# A 24-month clinical evaluation of composite resins with different viscosity and chemical compositions: a randomized clinical trial

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**Objectives:** To evaluate the clinical performance of two methacrylate-based flowable composites and an ormocer-based flowable composite in noncarious cervical lesions (NCCLs) in adult participants. **Method and materials:** In total, 183 restorations were performed on NCCLs. All cavities were restored using a universal adhesive system (Futurabond U, Voco) with selective enamel etching and with one of the three evaluated flowable composites (n = 61): low-viscosity methacrylate-based composite (GrandioSO Flow, LV), high-viscosity methacrylate-based composite (GrandioSO Heavy Flow, HV), and an ormocer-based flowable composite (Admira Fusion Flow, ORM). All restorations were evaluated using FDI and USPHS criteria after 24 months. Kruskall-Wallis analysis of variance rank (α = .05) was used for statistical analysis. **Results:** After 24 months of clinical evaluation, 16 restorations were lost (LV = 3, HV = 10, ORM = 3) and the retention rates (95% confidence interval) were 95.0% for LV, 82.2% for HV, and 95.0% for ORM, with statistical differences observed between HV and LV as well as HV and ORM ($P < .05$). When secondary parameters were evaluated, no significant differences between groups were observed ($P > .05$). Thirty-three restorations (LV = 8, HV = 13, ORM = 12) showed minor marginal staining, 71 restorations (LV = 26, HV = 20, ORM = 25) presented small marginal adaptation defects, and one restoration for HV presented recurrence of caries. **Conclusion:** The universal adhesive associated with the ormocer-based and methacrylate-based flowable composite showed promising clinical performance after 24 months. However, the heavy-flow restorations showed significantly more failures. *(Quintessence Int 2023;54:186–199; doi: 10.3290/j.qi.b3631841)*

**Key words:** clinical performance, dental restoration, noncarious cervical lesions, randomized clinical trial, retention rate

A noncarious cervical lesion (NCCL) is described as a loss of tooth structure at the cementoenamel junction (CEJ) that is not related to bacteria.[1] These lesions usually have a multifactorial etiology, mainly by combination of three major mechanisms: friction, occlusal stress, and biocorrosion.[2] Furthermore, the development of NCCLs may be associated with gingival recession in thin periodontal biotypes, suboptimal oral hygiene,[3] and in systemic diseases and conditions that affect the progression of periodontal diseases.[4] There is an important global impact of these lesions since the prevalence of NCCLs among adults worldwide is around 47%, reaching up to 93%.[5] Usually, the presence of NCCLs may lead to esthetic problems, as well as sensitivity, affecting an individual's quality of life.[6]

Several treatment strategies for NCCLs have been reported; restorative treatment, which entails the use of an adhesive system combined with a composite resin, is the strategy most commonly used by dental practitioners.[7] Even though the restoration with composite resin does not treat the etiology of these lesions, it allows for the restoration of the tooth's structure, reduces further wear, relieves dentin hypersensitivity, and improves esthetics.[8] On the other hand, composite resin restorations have presented some limitations in cervical areas related to polymerization shrinkage and tensile stress caused by occlusal loading, resulting in increased postoperative sensitivity, poor marginal adaptation, and low retention rates.[9]

The use of flowable composite resin instead of regular-viscosity composite resins has been proposed to restore NCCLs, as they show similar clinical performance and good handling properties.[10,11] The low viscosity of flowable composite resins stems from the inclusion of a lower filler load and less viscous resin content, resulting in a lower elastic modulus, which differs from regular viscosity.[12] In theory, this reduced elastic modulus can absorb the stresses generated during the polymerization shrinkage of composites and during mechanical loading under function.

However, flowable composite resins with high filler content have recently been launched in the market.[13] These materials are considered heavy-viscosity flowable composites, a term used and indicated by the manufacturers (G-aenial Universal Flo, GC; GrandioSO Heavy Flow, Voco), and they are claimed to have improved mechanical properties.[14] This improvement occurs because the manufacturers increase the filler content of a composite resin (around 78% w/w)[12] and, at the same time, add low-viscosity resinous monomers to maintain flowability.[15,16] When evaluated in Class 2 restorations, heavy-viscosity flowable composites showed satisfactory clinical performance, with the advantages of easy handling, better cavity-wall adaptation, and less time needed to place the restorations.[17,18] However, to the present authors' knowledge, only one short-term clinical trial has been conducted to evaluate these different viscosities of flowable composites in NCCLs.[19]

On the other hand, in an attempt to overcome the problems created by the polymerization shrinkage of conventional methacrylate-based composites resins, one alternative was developed, called ormocer (ORganically MOdified CERamic), which is formulated by inorganic-organic co-polymers with inorganic silanated filler particles.[20] Recently, flowable ormocer-based composite resins were launched on the market (eg, Admira Fusion Flow, Voco; Ceram X, Dentsply Sirona; Definite, Evonik [previously Degussa]) showing improved biocompatibility compared to methacrylate-based composite resin,[21] as well as an acceptable clinical performance in Class 2 restorations after 2 years.[22,23] Long-term clinical studies of the ormocer-based composites generally focus on regular-viscosity composites and posterior restorations.[24,25] Only one short-term clinical trial has been conducted to evaluate the different chemistries of these new flowable composite resins in NCCLs.[19]

Therefore, in an attempt to conduct a longer follow-up observation of the aforementioned restorative materials' clinical performance, the aim of this double-blind randomized controlled clinical trial was to evaluate the clinical performance of two methacrylate-based flowable composites and an ormocer-based flowable composite in NCCLs in adult participants. The null hypotheses tested were that:

- there is no statistical difference between the retention rates of NCCL restorations built up with an ormocer-based flowable composite and with methacrylate-based flowable composites with different viscosities when evaluated using World Dental Federation (FDI) or United States Public Health Service (USPHS) criteria
- there is no statistical difference in the secondary outcomes (marginal staining, marginal adaptation, recurrence of caries, and postoperative sensitivity) of NCCL restorations built up with an ormocer-based flowable composite and with methacrylate-based flowable composites with different viscosities when evaluated using FDI or USPHS criteria.

