

Clinical Evaluation of Noncarious Cervical Lesions of Different Extensions Restored With Bulk-fill or Conventional Resin Composite: Preliminary Results of a Randomized Clinical Trial

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Clinical Relevance

Regular nanofilled and regular bulk-fill resin composites showed good clinical performances for restoring noncarious cervical lesions of different sizes after 1 year.

SUMMARY

Purpose: This randomized clinical trial evaluated the influence of the occlusogingival distance (OGD) of noncarious cervical lesions (NCCLs) on the clinical performance of a

regular bulk-fill resin composite and a regular nanofilled resin composite.

Methods and Materials: A total of 140 restorations were randomly placed in 77 participants by one operator. NCCLs were divided into four groups ($n=35$) according to OGD ($1.5\text{ mm} \pm 10\%$ or $3\text{ mm} \pm 10\%$) and resin composites (Filtek

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Bulk Fill Posterior [B] or Filtek Z350 XT [C]) used: 1.5 mm-B, 1.5 mm-C, 3 mm-B, and 3 mm-C. A two-step self-etch adhesive (Clearfil SE Bond) was applied following manufacturer instructions in all restorative procedures. Restorations were polished 1 week after placement. Clinical evaluation was performed at baseline (7 days), 6 months, and 1 year by two calibrated examiners, according to the modified US Public Health Service criteria evaluating fractures/retention, marginal staining, marginal adaptation, recurrence of caries, anatomic form, postoperative sensitivity, and surface texture. The Kruskal-Wallis test was used for intergroup comparison in each follow-up; the Friedman analysis of variance, followed by the least significant difference test (multiple comparisons) was used for intra-group comparison between baseline and follow-up times ($\alpha=0.05$).

Results: Two restorations were lost at 12 months (1 for 1.5 mm-B and 1 for 3 mm-B). The retention rates at 12 months were 100% for 1.5 mm-C, 97% for 1.5 mm-B, 100% for 3 mm-C; and 97% for 3 mm-B, with no statistical difference among the groups ($p=0.570$). At 12 months, a statistically significant difference was found among the follow-up times for the same group (1.5 mm-B, 1.5 mm-C, and 3 mm-B) regarding the marginal staining criterion; moreover, the 3 mm-C group showed a significant difference from 6 months. No significant difference was found for the other parameters.

Conclusion: Both resin composites showed acceptable clinical performance, and the OGD of NCCLs did not influence the clinical performance of resin composite restorations after 12 months.

INTRODUCTION

Noncarious cervical lesions (NCCLs) are the result of the loss of cervical hard dental tissue at the level of the cemento-enamel junction.¹ The NCCLs result from the accumulation of tension, attrition, and biocorrosion of tooth structure.^{2,3} Therefore, they may represent superficial or more profound defects, and they may present different forms (wedge-shaped, flat, concave, or acute angle) and dimensions (vertical and horizontal width).^{1,4} Clinically, these morphologic features may influence the choice of treatment of NCCLs and the longevity of restoration.⁴⁻⁶

NCCLs should be restored to treat dental hypersensitivity, prevent against further loss of tooth tissues, and improve esthetics.^{7,8} However, restorative procedures are challenging because of the nonretentive shape of the cavity, the presence of sclerotic dentin, and the location of dentin and cement margins that are unfavorable for adhesion.^{7,9-11} Therefore, micromechanical or chemical retention preserving dental structure, good esthetics, and functional characteristics are essential aspects in the choice of restorative material.¹

Adhesive materials, such as glass ionomer cements¹²⁻¹⁴ and resin composites,^{1,2,15} are indicated to replace the lost tissue in the cervical region. Despite the high retention rate, glass ionomers usually have poorer esthetics (higher surface roughness, lower color stability, and lower wear resistance), and inferior mechanical properties (poor strength and hardness) compared with those of resin composites.^{13,14}

Resin composites have been widely used in the treatment of NCCLs. The development and improvement of these materials, especially with the addition of nanoparticles, has led to excellent physicomachanical properties, such as surface smoothness and reduction of polymerization shrinkage.^{16,17} Retention, marginal staining, and marginal adaptation are considered important parameters for evaluating resin restorations in NCCLs^{2,18,19} and are directly related to the stress produced in the tooth/restoration interface,^{20,21} which is influenced by the characteristics of the composite and the cavity to be restored.²² The results of some experimental studies showed a direct relationship between the marginal quality and cavity dimensions.^{22,23} These findings suggest that more severe microleakages are expected in restorations with larger dimensions, consequently, with a larger volume.

The bulk-fill resins were developed to overcome issues such as volumetric shrinkage and polymerization shrinkage stress. Thus, a bulk-fill resin may be appropriate for restorative treatment of NCCLs to minimize polymerization shrinkage.²⁴⁻²⁶ Other potential advantages are related to the simplification of the clinical technique, more compact fillings, and time savings.^{26,27} Favorable results have been reported from *in vitro* studies evaluating the physicomachanical properties of these materials.^{17,24,27-29} Recent studies with bulk-fill resins evaluated their clinical performance as the base or lining of Class I and II restorations.³⁰⁻³⁵ In NCCLs, a flowable bulk-fill resin was reported to have a similar clinical

performance to conventional composite resins after 1 year of follow-up.¹⁵

The influence of various clinical characteristics and factors associated with NCCLs and the influence of technique and restorative material on the longevity of the treatment have been reported.^{2,9,13,15,18,36–39} This research is of relevance because the treatment protocols for NCCLs, as for those analyzed in this study (the influence of the size of NCCLs), had not been tested previously, and other factors influencing the longevity of restorations have not yet been investigated. Thus, this randomized controlled clinical trial aimed to evaluate the influence of the occlusogingival distance (OGD) of NCCLs and the type of resin composite (regular bulk-fill or regular nanofilled) on the 1-year performance of resin composite restorations.

