



A 2-year clinical evaluation of direct and semi-direct resin composite restorations in non-carious cervical lesions: a randomized clinical study

Taciana Marco Ferraz Caneppele¹ · Laura Célia Fernandes Meirelles¹ · Rafael Santos Rocha¹ · Lucélia Lemes Gonçalves¹ · Daniele Mara Silva Ávila¹ · Sérgio Eduardo de Paiva Gonçalves¹ · Eduardo Bresciani¹

Received: 11 February 2019 / Accepted: 3 July 2019 / Published online: 11 July 2019
© Springer-Verlag GmbH Germany, part of Springer Nature 2019

Abstract

Objectives The purpose of this study was to evaluate the 2-year success of resin composite restorations in non-carious cervical lesions (NCCLs) using the direct or semi-direct techniques.

Materials and methods Thirty volunteers presenting with at least two NCCLs were included. Each participant received one restoration using the direct technique and the other using the semi-direct technique, totaling 60 restorations. Time for completing the treatment was computed. Assessments at baseline, 7 days, and 6, 12, and 24 months were performed using the modified United States Public Health Service criteria. Descriptive analysis was reported as a percentage of successful treatments. For inferential analysis, the Student *t* test was used to evaluate the differences between extension, depth, and time. The chi-square/Fisher tests were used to compare treatment success after each period ($\alpha = 0.05$). The results were evaluated by using the Kaplan-Meier survival analysis.

Results Differences were detected regarding mean \pm standard deviation time, in which direct and semi-direct procedures were accomplished in 21.8 (\pm 14.5) and 35.3 (\pm 19.9) min, respectively. Of the 60 restorations placed, 7 failed in the direct group while 8 failed in the semi-direct group up to 2 years. No differences were detected between restorative protocols. The cumulative survival was 88.5% and 88.4% for the direct technique and semi-direct techniques after 24 months, respectively.

Conclusion The tested restorative protocols present similar results for NCCLs within the studied periods.

Clinical relevance The semi-direct technique exhibited clinical performance similar to direct technique for NCCL, demonstrating an alternative for restorations of these lesions.

Keywords Non-carious cervical lesions · Composite resin · Semi-direct technique · Randomized clinical trial

Introduction

Non-carious cervical lesions (NCCLs) represent a pathological condition characterized by the loss of dental structure at the cementum-enamel junction and are not associated with dental caries [1]. These lesions result from erosion, abrasion, and occlusal stress—abfraction that leads to different types of cavity with different depths. The appearance of NCCLs varies

according to their etiology and location, ranging from shallow depressions to disk-shaped or wedge-shaped lesions [1–3]. NCCLs are initially located in the enamel; however, they may progress to the dentin. With an aging population and increased retention of teeth, the prevalence of these lesions has increased [2, 4–6]. Thus, with increased life expectancy, the need to study these lesions and their optimal treatment becomes critical.

Direct restorations are frequently placed for NCCLs. However, challenges such as difficult access, moisture control, and especially damage to the marginal gingiva have been reported [7, 8]. Damage is a consequence of using rotary instruments during finishing/polishing, which might lead to discomfort, trauma, or gingival recession [9]. Other restorative techniques have been proposed to improve marginal adaptation [8] and to minimize the tensile stresses resulting from

✉ Taciana Marco Ferraz Caneppele
taciana.caneppele@unesp.br

¹ GAPEC - Academic Group of Clinical Research, Department of Restorative Dentistry, Institute of Science and Technology, São Paulo State University (UNESP), Av. Eng. Francisco José Longo, no. 777, São José dos Campos, São Paulo 12245-000, Brazil

polymerization shrinkage at the cavity walls [10]. In a semi-direct technique, the resin is placed and sculpted in the lesion, light-activated, and then removed [9]. Finishing and polishing are then performed extraorally, and the restoration cemented [9]. A minimal need to finish and polish such restorations has been reported to result in adequate contour and there is no need for flash removal, conditions rarely achieved with traditional restorative protocols [11].

Hoping to solve the previously reported problems caused by the direct restoration of NCCLs, Fahl Jr. [9] described a technique to minimize those drawbacks and to optimize the procedure with the semi-direct or direct-indirect technique. This provides a greater control over moisture and the tensile stresses generated by polymerization shrinkage. Moreover, it allows precise finishing and polishing of the restoration margins, since those procedures are performed extraorally. The definitive restoration presents precise margins and excellent surface smoothness, which leads to lower biofilm retention and a healthier periodontal condition. The procedure is comfortable for the patient because of less intraoral working time and opportunities for rest between the restoration steps. Limitations of the technique include longer chairside time and difficulty working with the small prototype restoration, both intraorally and extraorally.

Considering the long-term aspects of NCCL restorations performed with resin composite [12, 13], the objective of this clinical study was to evaluate and compare the effectiveness of direct and semi-direct class V restorations performed with resin composite in a randomized, controlled, and longitudinal clinical study.

Material and methods

Ethics approval and protocol registration

This study was approved by the local Institutional Review Board under protocol no. 1.379.948 and initiated only after IRB approval. The study was registered on the Brazilian Clinical Trials Registry platform under protocol no. RBR-2S5BHM. The methodology was reported following the standards of the 2010 CONSORT Statement [14] and 2013 SPIRIT Statement [15].

Study design

This clinical research used a split-mouth randomized controlled trial involving 30 volunteers who fit the study inclusion/exclusion criteria. The volunteers received two class V restorations in non-carious lesions, one performed with the direct (conventional) technique and the other with the semi-direct technique. A total of 60 class V restorations were provided in canines or premolars.

Randomization and blinding

The study followed a complete randomized experimental design using the Sealed Envelope website for randomization and sealed envelopes to conceal the randomization. The randomization was performed by a person not involved in the study. The treatment revealed from the envelope was performed in the tooth with the lower international tooth number, while the second included tooth received the other approach.

The two examiners were blinded to the restorative procedures, during all recalls.

Sample size calculation

Sample size was calculated on website software (www.sealedenvelope.com) [16]. An equivalence trial design was considered, with the percentage of success at 92.3% for both treatments, and an ability to detect differences greater than 17.9% between the treatments [17]. The number of study restoration was 30 per group, based on an 80% power and a statistical significance level set at 0.05.