## Method and materials

### *Ethics approval and protocol registration*

The Ethics Committee on Involving Human Subjects of the State University of Ponta Grossa/PR, Brazil, reviewed and approved the protocol and consent form for this study (protocol 3.604.611; 2019). This study was registered in the Brazilian Registry of Clinical Trials (REBEC) under the number RBR-998R5B. The experimental design followed the Consolidated Standards of Reporting Trials (CONSORT) statements.[26]

### *Trial design, settings, and locations of data collection*

All the restorations were inserted in the clinics of the State University of Ponta Grossa/PR, Brazil, from June 2019 to November 2019. The 24-month follow-up carried from July 2021 to November 2021.

### *Participant recruitment*

Subjects were recruited as they sought treatment in the State University of Ponta Grossa's dental clinics. Those who qualified for the study were recruited in the order in which they reported for screening session, forming a convenience sample. No advertisement was made for participant recruitment. The participants were informed about the nature and the objectives of the study, but they were not aware of what tooth received the specific treatments under evaluation. Written informed consent was obtained from all participants prior to starting the treatment.

### *Sample size*

The primary outcome of this study was retention rate. The sample size calculation was made using online software (https://sealeden-

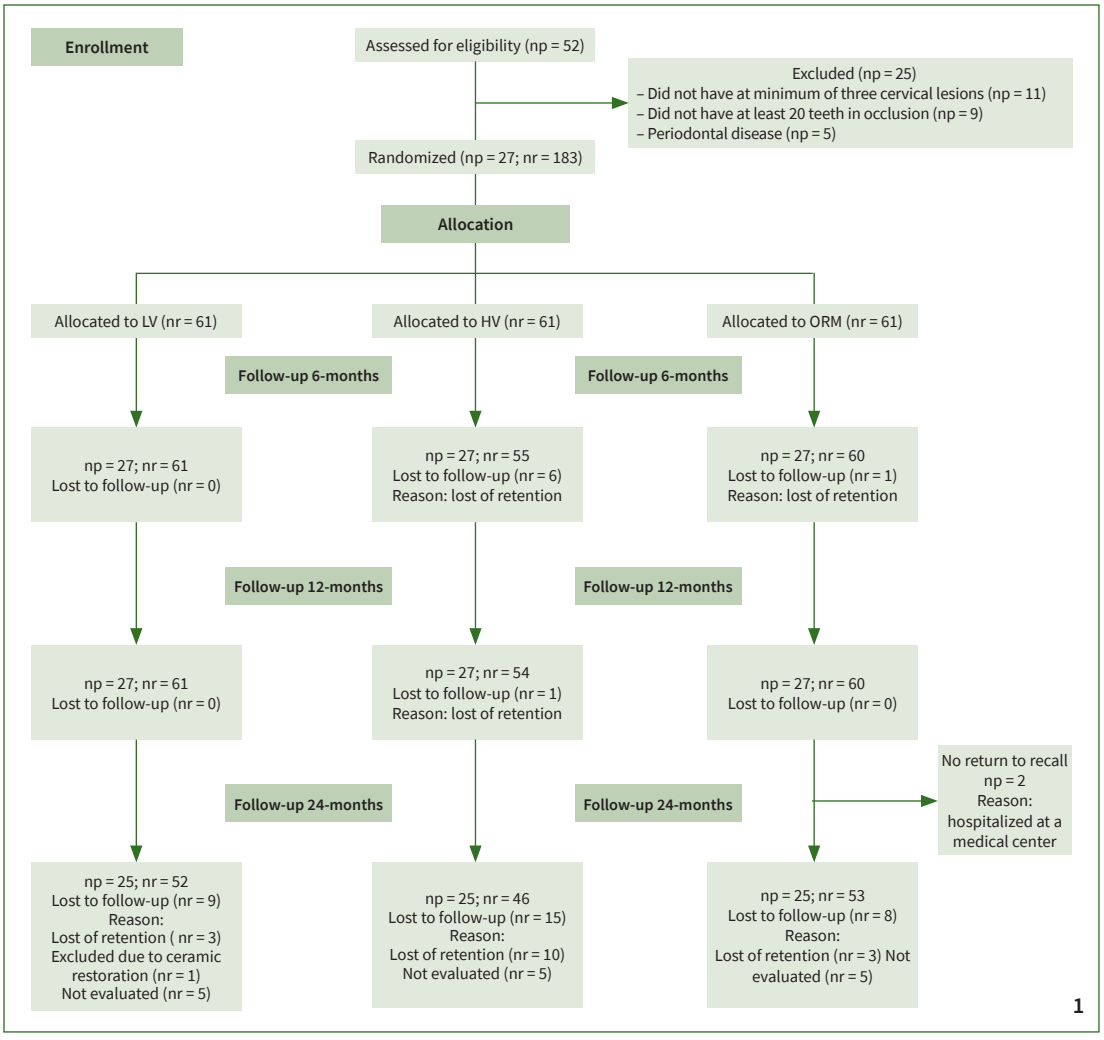



**Fig 1** Participant flow diagram in the different phases of the study design (HV, heavy viscosity; LV, low viscosity; np, number of participants; nr, number of restorations; ORM, ormocer).

velope.com), based on the retention rate of flowable composites at 3 years that was reported to be approximately 80%.[27] A minimal sample size of 56 restorations per group was required to detect a difference of 25% among the tested groups, with an α of .05, a power of 90%, and an equivalence limit of 25%. To prevent the dropout effect more 10% of restorations were added. Therefore, 61 restorations per group was used as the final sample size.