METHODS AND MATERIALS

Ethics Approval and Protocol Registration

The Institutional Review Board approved this study. The protocol was registered in the Brazilian Clinical Trials Registry (ReBEC-www.ensaiosclinicos.gov.br). This clinical investigation followed the Consolidated Standards of Reporting Trials statement (CONSORT).⁴⁰

Study Design and Locations of Data Collection

This was a randomized, controlled, parallel, blind (participants and examiners) clinical trial and was conducted between September 2016 and July 2018 at the clinic of the School of Dentistry.

Recruitment and Eligibility Criteria

Individuals seeking treatment in a screening clinic in the Restorative Dentistry Department of the local university were recruited for the study. A total of 128 participants were examined by two calibrated dental students to determine whether they met the eligibility criteria. Participants had to be at least 18 years old and be in good general and oral health, with an acceptable oral hygiene level and with at least 20 teeth in occlusion. In addition, they had to have at least one NCCL to be restored that was deeper than 1 mm in vital canines or premolars without mobility, with an opposing and adjacent tooth, and have an OGD of 1.5 mm or 3 mm ($\pm 10\%$). Patients with poor oral hygiene, severe or chronic periodontal disease, orthodontic appliances, severe bruxism; smokers; or participants undergoing tooth whitening procedures were excluded from the study.

Before measurement of the OGD, a dental screening and dental prophylaxis (rubber cup + pumice + water) was done in all participants. Then, two-step silicone impressions (Express XT Putty Soft + Express XT Light Body Quick; 3M/ESPE, St Paul, MN, USA) were made of each tooth with NCCLs that met the inclusion criteria. Gingival retraction cords (Ultrapak #000 and Ultrapak #00; Ultradent Products, Inc, South Jordan, UT, USA) were used in the gingival sulcus to better visualize the margin of the lesion. The impressions were disinfected and poured with gypsum (Durone IV; Dentsply Sirona, York, PA, USA) 3 hours after removal. The excess material was removed from all surfaces, and the cast was scanned with an extraoral scanner (inEos Blue; Dentsply Sirona, Vienna, Austria). The digitalized data were transmitted to a computer-aided design software program (Rhinoceros 4.0; McNeel North America, Seattle, WA, USA) in which the OGD (distance between the most apical point of the gingival margin to the occlusal margin, tracing a line parallel to the long axis of the tooth) of the lesions, was analyzed. After determining the OGD, the restorative treatment was randomly defined according to the sequence generated.

Sample-Size Calculation

The sample size was estimated by Sealed Envelope online software (Sealed Envelope Ltd. 2012. Power calculator for binary outcome equivalence trial. [Online] Available from: <https://sealedenvelope.com/power/binary-equivalence/> [Accessed May 02 2016]) An annual failure rate of 2.2% to two-step self-etch adhesives in NCCLs was considered.¹⁰ Thus, after 2 years, the retention rate of this material will be approximately 95.6%. The minimal sample size was 33 restorations using an alpha of 0.05, a power of 80%, and a two-sided test to detect a difference among the groups of 15%. Considering the estimated dropout rate throughout the experimental period, 35 teeth per group was determined.

Randomization and Allocation Concealment

The randomization lists were prepared using a website (www.random.org) with an equal allocation ratio for all comparison groups: NCCLs with OGD 1.5 mm ($\pm 10\%$) restored with either Filtek Z350 XT [C] or Filtek Bulk Fill Posterior [B] (3M ESPE, St Paul, MN, USA); and NCCLs with OGD 3 mm ($\pm 10\%$) restored with either Filtek Z350 XT [C] or Filtek Bulk Fill Posterior [B], for a total of four groups (n=35): 1.5 mm-B, 1.5 mm-C, 3 mm-B, and 3 mm-C.

Table 1: Information About Restorative Materials Used		
Material	Manufacturer	Composition
Clearfil SE Bond	Kuraray America, Inc, New York, NY, USA	Primer: 10-MDP, HEMA, DMA, catalyst, water. Bond: 10-MDP, HEMA, DMA, Bis-GMA, filler, catalyst.
Filtek Z350 XT	3M ESPE, St Paul, MN, USA	Filler: 78.5 wt% (59.5 vol%) silica, zirconia, aggregated zirconia/silica. Matrix: Bis-GMA, UDMA, TEGDMA, dimethacrylate.
Filtek Bulk Fill Posterior	3M ESPE	Filler: 76.5 wt% (58.4 vol%) Silica, zirconia, ytterbium trifluoride, aggregated zirconia/silica. Matrix: AUDMA, AFM, UDMA, DDDMA, EDMAB.
Abbreviations: AFM, addition-fragmentation monomer; AUDMA, aromatic urethane dimethacrylate; Bis-GMA, bisphenol-glycidyl methacrylate; DDDMA, 1, 12-dodecanediol dimethacrylate; DMA, dimethacrylate; EDMAB, ethyl 4-dimethyl aminobenzoate. HEMA, 2-hydroxyethyl methacrylate; 10-MDP, 10-methacryloyloxydecyl dihydrogen phosphate; TEGDMA, triethylene glycol dimethacrylate; UDMA, urethane dimethacrylate;		

For the allocation, opaque and sealed envelopes were used and numbered by a person not involved in the study. Just before the restorative procedure began, the envelope was opened, which ensured allocation concealment. In cases where the participant presented lesions with the same OGD, the tooth located in the quadrant of the smaller number and more mesial in this quadrant was the first to be assigned, continuing similarly until all teeth meeting the inclusion criteria were restored.