Study population

A description of the study was given verbally to possible participants. Volunteers signed the informed consent before inclusion in the study.

Inclusion criteria were as follows: (a) age of 18 years or more; (b) no medical condition that interfered with routine dental care; (c) good oral hygiene; (d) presence of antagonist tooth; (e) presence of at least two non-carious cervical lesions in canines or premolars with a minimum depth and extent of 1 mm.

Exclusion criteria were as follows: (a) medical condition that may interfere with the safety of the volunteer during the study period, such as diabetes or allergic reactions to substances and/or products to be used; (b) use of removable prostheses with clasps engaging the target teeth; (c) caries or periodontal disease in the target area; (d) patients under orthodontic treatment; (e) teeth that had received endodontic treatment; and (f) presence of parafunctional habits.

Clinical procedure

The clinical procedure was performed at the clinic of the School of Dentistry by three operators calibrated in a previous pilot study. No tooth preparation was performed.

Prophylaxis was performed, and the gingival condition was assessed. The first envelope was opened, and the treatment was selected for the tooth with the lower universal tooth classification code. The second included tooth received the other treatment option.

The restoration was placed under cotton roll isolation [18], cheek retractors, and suction. Local anesthesia was administered, and a gingival displacement cord inserted (Pro Retract 000, FGM, Joinville, Santa Catarina, Brazil).

Direct technique

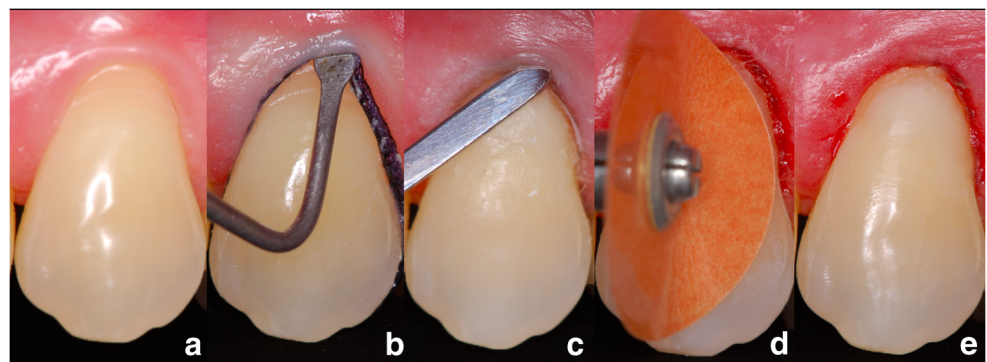
In the direct technique, the enamel and dentin were acid etched with 37% phosphoric acid gel (3M ESPE, Sumaré, São Paulo, Brazil), for 30 and 15 s, respectively. The lesions were then washed and further dried with absorbent paper. The Single Bond Universal adhesive system (3M ESPE, Sumaré, São Paulo, Brazil) was actively applied for 20 s, followed by a 5-s air drying. Light activation was performed for 10 s under LED irradiance at 800 mW/cm² (Ratii-cal SDI, Victoria, Australia). The restoration was placed with Z350 XT resin composite (3M ESPE, Sumaré, São Paulo, Brazil) with the incremental technique and light-activated for 20 s (Ratii-cal SDI—800 mW/cm²) at each increment.

Finishing was performed with a fine-grit diamond rotary instrument FG 2135F (KG Sorensen, Cotia, São Paulo, Brazil) and abrasive disks (Sof-Lex—3M ESPE, Sumaré, São Paulo, Brazil). Polishing was done with diamond paste (KG Sorensen, Cotia, São Paulo) and felt disks (FGM, Joinville, Santa Catarina, Brazil). The finishing and polishing procedures were performed in the same session as the restoration. A representative restoration sequence is shown in Fig. 1.

Semi-direct technique

The semi-direct technique consisted of inserting excess resin composite in the cavity before any restorative step. The resin was adapted in excess to the cavity walls and light-activated for 20 s with 800 mW/cm² irradiance (Ratii-cal SDI, Victoria, Australia). The unfinished restoration was removed from the cavity, attached to an adhesive tip (KG Stick-KG Sorensen, Cotia, São Paulo, Brazil), and given additional extraoral light polymerization for 20 s. The finishing and polishing steps were performed extraorally.

Fig. 1 Direct technique protocol: A initial aspect of the NCCL; B retractor cord placement; C composite resin insertion; D finishing and polishing; E immediate postoperative result



A pencil was used to outline the imprinted restoration margin and to aid the removal of flash. The sequence of Sof-Lex Pop-on disks (3M ESPE, Sumaré, São Paulo, Brazil) was used to remove flash and to obtain a proper emergence profile. The emergence profile and the restoration fit were evaluated by positioning the restoration in the cavity before and after polishing. The restorations were polished with diamond paste (KG Sorensen, Cotia, São Paulo, Brazil) and felt disks (FGM, Joinville, Santa Catarina, Brazil). The intaglio surface of the unfinished restoration was airborne particle abraded with aluminum oxide, followed by cleaning with 37% phosphoric acid (3M ESPE, Sumaré, São Paulo, Brazil) for 10 s, washing, and drying with cotton pellets.

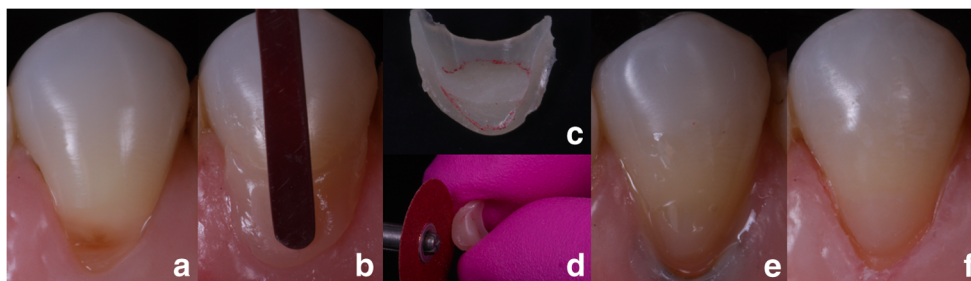
The tooth surface receiving the restoration was conditioned with 37% phosphoric acid and received the bonding procedure as previously described. A flowable resin layer (Natural Flow, Nova DFL-Rio De Janeiro, Brazil) was used to cement the polished restoration in the cavity. The restoration was placed in the cavity with the aid of an adhesive tip applicator (KG Stick-KG Sorensen, Cotia, São Paulo, Brazil), and resin excess was removed. Light activation was performed for 40 s. At the end of the restoration, the displacement cord was removed, and the first restoration evaluation performed. A representative restoration sequence is shown in Fig. 2.