## *Eligibility criteria*

A total of 52 participants were examined by two-precalibrated dental practitioners to ensure the subjects met the inclusion and exclusion criteria. Following theses examinations, 25 participants were excluded, and 27 were recruited after accepting the terms of the research (Fig 1). The evaluations were performed using a mouth mirror, explorer, and periodontal probe.

Participants had to be in good general health (ASA I, a normal healthy participant; and ASA II, a participant with mild systemic disease without substantive functional limitations),[28] be older than 18 years old, have an acceptable oral hygiene level according to the Simplified Oral Hygiene Index (OHI-S),[29] and present at least 20 teeth under occlusion. They were required to have at least three comparable NCCLs (in size, format, and dimensions) in three different teeth that needed restoration. These lesions had to be noncarious, nonretentive, deeper than 1 mm, and involve both the enamel and dentin of vital teeth without mobility. The cavosurface margin could not involve more than 50% of enamel.[30] All subjects were given oral hygiene instructions before performing the operative treatment. Subjects with extremely poor oral hygiene (OHI-S more than 3),[29] severe or chronic periodontitis (teeth with probing pocket depth more than 4 mm with bleeding on probing and clinical attachment loss more than

**Table 1** Application mode of the adhesive system and composite resin in the different groups

| Materials | Composition | Application mode |
|---|---|---|
| Vococid (Voco) | 35% phosphoric acid. | Apply etchant only on enamel for 15 s (selective enamel etching). Rinse for 10 s. |
| Futurabond U (Voco) | HEMA, bis-GMA, HEDMA, methacrylate phosphoric acid ester, methacrylate-modified polyacid, UDMA, initiators and ethanol. | Air dry to remove excess of water. Keep dentin dry, do not overdry. Apply the adhesive for 20 s with vigorous agitation. Gently air thin for 5 s. Light-cure for 10 s. (Bluephase N, 1200 mW/cm$^2$) |
| GrandioSO Flow (low viscosity [LV]; Voco) | Organic matrix: bis-GMA, HEDMA, TEGDMA, bis-EMA, canforquinone, amine and butylhydroxytoluene. | Placed in increments of 2 mm maximum. Light-curing for 20 s each layer (Bluephase N, 1200 mW/cm$^2$) |
| | Inorganic fillers: barium aluminum borosilicate glass ceramic filler, silicon dioxide nanoparticles (0.02 to 1 µm). Filler content: 87% w/w. | |
| GrandioSO Heavy Flow (heavy viscosity [HV], Voco) | Organic matrix: bis-GMA, TEGDMA, bis-EMA, canforquinone, amine and butylhydroxytoluene. | Placed in increments of 2 mm. Light-curing for 20 s each layer (Bluephase N, 1200 mW/cm$^2$) |
| | Inorganic fillers: barium aluminum borosilicate glass ceramic filler, silicon dioxide nanoparticles (0.02 to 0.04 µm). Filler content: 89% w/w. | |
| Admira Fusion Flow (ormocer [ORM]; Voco) | Organic matrix: organically modified ceramic (Ormocer). | Placed in increments of 2 mm. Light-curing for 20 s each layer (Bluephase N, 1200 mW/cm$^2$) |
| | Inorganic fillers: barium aluminum borosilicate glass ceramic filler, silicon dioxide nanoparticles (0.02 to 1 µm). Filler content: 83% w/w. | |

bis-EMA, bisphenol-A ethoxylated dimethacrylate; bis-GMA, bisphenol-A glycidyl methacrylate; HEDMA, 1,6-exanodiol dimethacrylate; HEMA, 2-hydroxyethylmethacrylate; TEGDMA, triethyleneglycol dimethacrylate; UDMA, urethane dimethacrylate.

3 mm in more than four teeth),[31] heavy bruxism habits (severe masticatory muscle pain, temporomandibular joint pain, or extreme tooth wear),[32] or use of orthodontic devices or removable prothesis were excluded from the study.

### *Randomization sequence generation and allocation concealment*

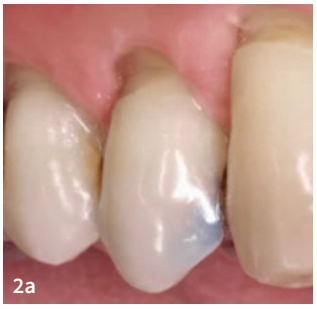
The randomization process was performed using online software (https://sealedenvelope.com) by a staff member not involved in the research protocol. In total, 183 teeth were treated as the experimental unit and were randomized in blocks of three to ensure an equal number of restorations in each of the three research groups. Details of the allocated groups were recorded on cards contained in sequentially numbered, opaque, and sealed envelopes. These were prepared by a staff member not involved in any of the phases of the clinical trial. The allocation assignments were revealed by opening the envelope immediately before the restorative procedure to guarantee the concealment of the random sequence and prevent selection bias. The examiners and the participants were blinded to the group assignments.