Restorative Procedures

Before starting the restorative procedure, participants signed the informed consent form. The dental prophylaxis (rubber cup + pumice + water) was performed and verbal oral hygiene instructions provided.

The shape of the lesions (labeled as saucer-shaped, wedge-shaped, or mixed-shape) were analyzed by a computer-aided design software program (Rhino-ceros 4.0). The presence of wear facets was recorded. Preoperative sensitivity was also evaluated by applying air for 10 seconds from a dental syringe placed 2 cm from the tooth surface.

An experienced dentist with more than 5 years of dental practice experience restored all teeth. Participants received restorations in previously selected lesions that met the inclusion criteria.

A predetermined procedure was performed, which included cavity cleaning with rubber cup, pumice and water, rinsing, and drying. A shade guide was used for shade selection. No additional retentive features or bevels were placed in the cavities as per the guidelines recommended by the American Dental Association.⁴¹ The relative isolation method was performed in all procedures. For this, gingival retraction cord (Ultrapak #000; Ultradent Products, Inc), cotton rolls, and a saliva aspirator were used.

The cavities received the two-step self-etch adhesive Clearfil SE Bond (Kuraray America, Inc, New

York, NY, USA), according to the manufacturer's instructions (Table 1). One coat of primer was applied on the entire lesion surface for 20 seconds. A gentle air stream was applied for approximately 5 seconds to evaporate the solvent. Then, the adhesive was applied and light cured for 10 s at 800 mW/cm² (Radii cal, SDI, Victoria, Australia).

The cavities were restored with two different resin composites (Table 1). Filtek Bulk Fill Posterior was placed in a single increment and light cured for 40 seconds using a calibrated light-curing unit (Radii cal, SDI) at 800 mW/cm² with a radiometer (Demetron; Kerr, Orange, CA, USA) for half the lesions according to the predetermined OGD (1.5 mm±10% and 3 mm±10%). Filtek Z350 XT was used in up to three increments for cavities with an OGD of 3 mm (±10%) and in a single increment for cavities with an OGD of 1.5 mm (±10%). Light-curing of each increment was performed for 20 seconds at 800 mW/cm².

Final contouring was carried out with 12-fluted tungsten carbide burs (FG Bur; KG Sorensen, Barueri, SP, Brazil) immediately after the restorative procedure. Polishing was performed with disks (Sof-Lex, 3M ESPE) 7 days after placement.

Calibration Procedures

For calibration, 10 representative photographs of each score for each criterion were examined by two independent experienced dentists. Also, 10 patients, not involved in this study, were evaluated on two consecutive days. Before the evaluations, an intra-examiner and interexaminer agreement of at least 85% was obtained.⁴²

Blinding

The two examiners and all participants were blinded to the group allocation during all recalls, resulting in a double-blind trial design.

Table 2: *Category and Grade Descriptions for the Clinical Evaluation According to the Modified US Public Health Service Criteria*

Category	Grade	Criterion
Retention	Alfa	No loss of restorative material
	Charlie	Partial or complete loss of restorative material
Marginal staining	Alfa	No discoloration along the margin
	Bravo	Slight and superficial staining (removable, usually localized)
	Charlie	Deep staining cannot be polished away
Marginal adaptation	Alfa	Restoration is continuous with existing anatomic form, explorer does not catch
	Bravo	Detectable V-shaped defect in enamel only. Catches explorer going both ways
	Charlie	Detectable V-shaped defect to dentin-enamel junction
Recurrence of caries	Alfa	No evidence of caries contiguous with the margin
	Charlie	Evidence of presence of caries
Anatomic form	Alfa	Continuous with adjacent anatomy
	Bravo	Missing of restorative material without exposing the dentin or base
	Charlie	Missing restorative material sufficient to expose the dentin or base
Postoperative sensitivity	Alfa	No postoperative sensitivity directly after the restorative process and during the study period
	Charlie	Sensitivity present at any time during the study period
Surface Texture	Alfa	Surface texture similar to that of enamel
	Bravo	Surface texture similar to composite resin surface
	Charlie	Surface texture with porosities, catches explorer

Clinical Evaluation

Two examiners evaluated all the restorations independently. When disagreements occurred, a discussion led to a consensus. The parameters evaluated by each examiner were individually recorded in a standardized form during all recall times.

The restorations were evaluated at baseline (7 days) and at 6 and 12 months after restoration placement using the modified US Public Health Service (USPHS) criteria (Table 2). The primary measurable variable was restoration retention or presence of fractures, followed by the secondary measurable variables: marginal staining, marginal adaptation, recurrence of caries, anatomic form, postoperative sensitivity, and surface texture. Seven days after the restoration placement, postoperative sensitivity was evaluated. Air from a dental syringe positioned 2 mm from the tooth surface was applied for 10 seconds. These variables were ranked with the following scores: Alfa (acceptable restoration), Bravo (minor change of the restoration), and Charlie (unacceptable restoration).