Time of procedure and evaluation of restorations

The time of each restorative procedure, from beginning to end, was measured with a digital chronometer.

Assessments were performed at baseline (after restoration completion), after 7 days, and at 6, 12, and 24 months. The modified United States Public Health Service (USPHS) criteria were used as the assessment tool (Table 1). The characteristics of retention, marginal discoloration and adaptation, anatomic form, secondary caries, texture, postoperative sensitivity, and gingival trauma were assessed. Each patient was evaluated by two blinded independent evaluators who had previously been calibrated in a pilot study (Kappa = 0.481, 87.8% in agreement). In case of disagreement, the evaluators reached a consensus. Success rates were determined by all

Fig. 2 Indirect technique protocol: A initial aspect of the NCCL; B composite resin applied and sculpted onto the cervical lesion; C margins outlined with a pencil for precise visualization; D finishing and polishing; E cementation; F immediate postoperative result



assessed variables within the clinically acceptable USPHS criteria, whereas survival rates considered also unsuccessfully graded restorations that were still present in the mouth.

Statistical analysis

The success rates of the restorative procedure were considered the primary outcome, and the changes in each criterion within the clinically acceptable range and the time to complete the restoration were considered the secondary outcomes. The tested null hypothesis considers both treatment approaches to have similar success rates at the 24-month follow-up.

Data analysis was performed through descriptive statistics using the percentage of success of the restorations according

to the obtained scores in each criterion. The inferential analysis was performed by the Student *t* test to evaluate the differences between extension, depth, and time within the treatment groups. The chi-square/Fisher test was used to compare the rates between groups after each study period ($\alpha = 0.05$). The results were also evaluated by using annual survival rates (Kaplan-Meier).

Results

Demographic data within both technique groups are presented in Table 2. All the included lesions had a wedge shape. Data referring to the lesion extent and depth and the time spent on

Table 1 The modified USPHS criteria

Criterion	Classification	Characteristics
Retention/Fracture	Alfa (A)	Restoration completely retained
	Charlie (C)	Restoration partially or completely lost
Marginal discoloration	Alfa (A)	There is no visual evidence of marginal discoloration. No discoloration between material and tooth
	Bravo (B)	There is visual evidence of marginal discoloration between tooth structure and restoration, removable with polish
	Charlie (C)	There is visual evidence of marginal discoloration between tooth structure and restoration, not removable with polishing
Marginal adaptation	Alfa (A)	Adequate, no explorer retention on the explorer
	Bravo (B)	There is a visible defect, with explorer retention, without dentin exposure
	Charlie (C)	Failure of margin with dentin exposure
Caries	Alfa (A)	No caries present
	Charlie (C)	Caries present
Anatomic form	Alfa (A)	Continuous with adjacent anatomy
	Bravo (B)	Clinically acceptable small discontinuity without dentin exposure
	Charlie (C)	Without continuity, loss of sufficient material with dentin exposure
Surface texture	Alfa (A)	Surface has a smooth appearance. No tactile perception of roughness
	Bravo (B)	Surface presents with roughness or feels rough when inspected with explorer. There is no clear of pores or craters
	Charlie (C)	Surface of restoration presents pores or craters. When tip of explorer is passed over pores or craters it is trapped
Postoperative sensitivity	Present	Postoperative sensitivity
	Absent	No postoperative sensitivity
Gingival trauma	Present	Gingival trauma
	Absent	No gingival trauma

Table 2 Demographic data of participants (mean ± standard deviation) and included teeth

Data	Direct	Semi-direct
Age (years)	57.53 (± 8.67)	
% male	60	
Canine	4	6
First premolars	16	12
Second premolars	10	12

restoration according to the technique used are presented in Table 3. These data were analyzed by the Student *t* test, and only the time was different according to the treatment performed ($p = 0.004$). Semi-direct restorations took longer for completion of the procedure.

The assessed USPHS scores, according to each criterion, for the two tested techniques at baseline, 7 days, and 6, 12, and 24 months are displayed in Table 4. At the 7-day assessment, 1 direct restoration was lost due to lack of retention, while no semi-direct restoration was lost. No participant was absent at the 7-day evaluation. At 6 months, four direct restorations were lost due to lack of retention, while five semi-direct restorations were lost for the same reason. One participant was not followed up. At the 12-month follow-up, two restorations in each treatment were lost to lack of retention and two more participants did not attend the recall. At 24 months, two more participants were absent, and no direct restoration failed. In the semi-direct technique, one restoration was lost due to lack of retention (Fig. 3). Only four participants in the semi-direct group were considered absent to follow-up at the 24-month evaluation, since one participant who was not evaluated had a semi-direct restoration that had failed in a previous assessment. The criteria of marginal staining, marginal adaptation, anatomic shape, presence of caries, texture, sensitivity, and trauma did not present statistically significant differences between the techniques used in the evaluated periods ($p > 0.05$).

Data were submitted to the Kaplan-Meier survival test, resulting in the cumulative survival rates of the direct technique of 99%, 93.1%, 88.5%, and 88.5% at the 7-day and 6, 12, and 24-month periods, respectively. In the semi-direct technique, cumulative survival rates were 100% and 92.8%,

Table 3 Data on lesion characteristics and time for restorative procedure (mean ± standard deviation/median (1st–3rd quartiles))

Data	Direct	Semi-direct
Extension	3.6 mm (± 1.3)/3 (3–5)	3.8 mm (± 1.5)/4 (2–5)
Depth	1.7 mm (± 0.7)/2 (1–2)	1.8 mm (± 0.8)/1 (1–2.75)
Time	21.8 min (± 14.5)*	35.3 min (± 19.9)

*Significant difference between direct and semi-direct techniques for each assessed variable, using a *t* test ($p < 0.05$)

88.4%, and 83.7% at the 7-day and 6, 12, and 24-month periods, respectively. Graphs with cumulative survival rates are shown in Fig. 4 a and b.