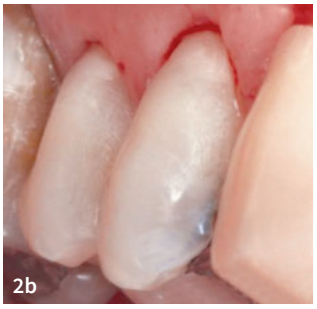
### *Baseline characteristics of the selected teeth*

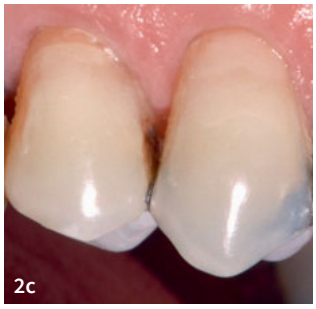
The features of the NCCLs were evaluated before the placement of the restorations by two trained and calibrated dental practitioners involved in the selection of participants, and who carried out the restorative procedures. The degree of dentin sclerosis was evaluated according to an earlier scoring system[33] modified by Swift et al,[34] as follows:

1. No sclerosis present; dentin is light yellowish or whitish, with little discoloration; dentin is opaque, with little translucency or transparency
2. More sclerosis than in category 1 but less than halfway between categories 1 and 4
3. Less sclerosis than in category 4 but more than halfway between categories 1 and 4
4. Significant sclerosis present; dentin is dark yellow or even discolored (brownish); glassy appearance, with significant translucency or transparency evident.

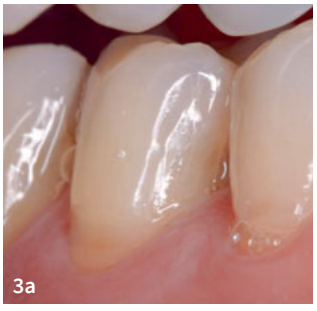
The lesion dimensions in mm (height, width, and depth) and the geometry of the lesion (evaluated by profile photograph and labeled at < 45, 45 to 90, 90 to < 135, and > 135 degrees)

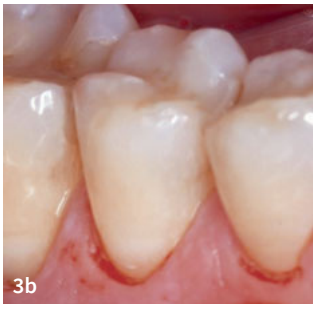


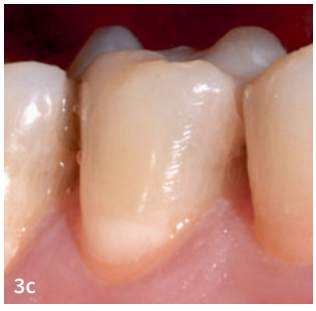




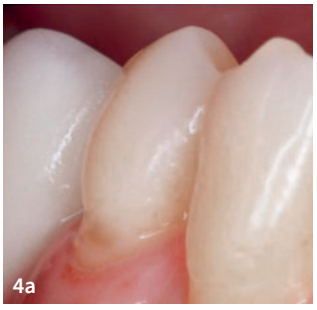

**Figs 2a to 2c** Representative photographs of clinical performance of low-viscosity, composites at *(a)* baseline, *(b)* immediately after restorative procedure, and *(c)* at the 24-month evaluation. Description according to the FDI criteria: tooth 14 "clinically very good" in all parameters.

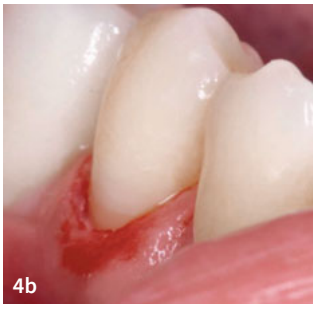


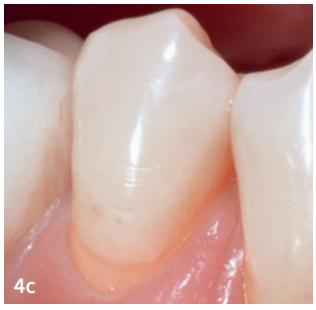





**Figs 3a to 3c** Representative photographs of heavy-viscosity composites at *(a)* baseline, *(b)* immediately after restorative procedure, and *(c)* at the 24-month evaluation. Description according to the FDI criteria: tooth 45 "clinically very good" in all parameters.








**Figs 4a to 4c** Representative photographs of ormocer-based flowable composites at *(a)* baseline, *(b)* immediately after restorative procedure, and *(c)* at the 24-month evaluation. Description according to the FDI criteria: tooth 44 "clinically good" in marginal staining and marginal adaptation.

were recorded.[35] Other features, such as the presence of attrition facets,[36] were also observed and recorded. Preoperative sensitivity was evaluated prior to examination (spontaneous), by applying air stream for 10 seconds from a dental syringe placed 2 cm from the tooth surface (air dry). These features were recorded to allow comparison of the baseline features of the dentin cavities among experimental groups.

For the calibration procedure step, the study director placed one restoration of each group in order to identify all steps involved in the protocol. Then, two operators placed three restorations in a clinical setting, one of each group under the supervision of the study director in a clinical setting. Any defects of the restorative protocol were identified and discussed with the operator before starting the study. At this point, the operators were considered calibrated to perform the restorative procedures. The calibrated operators restored all teeth under the supervision of the study director.

## *Intervention: restorative procedure*

In order to avoid contamination, each tooth was separately restored from others, even when restorations in neighboring teeth were to be performed. A detailed protocol standardized the interventions, summarized as follows. A preliminary dental prophylaxis of the tooth surface was performed with pumice and water in a rubber cup with the aim of removing any remaining dental plaque, followed by rinsing and drying. Using a shade guide, the proper shade of the resin composite was determined. Local anesthesia was applied with 3% mepivacaine solution (Mepisv, DFL), and the restoration was placed under rubber dam isolation. Following the guidelines of the American Dental Association,[37] the operators did not prepare any additional retention or bevel. The universal adhesive system Futurabond U (Voco) was applied in the self-etch mode associated with selective enamel etching (Vococid; 35% phosphoric acid, Voco) applied

for 15 seconds according to the manufacturer's instructions, in all cavities. After adhesive application, the adhesive layer was light-cured for 10 seconds at 1,200 mW/cm$^2$ (Bluephase N, Ivoclar Vivadent). The composition and application mode are described in Table 1. Subsequently, the cavities were restored with one out of the following three flowable composites:

- Ormocer-based flowable composite (Admira Fusion Flow, Voco) was directly placed in increments of 2 mm maximum, followed by light-curing with an irradiance of 1,200 mW/cm$^2$ (Bluephase N, Ivoclar Vivadent) for 20 seconds each.
- Low-viscosity methacrylate-based composite (GrandioSo Flow, Voco) was placed as reported for the ormocer-based flowable composite.
- High-viscosity methacrylate-based composite (GrandioSo Heavy Flow, Voco) was placed as reported for the ormocer-based flowable composite.