Statistical Analysis

R statistical language R Studio (version 3.4.4, R Studio Team, Boston, MA, USA) was used for statistical analysis of each criterion. The descriptive statistical analyses included the evaluated restorations, not considering the dropouts. The inferential statistical analyses followed the intention-to-treat

protocol suggested by CONSORT,⁴⁰ which involved all teeth initially randomized, including those that were not evaluated at the specified time. In this case, the missing data were included with the score of the last evaluation.

The Kruskal-Wallis test was performed to analyze all evaluated criteria among the groups at each evaluation time. The Friedman repeated analysis of variance assessed the difference in the performance of each group among three recall times (baseline, 6 months, and 12 months), followed by the least significant difference test for multiple comparisons, when applicable. The Cohen kappa statistics were used to test interexaminer agreement. A significance level of 5% was adopted in all tests.

RESULTS

Characteristics of Included Participants

In this study, 128 individuals were examined. Fifty-one did not fulfill the inclusion criteria, so they were not included. Thus, 77 participants were enrolled in the clinical trial. A total of 140 restorations were placed, 35 in each of the four groups (Figure 1). Details about the participants and characteristics of the NCCLs are presented in Table 3.

At baseline (7 days) and after 6 months, all participants were evaluated (Figure 1). After 12 months, the recall rate was 97.1% (136 restorations of 140). Four restorations were not evaluated

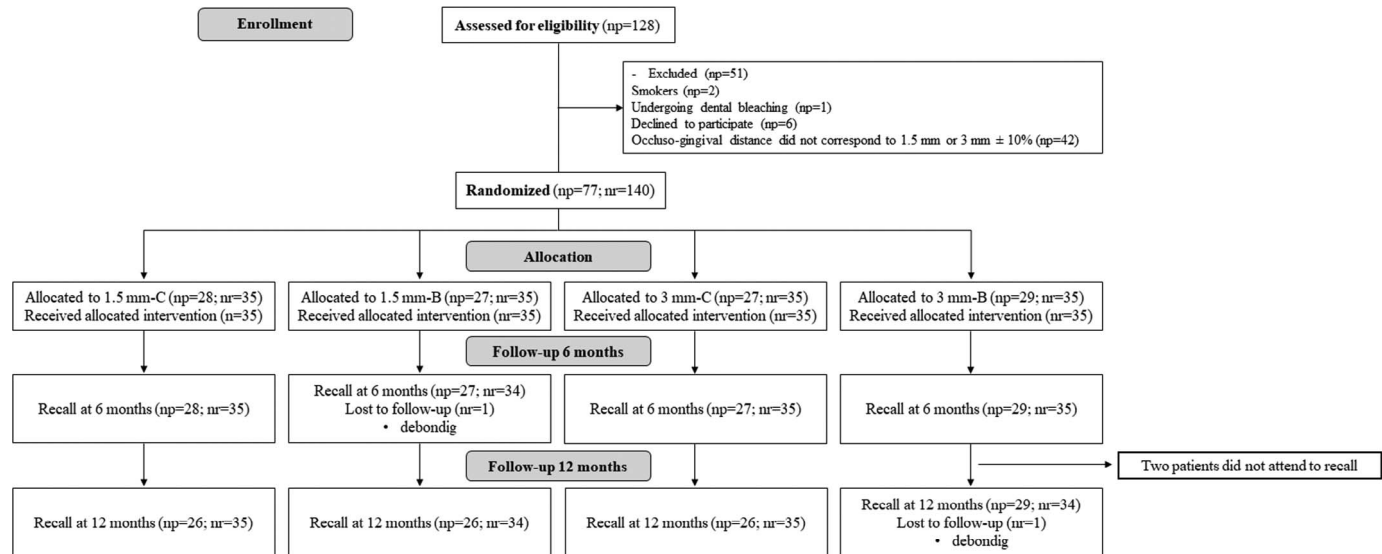


Figure 1. Flow diagram with details about recruitment and allocation; 1.5 mm-C, NCCLs with OGD 1.5 mm restored with Filtek Z350 XT; 1.5 mm-B, NCCLs with OGD 1.5 mm restored with Filtek Bulk Fill Posterior; 3 mm-C, NCCLs with OGD 3 mm restored with Filtek Z350 XT; 3 mm-B, NCCLs with OGD 3 mm restored with Filtek Bulk Fill Posterior. NCCL, noncarious lesions; np, number of participants; nr, number of restorations; OGD, occlusogingival distance.

because the participants did not attend during the follow-up period; of these, 2 restorations were in the 1.5 mm-C group, 1 restoration in the 1.5 mm-B group, and 1 restoration in the 3 mm-C group.

Overall Analysis

Two restorations were lost, one after 6 months and another after 12 months. According to the USPHS modified criteria, the 12-month retention rates (95% confidence interval) were 100% (90% to 100%) for 1.5 mm-C; 97% (85% to 99%) for 1.5 mm-B; 100% (90% to 100%) for 3 mm-C; and 97% (85% to 99%) for 3 mm-B, with no statistical difference among the groups ($p=0.570$) (Table 4). Also, no significant differences were found in marginal staining, marginal adaptation, recurrence of caries, anatomic form, postoperative sensitivity and surface texture among experimental groups.

The only significant difference among the follow-ups for the same group was found in marginal staining. In this parameter, the score Bravo increased significantly with time for 1.5 mm-C ($p=0.049$) and 1.5 mm-B groups ($p=0.049$). However, the only significant difference was found between the baseline and the 12-month follow-up. For the 3 mm-B group, three restorations had Bravo scores after 12 months of follow-up, showing a significant increase compared with the other recall times ($p=0.049$). In the 3 mm-C group, although more restorations rated as Bravo at the 12-month follow-up compared with those at the 6-month follow-up,

there was no significant difference between them, only for baseline ($p<0.01$).