The success rates of the two treatments were compared using the chi-square test. Accounting for the intention to treat (losses were computed following the results of the last evaluations performed), there were no differences ($p = 0.766$) between the two treatment protocols.

Once failed restorations were all related to missing restorations in the present study, no differences were present between success proportions and the estimation of the cumulative survival rates.

No differences between the direct and semi-direct techniques were detected for gingival trauma at baseline ($p = 0.165$), but a reduction over time in both techniques was noticed.

The presence of sensitivity prior to restoration and at the 24-month follow-up was compared (paired *t* test). No significant statistical difference was observed between the techniques; however, a reduction in sensitivity after 24 months was detected for both approaches ($p = 0.009$).

Discussion

The null hypothesis was not rejected as no differences were found in the success rates of the two treatments. The failure rates detected over the analyzed period all resulted from retention problems (Table 4). The cumulative survival rates of the direct and semi-direct techniques were also similar between the techniques and the assessed periods (Fig. 4a, b). The similarity between the success rates of the tested techniques is stressed as many of the patient-related factors possibly influencing the clinical service of the restorations were reduced due to the split-mouth design of the study. Other possible concerns about the success of restorative treatment are the size and shape of the cavities [6, 19], operator variability [20], occlusion characteristics, method of light polymerizing the materials, restorative materials used, conditioning time [13, 21, 22], bonding system used, restorative technique [23], patient age, moisture control [24], and contamination [19]. Although those reported factors might have been a concern for the success of the tested treatments, their influence was reduced in the present study by the previous training and calibration of operators, by the similarities in cavity depth and extension within the protocols (Table 3), and finally by the same resin composite being used in both treatment strategies.

Another possible reason for the failure (lack of retention) of class V restorations could be related to cavity geometry, its C factor, and the amount of the increment used during restoration, as they influence the tensile stresses generated at the interface during the light-polymerization procedure [10, 25]. The stress generated at the adhesive interface, mainly due to the polymerization shrinkage of the resin composites, is the main cause of marginal gaps,

Table 4 Number (percentage) of evaluated restorations in each recall according to the techniques, classified according to the modified USPHS criteria

Criteria	Score	Baseline			7 days			6 months			12 months			24 months		
		Direct N = 30	Semi-direct N = 30	Direct N = 30	Semi-direct N = 30	Direct N = 28	Semi-direct N = 29	Direct N = 22	Semi-direct N = 22	Direct N = 18	Semi-direct N = 19					
Retention	Alfa	30 (100%)	30 (100%)	29 (96.66%)	30 (100%)	24 (82.75%)	20 (90.90%)	20 (90.90%)	18 (100%)	18 (94.7%)						
	Charlie	–	–	1 (3.33%)	–	4 (14.28%)	5 (17.24%)	2 (9.09%)	–	1 (5.26%)						
Marginal discoloration	Alfa	30 (100%)	30 (100%)	29 (96.66%)	29 (96.66%)	22 (78.57%)	17 (77.27%)	18 (81.81%)	16 (88.88%)	16 (84.21%)						
	Bravo	–	–	–	1 (3.33%)	2 (7.14%)	3 (13.63%)	2 (9.09%)	2 (11.11%)	2 (10.52%)						
Marginal adaptation	Charlie	–	–	–	–	–	–	–	–	–						
	Alfa	23 (76.66%)	22 (73.33%)	19 (63.33%)	19 (63.33%)	16 (57.14%)	12 (41.37%)	11 (50%)	9 (50%)	8 (42.10%)						
Anatomical form	Bravo	7 (23.33%)	8 (26.66%)	10 (33.33%)	11 (36.66%)	8 (28.57%)	12 (41.37%)	9 (40.90%)	9 (50%)	10 (52.63%)						
	Charlie	–	–	–	–	–	–	–	–	–						
Secondary caries	Alfa	28 (93.33%)	28 (93.33%)	27 (90%)	27 (90%)	21 (75%)	20 (68.96%)	17 (77.27%)	16 (88.88%)	17 (89.47%)						
	Bravo	2 (6.66%)	2 (6.66%)	2 (6.66%)	3 (10%)	3 (10.71%)	4 (13.79%)	3 (13.63%)	2 (11.11%)	1 (5.26%)						
Texture	Charlie	–	–	–	–	–	–	–	–	–						
	Alfa	30 (100%)	30 (100%)	28 (93.33%)	29 (96.66%)	24 (85.71%)	24 (82.75%)	20 (90.90%)	18 (100%)	19 (100%)						
Postoperative sensitivity	Charlie	–	–	–	–	–	–	–	–	–						
	Alfa	26 (86.66%)	26 (86.66%)	23 (76.66%)	21 (70%)	19 (67.85%)	16 (55.17%)	15 (68.18%)	13 (72.22)	11 (57.89%)						
Gingival trauma	Bravo	4 (13.33%)	4 (13.33%)	5 (16.66%)	8 (26.66%)	5 (17.85%)	7 (24.13%)	9 (40.90%)	5 (27.77)	7 (36.84%)						
	Charlie	–	–	–	–	–	–	–	–	–						
Postoperative sensitivity	Present	–	–	4 (13.33%)	4 (13.33%)	3 (10.71%)	7 (24.13%)	4 (18.18%)	2 (11.11%)	2 (10.52%)						
	Absent	–	–	26 (86.66%)	26 (86.66%)	21 (75%)	17 (58.62%)	16 (72.72%)	16 (88.88%)	16 (84.21%)						
Gingival trauma	Present	23 (76.66%)	18 (60%)	7 (23.33%)	7 (23.33%)	5 (17.85%)	8 (27.58%)	1 (4.54%)	1 (5.55%)	–						
	Absent	7 (23.33%)	12 (40%)	23 (76.66%)	23 (76.66%)	19 (67.85%)	16 (55.17%)	19 (86.33%)	17 (94.44%)	18 (94.73%)						