A radiometer (Bluephase Meter II, Ivoclar Vivadent) was used to check the irradiance for every three restorations. After cavity filling, the restorations were finished immediately with fine and extra-fine #2200 diamond burs (KG Sorensen) and polished with OptraPol NG (Ivoclar Vivadent) under constant water-cooling.

### *Clinical evaluation*

Two blinded, experienced, and calibrated dental practitioners (that were not involved in the restoration procedure) performed the clinical evaluation. Participants were also blinded to group assignment in a double-blind randomized controlled trial. For training purposes, the examiners observed 10 photographs that were representative of each score for each criterion. They evaluated 10 to 15 subjects each on two consecutive days. These subjects had cervical restorations and did not participate in this project. An intra-examiner and inter-examiner agreement of at least 85% was necessary before beginning the evaluation.[35]

All parameters during evaluation were recorded using a standardized paper case report form and intraoral digital photographs. The evaluation paper had to be sent after each observation to the research staff, so that evaluators were blinded to group assignment during follow-up recalls. Two criteria were used for evaluation of the restorations: the FDI[37,38] and USPHS criteria (adapted by Dalton Bittencourt et al[39] and Perdigão et al[40] immediately after restorative procedure [baseline], and after 6, 12, 18, and 24 months of clinical service).

The primary outcome was retention/fracture, but the following secondary outcomes were also evaluated: marginal staining, marginal adaptation, postoperative sensitivity, and recurrence of caries. The postoperative sensitivity was performed 1 week after the restorative procedure, by asking the participant if they experienced any pain during the period. These variables were ranked according to the criteria in the following scores:

- FDI criteria: clinically very good [VG]; clinically good [GO]; clinically sufficient/satisfactory [SS]; clinically unsatisfactory [UN], and clinically poor [PO]
- USPHS criteria: Alpha [excellent]; Bravo [acceptable]; and Charlie [bad].

Both examiners evaluated all the restorations once and independently. When disagreements occurred during the evaluations, a consensus had to be reached before the participant was dismissed. All restorations scored as clinically unsatisfactory or poor by FDI criteria at one recall were accounted as cumulative failure at the next follow-up evaluation. Each failed restoration due to retention loss was replaced with a new composite resin restoration.[37] These new restorations were not included as part of the study for further evaluations. Repaired restorations (ie, due to secondary caries) were considered as a relative failure and could be monitored and evaluated as an integral part of restoration for further evaluations.[38] Participants' restorations whose evaluation was not possible to be performed, as well as excluded restorations were considered lost to follow-up.

### *Statistical analysis*

The statistical analysis followed the intention-to-treat protocol, according to CONSORT's suggestion.[26] Descriptive statistics were used to describe the distributions of the evaluated criteria. The survival rates (retention/fracture data) of different groups of materials were calculated by the Kaplan–Meier procedure, estimating the hazard ratios (HRs) and 95% confidence intervals (CIs). The log-rank test was used to compare the survival distributions of these restorations ($\alpha = .05$).

For the secondary outcome (marginal staining, marginal adaptation, postoperative sensitivity, and recurrence of caries), in each overall parameter (FDI and USPHS), the differences between the ratings of the three groups after 24 months were tested by Kruskall–Wallis analysis of variance rank and Mann–Whitney test ($\alpha = .05$). Cohen kappa statistics were used to test the inter-examiner agreement ($\alpha = .05$) (MedCalc Software, Version 19.1).

## Results

Twenty-five of 52 subjects were excluded from the study because they did not fulfill the inclusion criteria. Therefore, the study in-

**Table 2** Characteristics of the research subjects and the noncarious cervical lesions (NCCLs) per group

| Characteristic | | | No. of subjects | | |
|---|---|---|---|---|---|
| Characteristics of research subjects | Gender distribution | Male | 12 | | |
| | | Female | 15 | | |
| | Age distribution (y) | 20–29 | 3 | | |
| | | 30–39 | 2 | | |
| | | 40–49 | 6 | | |
| | | 50–59 | 11 | | |
| | | 60–69 | 2 | | |
| | | > 69 | 3 | | |
| **Characteristic** | | | **No. of lesions** | | |
| | | | **LV** | **HV** | **ORM** |
| Characteristics of NCCL lesions | Shape, degree of angle, degrees | < 45 | 6 | 7 | 9 |
| | | 45–90 | 26 | 17 | 18 |
| | | 90–135 | 7 | 6 | 9 |
| | | > 135 | 22 | 31 | 25 |
| | Cervico-incisal height, mm | < 1.5 | 7 | 10 | 13 |
| | | 1.5–2.5 | 21 | 21 | 24 |
| | | 2.6–4.0 | 28 | 24 | 19 |
| | | > 4.0 | 4 | 5 | 4 |
| | Degree of sclerotic dentin | 1 | 18 | 17 | 20 |
| | | 2 | 14 | 13 | 12 |
| | | 3 | 12 | 9 | 12 |
| | | 4 | 7 | 12 | 7 |
| | Presence of antagonist | Yes | 61 | 61 | 61 |
| | | No | 0 | 0 | 0 |
| | Attrition facet | Yes | 12 | 11 | 16 |
| | | No | 49 | 50 | 45 |
| | Preoperative sensitivity (spontaneous) | Yes | 61 | 61 | 61 |
| | | No | 0 | 0 | 0 |
| | Preoperative sensitivity (air dry) | Yes | 23 | 17 | 23 |
| | | No | 38 | 45 | 37 |
| | Tooth distribution — Anterior | Incisor | 6 | 9 | 16 |
| | | Canines | 14 | 8 | 9 |
| | Tooth distribution — Posterior | Premolar | 34 | 29 | 26 |
| | | Molar | 12 | 12 | 8 |
| | Arc distribution | Maxillary | 33 | 31 | 29 |
| | | Mandibular | 28 | 30 | 32 |