DISCUSSION

In a clinical trial, different parameters are used to determine the clinical performance of a restorative material or technique. In NCCLs, retention, marginal staining and marginal adaptation are the criteria that determine the longevity of the restorations.^{2,18,19} These parameters are directly related to the stress produced at the tooth/restoration interface,^{20,21} which is influenced by the nonretentive shape and geometry of the cavity. Also, the enamel bevel,^{3,5} adhesion strategies, methods of photoactivation, viscosity of adhesive materials, application of low-viscosity resins and placement technique^{3,43} contribute to the development of stress at the interface. The authors are unaware of a previous study that assessed the clinical performance of a regular bulk-fill resin composite in NCCLs besides the influence of the OGD of NCCLs. According to Aw et al.,⁴⁴ in a study of the prevalence of NCCLs, the OGD of evaluated NCCLs ranged from 1 to 4 mm in most of the lesions (91%). Then, two different sizes (small [$1.5\text{ mm}\pm 10\%$] or big [$3\text{ mm}\pm 10\%$] lesions) within that previously reported range were determined. The results of the present study showed that after 12 months, both resin composites exhibited acceptable clinical performances, despite marginal staining and regardless of the OGD.

Table 3: Details Regarding Research Participants (Sex and Age), Characteristics, and Distribution of NCCLs

Characteristics	Number of Participants, %			
Sex distribution				
Male	34 (44.1)			
Female	43 (55.8)			
Age distribution (years)				
21-40	12 (15.6)			
41-60	52 (67.5)			
61-80	13 (16.9)			
Characteristics of NCCLs	Number of Lesions, %			
	1.5 mm-C	1.5 mm-B	3 mm-C	3 mm-B
Tooth distribution				
Canines	7	7	9	7
Premolars	28	28	26	28
Arch distribution				
Maxillary	15	25	16	14
Mandibular	20	10	19	21
Shape				
Saucer-shaped	15	15	23	24
Wedge-shaped	16	17	7	3
Mixed-shape	4	3	5	8
Wear facets				
Yes	18	21	21	20
No	17	14	14	15
Preoperative sensitivity (air dry)				
Yes	18	22	20	15
No	17	13	15	20
Abbreviations: 1.5 mm-C, NCCLs with OGD 1.5 mm restored with Filtek Z350 XT; 1.5 mm-B, NCCLs with OGD 1.5 mm restored with Filtek Bulk Fill; 3 mm-C, NCCLs with OGD 3 mm restored with Filtek Z350 XT; 3 mm-B, NCCLs with OGD 3 mm restored with Filtek Bulk Fill; NCCL, noncarious cervical lesion				

A two-step self-etch adhesive was evaluated in this clinical trial because of the lower sensitivity of the technique and better clinical performance, with a failure rate of 2.2% after 24 months.¹⁰ Clearfil SE Bond contains functional monomer 10-methacryloxydecyl phosphate (MDP), which bonds chemically with the hydroxyapatite of the tooth through its phosphate groups,⁴⁵ providing a more effective bond and more stability in water than other monomers, even without additional mechanical retention.⁴⁶ The good clinical performance of the restorative materials at 12 months may be attributed to these characteristics.

In this study, the retention rates were 100%, 97%, 100%, and 97% at 12 months for the 1.5 mm-C, 1.5 mm-B, 3 mm-C, and 3 mm-B groups, respectively, without statistical difference among the groups during this period ($p=0.57$). Also, no significant

difference was detected for the other parameters among any groups (Table 4).

These results demonstrated that regular bulk-fill resin composite is a viable option for the restoration of NCCLs, with excellent performance after 12 months of clinical service. Similar findings have also been reported in previous clinical trials.¹⁵ Recently, Canali et al.¹⁵ assessed the 1-year clinical performance of a bulk-fill flowable and a regular nanofilled resin composite in NCCLs. The authors concluded that both resin composites showed acceptable clinical performances for the restoration of NCCLs. In a study with mathematical models, NCCLs restored with regular bulk-fill resin composite presented more favorable biomechanical behavior compared with another material and filling technique.⁴³ According to the manufacturer, Filtek Bulk Fill Posterior contains AUDMA (aromatic urethane dimethacrylate) and AFM (addition-fragmentation monomer), which are responsible for decreasing the number of reactive groups in the resin and for reducing the polymerization stress, respectively. Perhaps, this restorative protocol may decrease the restoration failure rates in NCCLs, improving clinical longevity. However, longer follow-ups are needed to understand the clinical performance of this material in NCCLs.

Restorations placed in lesions with 1.5 mm OGD showed no significant differences in retention rates compared with restorations placed in lesions with 3 mm OGD. A similar finding was reported in another clinical trial.⁶ These authors suggested that only some characteristics predispose restorations to retentive failure, such as obtusely angled lesions with group function in posterior immobile teeth (especially molars) in male patients.