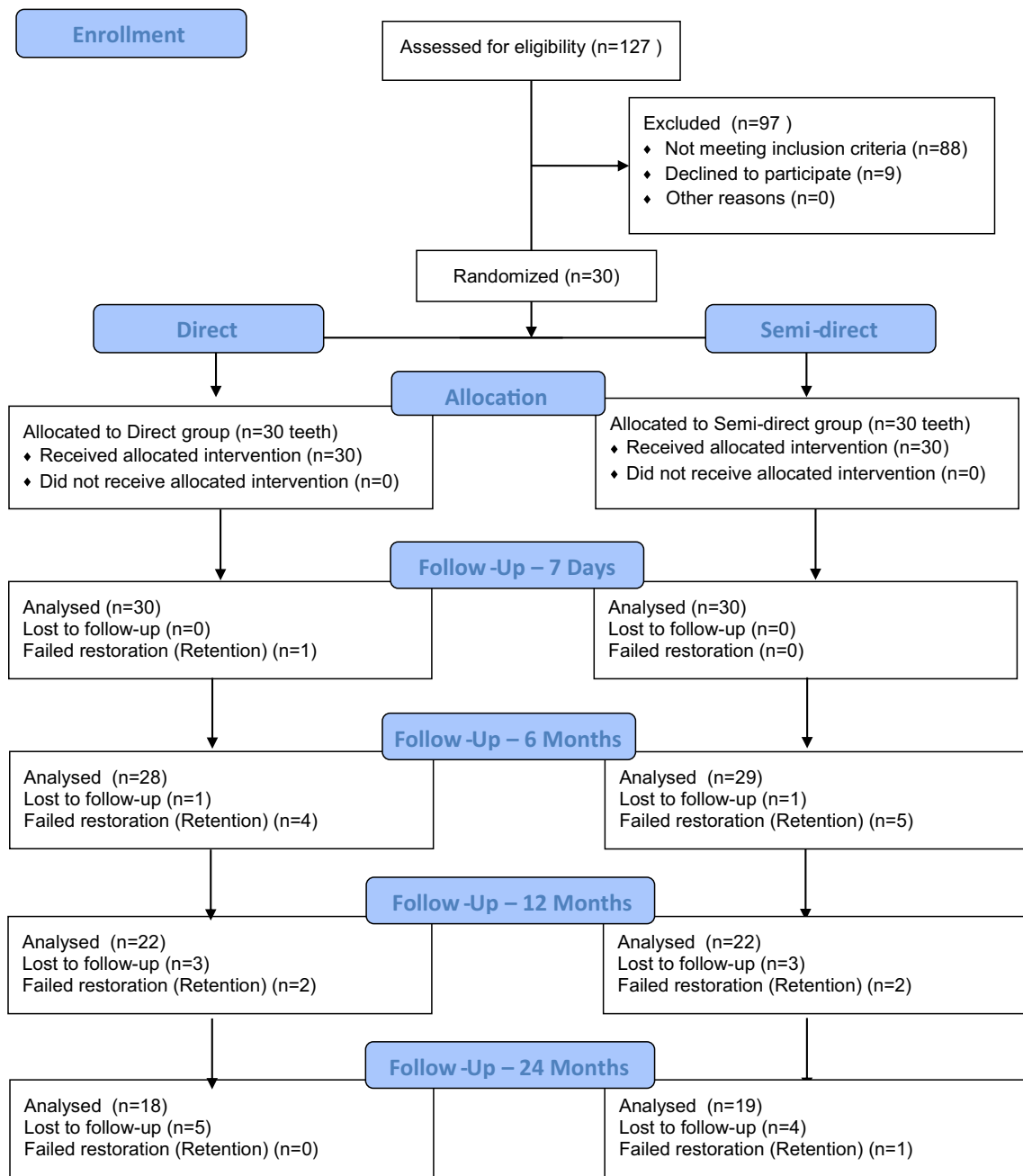


Fig. 3 Flow diagram with details about recruitment and allocation

microleakage, and pulp problems [26, 27], with possible future retention problems or development of secondary caries. The semi-direct restoration protocol used in the present study was intended to minimize those disadvantages, since the light activation of the restoration prior to its bonding procedure in association with the use of a small amount of resin cement (in the present study a flowable resin composite was used) should both help to avoid stresses at the interface [28]. Moreover, the additional light polymerization of the cemented restoration may improve its physical and mechanical properties [29].

The choice of a flowable resin composite as the cementing agent for the semi-direct technique is based on its properties. It is light-activated, it reduces the incorporation of voids as there is no need for a mixing step [30], and it presents excellent physical and optical properties [31]. For the clinical procedure itself, it promotes improved cementation control, since the operator can control the working time. Considering the long-term evaluation, it presents a lower potential for discoloration than chemical or dual-resin cements because of minimal tertiary amine in its chemical composition. Although advantages have been reported that would favor the semi-direct technique,

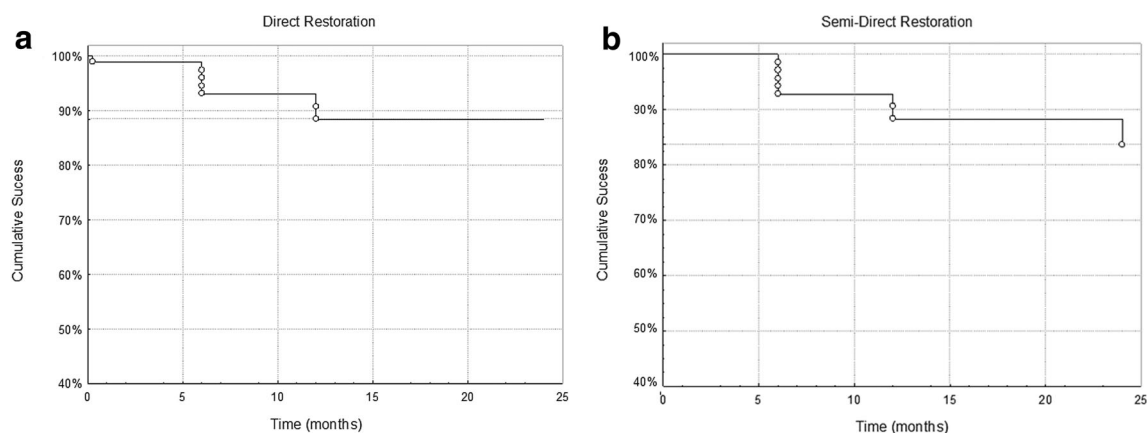


Fig. 4 Cumulative survival rates

both protocols behaved similarly. Longer clinical follow-up might detect such differences, suggesting studies with longer follow-up periods.