HV, high viscosity; LV, low viscosity; ORM, ormocer.

cluded 27 subjects (12 male and 15 female). In total, 183 restorations were placed, 61 in each group (Fig 1). From the 27 selected participants, two participants received 12 restorations each, three participants received nine restorations each, and 22 participants received six restorations each. The restorative procedures were implemented exactly as planned, and no modification was performed. Some gingival inflammation was observed immediately after the restoration placement (Figs 2 to 4, Baseline). However, during the follow-ups, gingival health was completely recovered without signs of recession or any periodontal condition in the restored teeth (Figs 2 to 4). Table 2 shows all baseline details relative to the research subjects and characteristics of the restored lesions. The overall Cohen kappa statistics (0.96) showed strong agreement between the examiners. All research subjects were evaluated at baseline and at the 6- and 12-month recalls. Two subjects did not attend at the 24-month recall because they were hospitalized at a local medical center. One restoration was excluded because the tooth received a ceramic crown restoration.

### Retention and fracture

Tables 3 and 4 display the data regarding follow-up times. After 24 months of clinical evaluation, 16 restorations were lost (three for LV, three for ORM, and 10 for HV). According to FDI and USPHS criteria, the 24-month retention/fracture rates (95% CI) were 95.0% (95% CI 85.4 to 98.2%) for LV, 82.2% (95% CI 70.1 to 90.0%) for HV, and 95.0% (95% CI 85.4 to 98.2%) for ORM (Table 5).

The Kaplan–Meier curves showed significant differences (Log-rank test, $P = .0007$) among the cumulative probability of the primary endpoint, which was loss of retention/fracture (Fig 5). Table 6 depicts the paired comparisons among the three resin composites as the hazard ratios. Significant differences were observed in the comparisons of HV and LV (HR = 2.73; 95% CI 1.41 to 5.27, $P = .0007$) as well as HV and ORM (HR = 2.50; 95% CI 1.29 to 4.83, $P = .0007$), meaning that NCCLs receiving the HV composite resin were on average 2.7 and 2.5 times more likely to debond/fracture than those receiving the ORM or LV composite resin, respectively.

Regarding the participants, one restoration of each group was lost in three participants. Seven different participants lost one restoration each, all from the HV group. As some cavity characteristics could be considered responsible for influencing the clinical performance of cervical composite restorations, a more accurate description of the lost restoration was performed. Regarding the sclerotic dentin, the loss of restorations was distributed as follows: GradioSO Flow (degree 1, 33%; degree 3, 67%); GradioSO Heavy Flow (degree 1, 30%; degree 2, 30%; degree 3, 10%; degree 4, 30%); and ormocer (degree 1, 67%; degree 3, 33%). Regarding the degree of angle, the loss of restorations was distributed as follows: GradioSO Flow (< 45 degrees, 33%; 45 to 90 degrees, 33%; > 135 degrees, 33%); GradioSO Heavy Flow (< 45 degrees, 30%; 45 to 90 degrees, 20%; 90 to 135 degrees, 30%; > 135 degrees, 20%); and ormocer (< 45 degrees, 33%; 90 to 135 degrees, 67%). Although no statistical analysis was performed, mainly due to the low number of loss restorations, the descriptive statistics suggested that a similar percentage of restorations were lost, regardless of sclerotic dentin degree or degree of cavity angle.

### Marginal staining

After 24 months of clinical evaluation, 33 restorations (13 for HV, 12 for ORM, and 8 for LV) showed minor marginal staining according to the FDI criteria (Table 3), and four restorations (two for HV and two for ORM) according to USPHS criteria (Table 4). No significant difference was detected between any pair of groups at the 24-month recall ($P = 1.0$; Tables 3 and 4).

### Marginal adaptation

After 24 months of clinical evaluation, 71 restorations (20 for HV, 25 for ORM, and 26 for LV) showed minor marginal adaptation discrepancies according to the FDI criteria (Table 3), and six restorations (four for HV, one for ORM, and one for LV) according to USPHS criteria (Table 4). No significant difference was detected between any pair of groups at the 24-month recall ($P = 1.0$; Tables 3 and 4).

### Other parameters

No restorations had postoperative sensitivity to air at the 1-week evaluation or at the 6-, 12-, or 24-month recall according to both criteria ($P = 1.0$; Tables 3 and 4). One restoration for HV showed recurrence of caries after 24 months of clinical evaluation according to FDI and USPHS criteria ($P = .31$; Tables 3 and 4).

## Discussion

The present double-blind, randomized controlled clinical trial indicated that after 24 months of evaluation, NCCL restorations built up with low-viscosity flowable composite (GrandioSo Flow) showed a higher retention rate than those with heavy-viscosity flowable composite (GrandioSo Heavy Flow). Therefore, the first null hypothesis was partially rejected.