Irrespective of the resin composite and OGD, the only signs of degradation in this study presented as marginal staining after 12 months of clinical evaluation. In clinical trials, marginal staining has been associated with the presence of a marginal defect.^{2,47} This defect may be the result of the marginal deterioration at the enamel side, since demineralization, in depth and extent, is restricted for mild self-etch adhesives; a chemical interaction is found between monomers and residual hydroxyapatite.⁴⁸ Indeed, some authors have reported that superficial discoloration is more frequent in the self-etch approach.^{36,37} Furthermore, oral microflora and dietary habits of patients can be associated with marginal staining.⁴⁹ In the present study, despite a rather rapid development, the staining was considered clinically acceptable (Bravo), ac-

Table 4: Number (Percentage) of Evaluated Restorations for Each Recall Time According to Experimental Group, Classified According to Modified US Public Health Service Criteria Compared by Kruskal-Wallis Test at p<0.05

Evaluated Criteria	Score ^a	Baseline					6 months					12 months				
		1.5 mm-C	1.5 mm-B	3 mm-C	3 mm-B	p	1.5 mm-C	1.5 mm-B	3 mm-C	3 mm-B	p	1.5 mm-C	1.5 mm-B	3 mm-C	3 mm-B	p
Retention	Alfa	35 (100)	35 (100)	35 (100)	35 (100)	>0.99	35 (100)	34 (97.1)	35 (100)	35 (100)	0.39	33 (100)	33 (97)	34 (100)	34 (97.1)	0.57
	Charlie	–	–	–	–		–	1 (2.9)	–	–		–	1 (3)	–	1 (2.9)	
Marginal staining	Alfa	35 (100)	35 (100)	35 (100)	35 (100)	>0.99	33 (94.3)	32 (94.1)	33 (94.3)	35 (100)	0.55	29 (87.9)	29 (87.9)	25 (73.5)	31 (91.2)	0.08
	Bravo	–	–	–	–		2 (5.7)	2 (5.9)	2 (5.7)	–		4 (12.1)	4 (12.1)	9 (26.5)	3 (8.8)	
Marginal adaptation	Alfa	35 (100)	35 (100)	35 (100)	35 (100)	>0.99	34 (97.1)	34 (100)	35 (100)	35 (100)	0.39	32 (97)	33 (100)	34 (100)	33 (97)	0.57
	Bravo	–	–	–	–		1 (2.9)	–	–	–		1 (3)	–	–	1 (3)	
Recurrence of caries	Alfa	35 (100)	35 (100)	35 (100)	35 (100)	>0.99	35 (100)	34 (100)	35 (100)	35 (100)	>0.99	33 (100)	33 (100)	34 (100)	34 (100)	>0.99
Anatomic form	Alfa	35 (100)	35 (100)	35 (100)	35 (100)	>0.99	35 (100)	34 (100)	35 (100)	35 (100)	>0.99	33 (100)	33 (100)	34 (100)	34 (100)	>0.99
Postoperative sensitivity	Alfa	32 (91.4)	32 (91.4)	32 (91.4)	35 (100)	0.36	32 (91.4)	33 (97)	32 (91.4)	35 (100)	0.26	33 (100)	31 (93.9)	32 (94.1)	32 (94.1)	0.41
	Bravo	3 (8.6)	3 (8.6)	3 (8.6)	–		3 (8.6)	1 (3)	3 (8.6)	–		–	2 (6.1)	2 (5.9)	2 (5.9)	
Surface texture	Alfa	35 (100)	35 (100)	35 (100)	35 (100)	>0.99	34 (97.1)	32 (94.1)	35 (100)	34 (97.1)	0.55	32 (97)	32 (97)	32 (94.1)	33 (97)	0.87
	Bravo	–	–	–	–		1 (2.9)	2 (5.9)	–	1 (2.9)		1 (3)	1 (3)	2 (5.9)	1 (3)	

Abbreviations: 1.5 mm-C, NCCLs with OGD 1.5 mm restored with Filtek Z350 XT; 1.5 mm-B, NCCLs with OGD 1.5 mm restored with Filtek Bulk Fill; 3 mm-C, NCCLs with OGD 3 mm restored with Filtek Z350 XT; 3 mm-B, NCCLs with OGD 3 mm restored with Filtek Bulk Fill; NCCL, noncarious cervical lesion; OGD, occlusogingival distance.

^a Scores Alfa and Bravo show clinically acceptable restoration, while Charlie score indicates failure.

cording to the modified USPHS criteria. In these situations, the restoration margins can be refinished and repolished without damage to improve esthetics. It should be emphasized that the discolorations were slight and superficial and required no intervention.

The stability and longevity of resin restorations in NCCLs are associated with etiologic factors and risk factors.^{7,39,50} Also, technique and adhesive material are important to the clinical performance.^{14,15,36–38} In the present study, OGD was not associated with restoration failure. The regular bulk-fill resin composite performed similarly and successfully compared with the nanofilled resin composite after a 1-year evaluation period. However, more extensive evaluations are necessary. These have been implemented to improve the understanding of the long-term performance of this material, mainly evaluating whether the OGD is important to the outcome.

CONCLUSION

This preliminary report on a 12-month evaluation had the following conclusions:

- 1. Both resin composites tested presented acceptable clinical results at the 12-month evaluation;
- 2. Filtek Bulk Fill Posterior showed similar retention rates to Filtek Z350 XT regardless of OGD;

- 3. The OGD did not affect the clinical performance of resin restorations.

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Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of the Institute of Science and Technology of São José dos Campos UNESP Review Board. The approval code for this study is 1.734.858.

Conflict of Interest

The authors of this manuscript certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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REFERENCES

1. Stojanac IL, Premovic MT, Ramic BD, Drobac MR, Stojisin IM, & Petrovic LM (2013) Noncarious cervical lesions restored with three different tooth-colored materials: Two-year results *Operative Dentistry* **38**(1) 12-20.