Retention of restorations was the main characteristic related to failure rates, as previously reported. Adhesion to dental substrate is the major clinical problem in NCCLs [13], mainly due to the non-retentive characteristics of cavities, the presence of none or almost no cervical enamel [32, 33], and the presence of sclerotic dentin. Although the study was not dichotomized according to such clinical characteristics, sclerotic dentin was observed in several lost restorations.

Also considering the retention of NCCL restorations, due to the non-retentive aspect of NCCLs, dentin adhesion is the most important factor to be highlighted [33, 34]. The clinical effectiveness of adhesives and restorations performed in class V cavities has been reported [6, 12, 35]. According to Fagundes et al. [36], the low retention rate of resin composite restorations is possibly caused by adhesive degradation over time. However, results from a study with self-etching adhesive systems on sclerotic dentin show a 20% decrease in bond strength compared with sound dentin [37]. In vitro studies have suggested an increase in the conditioning time as a possible strategy for improving the retention of restorations to sclerotic substrate [21, 34]. Besides the benefit of greater conditioning periods in sclerotic dentin, Farias et al. [38] found no effect of such a technique compared with sound dentin. Although the reported negative influences on the hybrid layer formation of the dentin characteristics of abrasion or abfraction cavities, the clinical efficacy of adhesive has been observed in NCCLs located in the dentin [39].

The universal adhesive system (under the total etch protocol) used in the present study is supported by studies reporting retention rates from 94 to 98% during the first 2 years of follow-up [40, 41]. Another relevant consideration in the selection of adhesive is that it is well-established in clinical practice. Although there is a tendency for a more simplified adhesive application, this simplification of steps seems to induce loss of effectiveness in NCCL restorations [42]. As both

protocols applied the same adhesive, this influence was minimized to differences in the restorative approach.

The presence of biomechanical forces might also be related to the lack of retention of NCCL restorations [43]. Cervical restorations performed with restorative materials with an elastic modulus similar to that of the tooth tend to flex when submitted to masticatory forces [44]. Therefore, the viscoelastic properties of restorative materials should be known prior to their selection, since the flexural deformation of a tooth in the cervical region is partially absorbed by the restorative material used [25]. As with the adhesive consideration, the effect of biomechanical forces was minimized as the same restorative material was used.

The annual failure rate (AFR) of resin restorations for NCCLs varies greatly, as reported by Peumans et al. [45] in a systematic review. The authors found an AFR ranging from 2.5 to 8.4. The present results revealed an AFR of 6.0 for the semi-direct approach and 5.9 for the direct approach. This discussed variability may be due to all previously reported factors that could influence the success of those restorations.

The criteria of marginal staining, marginal adaptation, anatomic shape, caries presence, texture, sensitivity, and trauma did not present statistically significant differences between the techniques used in the evaluated periods ($p > 0.05$) (Table 4). Changes over time were within the clinically acceptable parameter (Bravo). Longer evaluations may be required to detect differences related the failure.

The disadvantage of the semi-direct approach used in the present study is related to the clinical time (35.3 versus 21.8 min for the semi-direct and direct techniques, respectively). This was because of the intraoral and extraoral restorative stages and the difficulty of working with a small unfinished restoration, which made the technique dependent on the dentist's skill and training. In our experience, it was not uncommon to lose the restoration during finishing and polishing steps, being the procedure restarted and the restorative time increased [9]. Although the mean time for the semi-direct technique was more than 50% greater than for the direct approach, the

difference may not contraindicate the use of the technique in clinical treatment. The application of this technique might be questioned as the success rate was similar to that of the conventional approach and is more time-consuming. The success rate of NCCL restorations requires improvement in the form of additional studies on new restorative protocols. Moreover, with experience, the time for the semi-direct procedure should be reduced. Longer evaluation periods might identify improved success rates of the experimental technique, in which case the use of the technique would be recommended. However, at present, the authors believe the new technique does not represent an advantage over the conventional one.

The presence of sensitivity in NCCLs is frequent. Patients have reported reduced or resolved sensitivity after the restorative procedure because of the obliteration of the dentin tubules [34, 46] by the adhesive and restoration. Reduced sensitivity was observed in both evaluated techniques in the present study. However, problems with sensitivity might still occur [46]. In our study, after 24 months of follow-up, only two teeth in each technique (being the same patients) still presented some degree of sensitivity compared with the baseline condition, leading us to believe that the presence of sensitivity might also be inherent to patients. Moreover, cavity conformation and the C factor in class V restorations may influence the stress relief of polymerization contraction [25], which can result in problems such as postoperative sensitivity [47]. Over time, the sensitivity was similar in both restorative protocols (Table 4). One occasional observation was related to 6-month data from the semi-direct technique, in which an increase in sensitive teeth was detected. Sensitivity was evaluated under stimuli, and most patients reported the sensitivity detected at that specific data point did not impair their normal life routine. The authors believe this is an important observation that should be, however, interpreted with caution. Reasons for the increasing sensitivity might be related to the adhesion and cementation steps, in which the removal of the smear layer and the type of cement could have contributed [48].

According to Fahl Jr. (2015) [9], the greatest advantage of the semi-direct technique is accuracy in placing the restoration at the gingival margin and the finishing and polishing procedures which are performed extraorally. The definitive restoration presents greater surface smoothness, less retention of bio-film, and a healthier periodontal condition. The restoration texture in our study did not depend on the restorative protocol used, with no difference between techniques. In the present study, no differences were detected between techniques regarding the gingival condition after the restorations had been placed. This may be explained by the dentist's skills and training while performing direct restorations with proper marginal adaptation, adequate emergence profile, and minimum flash, which minimized the use of diamond rotary instruments for the finishing procedures. The use of displacement cord might also have influenced the observations, as similar gingival

trauma was observed after removal of the cord. Similar trauma reduction was detected over time in both techniques.

Limitations of this clinical, controlled, randomized, and longitudinal study were that it required many years of follow-up to obtain sufficient clinical validation and that a possibility of bias related to the operators may have existed.