To make a resin composite more flowable, a common alternative manufacturers use is to reduce the filler content and increase the volume of resin matrix compared to nonflowable composite,[15,16] allowing for a closer adaptation to the cavity walls as well as greater flow and flexibility. In this context, GrandioSo Flow, which shows lower viscosity than GrandioSo Heavy Flow, could be expected to present a lower amount of filler content, reduced properties and, consequently, poor clinical performance. However, this was not confirmed in the previous literature because these two methacrylate-based flowable composites have almost the same amount of filler.[12] In that study, the authors stated that GrandioSO Flow and GrandioSO Heavy Flow contain 77.3% w/w and 78.6% w/w of filler content, respectively, and that those values were even higher than the other flowable composites investigated.[12] Jager et al[12] proposed that the high filler content and maintained flowability could be a result of other factors, such as the small size of fillers and the quality of silanization, as well as the differences between resinous monomers' composition.

**Table 3** Number of evaluated restorations for each experimental group classified according to the World Dental Federation (FDI) Criteria[37,38]

| | | Baseline | | | 6 months | | | 12 months | | | 24 months | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| FDI criteria | Group | LV | HV | ORM | LV | HV | ORM | LV | HV | ORM | LV | HV | ORM |
| Marginal staining | VG | 61 | 61 | 61 | 60 | 52 | 59 | 60 | 51 | 59 | 44 | 33 | 41 |
| | GO | 0 | 0 | 0 | 1 | 2 | 1 | 1 | 2 | 1 | 8 | 11 | 10 |
| | SS | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 2 | 2 |
| | UN | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | PO | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Fractures and retention | VG | 61 | 61 | 61 | 60 | 52 | 57 | 60 | 51 | 57 | 48 | 43 | 51 |
| | GO | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 1 | 1 | 1 | 3 | 2 |
| | SS | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 1 | 1 | 3 | 0 | 0 |
| | UN | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 |
| | PO | 0 | 0 | 0 | 0 | 6 | 1 | 0 | 7 | 1 | 3 | 10 | 3 |
| Marginal adaptation | VG | 61 | 61 | 61 | 59 | 54 | 60 | 59 | 53 | 58 | 26 | 26 | 28 |
| | GO | 0 | 0 | 0 | 1 | 1 | 0 | 1 | 1 | 2 | 25 | 16 | 23 |
| | SS | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 1 | 4 | 2 |
| | UN | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | PO | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Postoperative (hyper-) sensitivity | VG | 61 | 61 | 61 | 61 | 55 | 60 | 61 | 54 | 60 | 52 | 46 | 53 |
| | GO | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | SS | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | UN | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | PO | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Recurrence of caries | VG | 61 | 61 | 61 | 61 | 55 | 60 | 61 | 54 | 60 | 52 | 45 | 53 |
| | GO | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | SS | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | UN | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | PO | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 |

GO, clinically good; HV, heavy viscosity; LV, low viscosity; ORM, ormocer; PO, clinically poor; SS, clinically sufficient/satisfactory; UN, clinically unsatisfactory; VG, clinically very good.

In fact, the filler content reported by Jager et al[12] did not match with the manufacturer's data because manufacturers assess the filler content after silanization of the fillers and silane quantity increases the percentage values; in contrast the authors had assessed the filler content after silane was eliminated by the calcination method, thus it was not taken into account in the measurements.[12]

According to the manufacturer's information, GrandioSo Heavy Flow contains 2.5% to 5% of bisphenol-A ethoxylated dimethacrylate (bis-EMA), a highly viscous monomer.[41] This explains the material's higher viscosity compared to GrandioSo Flow, as previously reported.[12] In contrast, GrandioSO Flow presents a lower amount of bis-EMA (≤ 2.5%) than GrandioSO Heavy Flow and contains 5% to 10% 1,6-exanodiol dimethacrylate (HEDMA, a diluent monomer), which decrease the material's viscosity. Although these characteristics did not affect either material's mechanical properties, they seem to significantly change their viscosity, with GrandioSO Flow showing lower viscosity than GrandioSO Heavy Flow.[12] The higher viscosity of GrandioSO Heavy Flow probably affects its ability to become moist and adapt well to cavity margins and walls in NCCLs, causing a significant loss of retention, as suggested by Matos et al.[19]

At first glance, the present study's results seem to demonstrate controversial results when compared to a systematic review published by Szesz et al.[27] In that study, the authors evaluated flowable composites' clinical performance in comparison with regular-viscosity composites of restorations placed in NCCLs. The results showed no significant improvement when a flowable composite was applied. However, a high-viscosity flowable composite was used in the present study instead (GrandioSO Heavy Flow). In the study by Szesz et al,[27] only the first generation of flowable composites was evaluated. Also, a flowable composite was compared to a regular-viscosity composite different from that evaluated in the present study. In several studies, highly filled flowable composites showed mechanical properties that are comparable to those of regular- and high-viscosity composites.[12,42-44] Therefore, future studies are necessary to evaluate the use of low-filled and flowable composites in comparison with high-filled and non-flowable composites to confirm the present hypothesis.

**Table 4** Number of evaluated restorations for each experimental group according to the modified United States Public Health Service (USPHS) criteria[39,40]

| USPHS criteria | Score | Baseline | | | 6-months | | | 12-months | | | 24-months | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | LV | HV | ORM | LV | HV | ORM | LV | HV | ORM | LV | HV | ORM |
| Marginal staining | Alpha | 61 | 61 | 61 | 61 | 55 | 60 | 61 | 54 | 60 | 52 | 44 | 51 |
| | Bravo | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 2 |
| | Charlie | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Retention | Alpha | 61 | 61 | 61 | 61 | 55 | 60 | 61 | 54 | 60 | 49 | 46 | 53 |
| | Bravo | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 0 | 0 |
| | Charlie | 0 | 0 | 0 | 0 | 6 | 1 | 0 | 7 | 1 | 3 | 10 | 3 |
| Fracture | Alpha | 61 | 61 | 61 | 60 | 53 | 58 | 60 | 52 | 58 | 49 | 46 | 52 |
| | Bravo | 0 | 0 | 0 | 1 | 2 | 2 | 1 | 2 | 2 | 3 | 0 | 1 |
| | Charlie | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Marginal adaptation | Alpha | 61 | 61 | 61 | 60 | 55 | 60 | 60 | 54 | 60 | 51 | 42 | 51 |
| | Bravo | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 1 | 4 | 2 |
| | Charlie | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Postoperative sensitivity | Alpha | 61 | 61 | 61 | 61 | 55 | 60 | 61 | 54 | 60 | 52 | 46 | 53 |
| | Bravo | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Charlie | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Recurrence of caries | Alpha | 61 | 61 | 61 | 61 | 55 | 60 | 61 | 54 | 60 | 52 | 45 | 53 |
| | Bravo | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Charlie | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 |