2. Kubo S, Yokota H, Yokota H, & Hayashi Y (2010) Three-year clinical evaluation of a flowable and a hybrid resin

- composite in non-carious cervical lesions *Journal of Dentistry* **38**(3) 191-200.
3. Kubo S, Yokota H, Yokota H, & Hayashi Y (2013) Challenges to the clinical placement and evaluation of adhesively-bonded, cervical composite restorations *Dental Materials* **29**(1) 10-27.
 4. Sugita I, Nakashima S, Ikeda A, Burrow MF, Nikaido T, Kubo S, Tagami J, & Sumi Y (2017) A pilot study to assess the morphology and progression of non-carious cervical lesions *Journal of Dentistry* **57** 51-56.
 5. 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 *Operative Dentistry* **39**(2) 144-151.
 6. Aw TC, Lepe X, Johnson GH, & Mancl LA (2005) A three-year clinical evaluation of two-bottle versus one-bottle dentin adhesives *Journal of the American Dental Association* **136**(3) 311-322.
 7. Tay FR & Pashley DH (2004) Resin bonding to cervical sclerotic dentin: A review *Journal of Dentistry* **32**(3) 173-196.
 8. Perez CR, Gonzalez MR, Prado NAS, de Miranda MSF, Macêdo MA, & Fernandes BMP (2012) Restoration of noncarious cervical lesions: when, why, and how *International Journal of Dentistry* **2012**(687058) 1-8.
 9. Luque-Martinez IV, Mena-Serrano A, Muñoz MA, Hass V, Reis A, & Loguercio AD (2013) Effect of bur roughness on bond to sclerotic dentin with self-etch adhesive systems *Operative Dentistry* **38**(1) 39-47.
 10. 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 *Dental Materials* **30**(10) 1089-1103.
 11. Santos MJ, Ari N, Steele S, Costella J, & Banting D (2014) Retention of tooth-colored restorations in non-carious cervical lesions—A systematic review *Clinical Oral Investigations* **18**(5) 1369-1381.
 12. 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 *Dental Materials* **24**(7) 915-922.
 13. 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 *Operative Dentistry* **39**(6) 578-587.
 14. Celik EU, Tunac AT, & Yilmaz F (2019) Three-year clinical evaluation of high-viscosity glass ionomer restorations in non-carious cervical lesions: A randomised controlled split-mouth clinical trial *Clinical Oral Investigations* **23**(3) 1473-1480, <http://dx.doi.org/10.1007/s00784-018-2575-y>
 15. Canali GD, Ignácio SA, Rached RN, & Souza EM (2019) One-year clinical evaluation of bulk-fill flowable vs. regular nanofilled composite in non-carious cervical lesions *Clinical Oral Investigations* **23**(2) 889-897.
 16. Ferracane JL (2011) Resin composite—State of the art *Dental Materials* **27**(1) 29-38.
 17. Leprince JG, Palin WM, Vanacker J, Sabbagh J, Devaux J, & Leloup G (2014) Physico-mechanical characteristics of commercially available bulk-fill composites *Journal of Dentistry* **42**(8) 993-1000.
 18. Moretto SG, Russo EM, Carvalho RC, De Munck J, Van Landuyt K, Peumans M, Van Meerbeek B, & Cardoso MV (2013) 3-year clinical effectiveness of one-step adhesives in non-carious cervical lesions *Journal of Dentistry* **41**(8) 675-682.
 19. Lawson NC, Robles A, Fu CC, Lin CP, Sawlani K, & Burgess JO (2015) Two-year clinical trial of a universal adhesive in total-etch and self-etch mode in non-carious cervical lesions *Journal of Dentistry* **43**(10) 1229-1234.
 20. Ichim I, Li Q, Loughran J, Swain MV, & Kieser J (2007) Restoration of non-carious cervical lesions Part I. Modeling of restorative fracture *Dental Materials* **23**(12) 1553-1561.
 21. Ichim I, Schmidlin PR, Kieser JA, & Swain MV (2007) Mechanical evaluation of cervical glass-ionomer restorations: 3D finite element study *Journal of Dentistry* **35**(1) 28-35.
 22. Braga RR, Boaro LC, Kuroe T, Azevedo CL, & Singer JM (2006) Influence of cavity dimensions and their derivatives (volume and “C” factor) on shrinkage stress development and microleakage of composite restorations *Dental Materials* **22**(9) 818-823.
 23. Pfeifer CSC, Braga RR, & Cardoso PEC (2006) Influence of cavity dimensions, insertion technique and adhesive system on microleakage of class V restorations *Journal of the American Dental Association* **137**(2) 197-202.
 24. Bucuta S & Ilie N (2014) Light transmittance and micro-mechanical properties of bulk fill vs. conventional resin based composites *Clinical Oral Investigations* **18**(8) 1991-2000.
 25. Kim RJ, Kim YJ, Choi NS, & Lee IB (2015) Polymerization shrinkage, modulus, and shrinkage stress related to tooth-restoration interfacial debonding in bulk-fill composites *Journal of Dentistry* **43**(4) 430-439.
 26. Rosatto CM, Bicalho AA, Verissimo C, Bragança GF, Rodrigues MP, Tantbirojn D, Versluis A, & Soares CJ (2015) Mechanical properties, shrinkage stress, cuspal strain and fracture resistance of molars restored with bulk-fill composites and incremental filling technique *Journal of Dentistry* **43**(12) 1519-1528.
 27. Par M, Gamulin O, Marovic D, Klaric E, & Tarle Z (2015) Raman spectroscopic assessment of degree of conversion of bulk-fill resin composites—Changes at 24 hours post cure *Operative Dentistry* **40**(3) e92-e101.
 28. Papadogiannis D, Tolidis K, Gerasimou P, Lakes R, & Papadogiannis Y (2015) Viscoelastic properties, creep behavior and degree of conversion of bulk fill composite resins *Dental Materials* **31**(12) 1533-1541.
 29. Gamarra VSS, Borges GA, Júnior LHB, & Spohr AM (2018) Marginal adaptation and microleakage of a bulk-fill composite resin photopolymerized with different techniques *Odontology* **106**(1) 56-63.
 30. van Dijken JW & Pallesen U (2016) Posterior bulk-filled resin composite restorations: A 5-year randomized controlled clinical study *Journal of Dentistry* **51** 29-35.

