended periods of clinical service (6 to 21 years). The absence of recurrent decay or pulpal complication has been another positive outcome of the technique. In the absence of any restoration failure, only minor restoration defects were observed such as slight anatomy change or partial marginal discoloration or irregularity. These defects were mainly found in restor-

ations made with the nanohybrid composite (Miris 2). This observation is partly substantiated by published *in vitro* physico-chemical characteristics of various composite types. Actually, some inhomogeneous nanohybrids containing prepolymerized and/or clusters of nanofillers (such as Miris 2) have shown significantly inferior mechanical performance in either static (flexural or compressive strength) or dynamic (fracture



toughness or flexural fatigue) tests. Flexural strength is considered an influential value for material wear resistance, as fracture toughness could be for the incidence of restoration fractures.²⁴⁻²⁶ Other studies using staircase, dynamic mechanical loading (in both a dry and moist environment) or testing for mechanical performance before and after storage in saliva and water also suggested the inferior performance of inhomogeneous nanohybrid composites.²⁷⁻²⁹ However, there is as yet no clinical data to confirm these *in vitro* findings. Interestingly, the present results suggest that material wear is not an issue for indirect, postcured composite restorations in an ordinary patient population, and that the clinical application of the CMR concept did not trigger any recurrent proximal decay within the surveyed cases. Despite the known limits of a

retrospective clinical evaluation and the low number of controlled restorations, the present data – combined with the numerous positive *in vitro* findings regarding the clinical protocols used here – support the continuous use of resin composite and indirect techniques for restoring extensive decays.

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Disclaimer

The authors declare that they have no conflicts of interest.

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