Conclusions

Based on the findings of this clinical study with a 24-month evaluation period, it was concluded that the semi-direct technique did not show any advantage over the conventional direct method and is more time-consuming.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

References

1. Pecie R, Krejci I, Garcia-Godoy F, Bortolotto T (2011) Noncarious cervical lesions—a clinical concept based on the literature review. Part 1: prevention. *Am J Dent* 24:49–56
2. Pegoraro LF, Scolaro JM, Conti PC, Telles D, Pegoraro TA (2005) Noncarious cervical lesions in adults: prevalence and occlusal aspects. *J Am Dent Assoc* 136:1694–1700
3. Wood I, Jawad Z, Paisley C, Brunton P (2008) Non-carious cervical tooth surface loss: a literature review. *J Dent* 36:759–766. <https://doi.org/10.1016/j.jdent.2008.06.004>
4. Borcic J, Anic I, Urek MM, Ferreri S (2004) The prevalence of non-carious cervical lesions in permanent dentition. *J Oral Rehabil* 31: 117–123
5. Kreulen CM, Van 't Spijker A, Rodriguez JM, Bronkhorst EM, Creugers NH, Bartlett DW (2010) Systematic review of the prevalence of tooth wear in children and adolescents. *Caries Res* 44:151–159. <https://doi.org/10.1159/000308567>
6. Aw TC, Lepe X, Johnson GH, Mancl L (2002) Characteristics of noncarious cervical lesions: a clinical investigation. *J Am Dent Assoc* 133:725–733
7. Rocha AC, Da Rosa W, Cocco AR, Da Silva AF, Piva E, Lund RG (2018) Influence of surface treatment on composite adhesion in noncarious cervical lesions: systematic review and meta-analysis. *Oper Dent* 43:508–519. <https://doi.org/10.2341/17-086-L>
8. Perez CR (2010) Alternative technique for class V resin composite restorations with minimum finishing/polishing procedures. *Oper Dent* 35:375–379. <https://doi.org/10.2341/09-310-TR>
9. Fahl N, Jr. (2015) Direct-indirect class V restorations: a novel approach for treating noncarious cervical lesions. *J Esthet Restor Dent* 27:267–284. <https://doi.org/10.1111/jerd.12151>