31. Bayraktar Y, Ercan E, Hamidi MM, & Çolak H (2017) One-year clinical evaluation of different types of bulk-fill composites *Journal of Investigative and Clinical Dentistry* **8**(2) 1-9.
32. Karaman E, Keskin B, & Inan U (2017) Three-year clinical evaluation of class II posterior composite restorations placed with different techniques and flowable composite linings in endodontically treated teeth *Clinical Oral Investigations* **21**(2) 709-716.
33. van Dijken JWV & Pallesen U (2017) Bulk-filled posterior resin restorations based on stress-decreasing resin technology: A randomized, controlled 6-year evaluation *European Journal of Oral Sciences* **125**(4) 303-309.
34. Yazici AR, Antonson SA, Kutuk ZB, & Ergin E (2017) Thirty-six-month clinical comparison of bulk fill and nanofill composite restorations *Operative Dentistry* **42**(5) 478-485.
35. Heck K, Manhart J, Hickel R, & Diegritz C (2018) Clinical evaluation of the bulk fill composite QuiXfil in molar class I and II cavities: 10-year results of a RCT *Dental Materials* **34**(6) e138-e147.
36. Perdigão J, Kose C, Mena-Serrano AP, De Paula EA, Tay LY, Reis A, & Loguercio AD (2014) A new universal simplified adhesive: 18-month clinical evaluation *Operative Dentistry* **39**(2) 113-127.
37. Peumans M, De Munck J, Van Landuyt K, & Van Meerbeek B (2015) Thirteen-year randomized controlled clinical trial of a two-step self-etch adhesive in non-carious cervical lesions *Dental Materials* **31**(3) 308-314.
38. Häfer M, Jentsch H, Haak R, & Schneider H (2015) A three-year clinical evaluation of a one-step self-etch and a two-step etch-and-rinse adhesive in non-carious cervical lesions *Journal of Dentistry* **43**(3) 350-361.
39. Oginni AO & Adeleke AA (2014) Comparison of pattern of failure of resin composite restorations in non-carious cervical lesions with and without occlusal wear facets *Journal of Dentistry* **42**(7) 824-830.
40. Schulz KF, Altman DG, Moher D, & CONSORT Group (2011) CONSORT 2010 statement: Updated guidelines for reporting parallel group randomised trials *International Journal of Surgery* **9**(8) 672-677.
41. American Dental Association Council on Scientific Affairs (2011) Acceptance program guidelines: dentin & enamel adhesive materials *American Dental Association* 1-12. Available from: www.ada.org
42. Cvar JF & Ryge G (2005) Reprint of criteria for the clinical evaluation of dental restorative materials *Clinical Oral Investigations* **9**(4) 215-232.
43. 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 *Journal of Dentistry* **76** 68-74.
44. Aw TC, Lepe X, Johnson GH, & Mancl LA (2002) Characteristics of noncarious cervical lesions: A clinical investigation. *Journal of the American Dental Association* **133**(6) 725-733.
45. Yoshihara K, Yoshida Y, Nagaoka N, Fukegawa D, Hayakawa S, Mine A, Nakamura M, Minagi S, Osaka A, Suzuki K, & Van Meerbeek B (2010) Nano-controlled molecular interaction at adhesive interfaces for hard tissue reconstruction *Acta Biomaterialia* **6**(9) 3573-3582.
46. Yoshida Y, Nagakane K, Fukuda R, Nakayama Y, Okazaki M, Shintani H, Inoue S, Tagawa Y, Suzuki K, De Munck J, & Van Meerbeek B (2004) Comparative study on adhesive performance of functional monomers *Journal of Dental Research* **83**(6) 454-458.
47. Van Landuyt KL, Peumans M, Fieuws S, De Munck J, Cardoso MV, Ermis RB, Lambrechts P, & Van Meerbeek B (2008) A randomized controlled clinical trial of a HEMA-free all-in-one adhesive in non-carious cervical lesions at 1 year *Journal of Dentistry* **36**(10) 847-855.
48. Van Landuyt KL, Kanumilli P, De Munck J, Peumans M, Lambrechts P, & Van Meerbeek B (2006) Bond strength of a mild self-etch adhesive with and without prior acid-etching *Journal of Dentistry* **34**(1) 77-85.
49. Burrow MF & Tyas MJ (2012) Clinical investigation of G-Bond resin-based adhesive to non-carious cervical lesions over five years *Australian Dental Journal* **57**(4) 458-463.
50. Rocha AC, Da Rosa W, Cocco AR, Da Silva A, Piva E, & Lund RG (2018) Influence of surface treatment on composite adhesion in noncarious cervical lesions: Systematic review and meta-analysis *Operative Dentistry* **43**(5) 508-519.