10. Correia AMO, Tribst JPM, Matos FS, Platt JA, Caneppele TMF, Borges ALS (2018) Polymerization shrinkage stresses in different restorative techniques for non-carious cervical lesions. *J Dent* 76: 68–74. <https://doi.org/10.1016/j.jdent.2018.06.010>
11. Magni E, Zhang L, Hickel R, Bossu M, Polimeni A, Ferrari M (2008) SEM and microleakage evaluation of the marginal integrity of two types of class V restorations with or without the use of a light-curable coating material and of polishing. *J Dent* 36:885–891. <https://doi.org/10.1016/j.jdent.2008.07.003>
12. Peumans M, De Munck J, Van Landuyt KL, Poitevin A, Lambrechts P, Van Meerbeek B (2012) A 13-year clinical evaluation of two three-step etch-and-rinse adhesives in non-carious class-V lesions. *Clin Oral Investig* 16:129–137. <https://doi.org/10.1007/s00784-010-0481-z>
13. Pecic R, Krejci I, Garcia-Godoy F, Bortolotto T (2011) Noncarious cervical lesions (NCCL)—a clinical concept based on the literature review. Part 2: restoration. *Am J Dent* 24:183–192
14. Moher D, Hopewell S, Schulz KF, Montori V, Gotzsche PC, Devereaux PJ, Elbourne D, Egger M, Altman DG (2010) CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *Bmj* 340:c869. <https://doi.org/10.1136/bmj.c869>
15. Agha RA, Altman DG, Rosin D (2015) The SPIRIT 2013 statement—defining standard protocol items for trials. *Int J Surg* 13:288–291. <https://doi.org/10.1016/j.ijsu.2014.12.007>
16. Julious SA (2004) Sample sizes for clinical trials with normal data. *Stat Med* 23:1921–1986. <https://doi.org/10.1002/sim.1783>
17. Reis A, Loguercio AD (2009) A 36-month clinical evaluation of ethanol/water and acetone-based etch-and-rinse adhesives in non-carious cervical lesions. *Oper Dent* 34:384–391. <https://doi.org/10.2341/08-117>
18. Daudt E, Lopes GC, Vieira LC (2013) Does operatory field isolation influence the performance of direct adhesive restorations? *J Adhes Dent* 15:27–32. <https://doi.org/10.3290/j.jad.a28194>
19. Stewardson D, Creanor S, Thomley P, Bigg T, Bromage C, Browne A, Cottam D, Dalby D, Gilmore J, Horton J, Roberts E, Westoby L, Burke T (2012) The survival of class V restorations in general dental practice: part 3, five-year survival. *Br Dent J* 212:E14. <https://doi.org/10.1038/sj.bdj.2012.367>
20. Kim KL, Namgung C, Cho BH (2013) The effect of clinical performance on the survival estimates of direct restorations. *Restor Dent Endod* 38:11–20. <https://doi.org/10.5395/rde.2013.38.1.11>
21. Lopes GC, Vieira LC, Araujo E, Bruggmann T, Zucco J, Oliveira G (2011) Effect of dentin age and acid etching time on dentin bonding. *J Adhes Dent* 13:139–145. <https://doi.org/10.3290/j.jad.a19028>
22. Opdam NJ, van de Sande FH, Bronkhorst E, Cenci MS, Bottenberg P, Pallesen U, Gaengler P, Lindberg A, Huysmans MC, van Dijken JW (2014) Longevity of posterior composite restorations: a systematic review and meta-analysis. *J Dent Res* 93:943–949. <https://doi.org/10.1177/0022034514544217>
23. Schroeder M, Correa IC, Bauer J, Loguercio AD, Reis A (2017) Influence of adhesive strategy on clinical parameters in cervical restorations: a systematic review and meta-analysis. *J Dent* 62:36–53. <https://doi.org/10.1016/j.jdent.2017.05.006>
24. Nakajima M, Sano H, Zheng L, Tagami J, Pashley DH (1999) Effect of moist vs. dry bonding to normal vs. caries-affected dentin with Scotchbond Multi-Purpose Plus. *J Dent Res* 78:1298–1303. <https://doi.org/10.1177/00220345990780070301>
25. Borges AL, Borges AB, Xavier TA, Bottino MC, Platt JA (2014) Impact of quantity of resin, C-factor, and geometry on resin composite polymerization shrinkage stress in class V restorations. *Oper Dent* 39:144–151. <https://doi.org/10.2341/12-440-L>
26. Braga RR, Yamamoto T, Tyler K, Boaro LC, Ferracane JL, Swain MV (2012) A comparative study between crack analysis and a mechanical test for assessing the polymerization stress of restorative composites. *Dent Mater* 28:632–641. <https://doi.org/10.1016/j.dental.2012.02.008>
27. Sarrett DC (2007) Prediction of clinical outcomes of a restoration based on in vivo marginal quality evaluation. *J Adhes Dent* 9(Suppl 1):117–120
28. Dejak B, Mlotkowski A (2015) A comparison of stresses in molar teeth restored with inlays and direct restorations, including polymerization shrinkage of composite resin and tooth loading during mastication. *Dent Mater* 31:e77–e87. <https://doi.org/10.1016/j.dental.2014.11.016>
29. Kramer N, Lohbauer U, Frankenberger R (2000) Adhesive luting of indirect restorations. *Am J Dent* 13:60D–76D
30. Peumans M, De Munck J, Van Landuyt KL, Kanumilli P, Yoshida Y, Inoue S, Lambrechts P, Van Meerbeek B (2007) Restoring cervical lesions with flexible composites. *Dent Mater* 23:749–754. <https://doi.org/10.1016/j.dental.2006.06.013>
31. Barceireiro Mde O, De Miranda MS, Dias KR and Sekito T, Jr. (2003) Shear bond strength of porcelain laminate veneer bonded with flowable composite. *Oper Dent* 28:423–428
32. Walter C, Kress E, Gotz H, Taylor K, Willershausen I, Zampelis A (2014) The anatomy of non-carious cervical lesions. *Clin Oral Investig* 18:139–146. <https://doi.org/10.1007/s00784-013-0960-0>
33. Carvalho RM, Manso AP, Geraldini S, Tay FR, Pashley DH (2012) Durability of bonds and clinical success of adhesive restorations. *Dent Mater* 28:72–86. <https://doi.org/10.1016/j.dental.2011.09.011>
34. Perdigao J (2010) Dentin bonding—variables related to the clinical situation and the substrate treatment. *Dent Mater* 26:e24–e37. <https://doi.org/10.1016/j.dental.2009.11.149>
35. Kim SY, Lee KW, Seong SR, Lee MA, Lee IB, Son HH, Kim HY, Oh MH, Cho BH (2009) Two-year clinical effectiveness of adhesives and retention form on resin composite restorations of non-carious cervical lesions. *Oper Dent* 34:507–515. <https://doi.org/10.2341/08-006C>
36. Fagundes TC, Barata TJ, Bresciani E, Santiago S, Franco EB, Lauris JR, Navarro MF (2014) Seven-year clinical performance of resin composite versus resin-modified glass ionomer restorations in noncarious cervical lesions. *Oper Dent* 39:578–587. <https://doi.org/10.2341/13-054-C>
37. Kwong SM, Tay FR, Yip HK, Kei LH, Pashley DH (2000) An ultrastructural study of the application of dentine adhesives to acid-conditioned sclerotic dentine. *J Dent* 28:515–528
38. Farias DC, Lopes GC, Baratieri LN (2015) Two-year clinical performance of a two-step etch-and-rinse adhesive in non-carious cervical lesions: influence of subject's age and dentin etching time. *Clin Oral Investig* 19:1867–1874. <https://doi.org/10.1007/s00784-015-1399-2>
39. van Dijken JW, Pallesen U (2008) Long-term dentin retention of etch-and-rinse and self-etch adhesives and a resin-modified glass ionomer cement in non-carious cervical lesions. *Dent Mater* 24: 915–922. <https://doi.org/10.1016/j.dental.2007.11.008>
40. Zanatta RF, Silva TM, Esper M, Bresciani E, Goncalves S, Caneppele T (2019) Bonding performance of simplified adhesive systems in noncarious cervical lesions at 2-year follow-up: a double-blind randomized clinical trial. *Oper Dent*. <https://doi.org/10.2341/18-049-C>
41. Loguercio AD, de Paula EA, Hass V, Luque-Martinez I, Reis A, Perdigao J (2015) A new universal simplified adhesive: 36-month randomized double-blind clinical trial. *J Dent* 43:1083–1092. <https://doi.org/10.1016/j.jdent.2015.07.005>
42. Heintze SD, Ruffieux C, Rousson V (2010) Clinical performance of cervical restorations—a meta-analysis. *Dent Mater* 26:993–1000. <https://doi.org/10.1016/j.dental.2010.06.003>
43. Grippo JO, Simring M, Schreiner S (2004) Attrition, abrasion, corrosion and abfraction revisited: a new perspective on tooth surface lesions. *J Am Dent Assoc* 135:1109–1118 quiz 1163–5

44. Heymann HO, Sturdevant JR, Bayne S, Wilder AD, Sluder TB, Brunson WD (1991) Examining tooth flexure effects on cervical restorations: a two-year clinical study. *J Am Dent Assoc* 122:41–47
45. Peumans M, De Munck J, Mine A, Van Meerbeek B (2014) Clinical effectiveness of contemporary adhesives for the restoration of non-carious cervical lesions. A systematic review. *Dent Mater* 30:1089–1103. <https://doi.org/10.1016/j.dental.2014.07.007>
46. Perez Cdos R, Gonzalez MR, Prado NA, de Miranda MS, Macedo Mde A, Fernandes BM (2012) Restoration of noncarious cervical lesions: when, why, and how. *Int J Dent* 2012(687058):1–8. <https://doi.org/10.1155/2012/687058>
47. Owens BM, Johnson WW (2005) Effect of insertion technique and adhesive system on microleakage of class V resin composite restorations. *J Adhes Dent* 7:303–308
48. Farias D, Walter R and Swift EJ, Jr. (2014) Critic appraisal. Postoperative sensitivity with indirect restorations. *J Esthet Restor Dent* 26:208–213. <https://doi.org/10.1111/jerd.12103>

Publisher's note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.