HV, heavy viscosity; LV, low viscosity; ORM, ormocer.

Regarding the ormocer-based flowable composite (Admira Fusion Flow), the results of the present study showed similar retention rates to the low-viscosity flowable composite (GrandioSO Flow) in NCCLs. Therefore, the first null hypothesis was partially rejected.

The first generation of ormocer-based composites showed poor long-term clinical behavior of restorations carried out with these materials compared to methacrylate-based composites. Recently, pure ormocer composites were developed, such as Admira Fusion Flow. According to the manufacturer, the composition contains no diluent methacrylate monomer. It is composed of inorganic-organic copolymers with inorganic silanated filler particles[20] in a three-dimensional structure, and these filler particles are similar to methacrylate-based composites. These characteristics allowed the ormocer to achieve a higher degree of conversion[45] without developing greater polymerization shrinkage and stress, compared to methacrylate-based composites,[45,46] even with the development of improved mechanical properties compared to methacrylate-based composites.[12,43,44,46,47] All these features confirm the good clinical performance of restorations performed with pure ormocer when evaluated in posterior teeth[22,23,48] and in NCCLs.[19,49-51]

It is worth mentioning that the retention rates of ormocer-based and methacrylate-based composites were similar to those observed in the literature.[45,46] For instance, Celik et al[50] found retention rates of 90% and 84% for restorations with ormocer and methacrylate-based composites, respectively, after 24 months of clinical evaluation. Albuquerque et al[49] found a retention rate of 94% when ormocer restorations were clinically evaluated after 18 months. Both retention rates are similar to those observed in the present study (95%).

Some structural characteristics of the NCCLs, such as cavity shape/angle and sclerotic dentin degree, could influence in the clinical performance of composite restorations.[52] In the present study, GradioSO Heavy Flow presented the lowest retention rate and a higher number of lesions with sclerotic dentin of degree 4 and the highest angle degree. However, a similar percentage of restoration lost was found in each sclerotic dentin degree (degree 1, 30%; degree 2, 30%; degree 3, 10%; degree 4, 30%) and in each degree of angle (< 45 degrees, 30%; 45 to 90 degrees, 20%; 90 to 135 degrees, 30%; > 135 degrees, 20%), ie, there was no significant influence of these characteristics on the material's retention rate. A recent systematic review and meta-analysis showed that the baseline characteristics may not affect the clinical restorative success.[53] Even so, a correlation statistical analysis should be done in future clinical studies for stronger evidence.

As noted, the primary outcome of the present study was retention rate, which will lead to a restoration replacement. How-

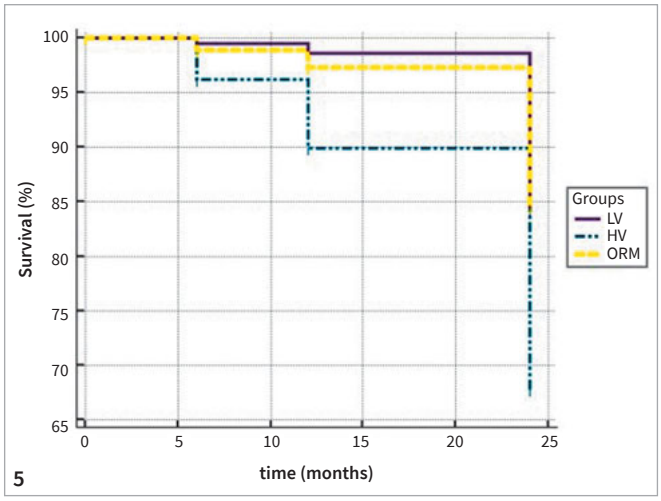



**Fig 5** Survival curves for all groups (HV, heavy viscosity; LV, low viscosity; ORM, ormocer).

**Table 5** Absolute risk (95% CI) and relative risk (95% CI) for outcome retention for different groups after 24-month of clinical evaluation

| Group | Absolute risk (95% CI) | Relative risk (95% CI)* |
|---|---|---|
| Low viscosity | 95.0 (85.4 – 98.2) | NA |
| Heavy viscosity | 82.2 (70.1 – 90.0) | 3.00 (0.08 – 1.03) |
| Ormocer | 95.0 (85.4 – 98.2) | 1.00 (0.45 – 2.21) |

*Related to low viscosity group.
NA, not applicable.

**Table 6** Retention loss hazard ratio (95% CI) for pairwise comparison of different groups

| Pairwise comparison | Hazard ratio (95% CI) |
|---|---|
| Heavy viscosity vs low viscosity | 2.73 (1.41 – 5.27)* |
| Ormocer vs low viscosity | 1.09 (0.56 – 2.11) |
| Heavy viscosity vs Ormocer | 2.50 (1.29 – 4.83)* |

*Indicates groups significantly different.

ever, secondary outcomes, such as secondary caries, could lead to a restoration replacement or repair.[37] Restoration replacement affects its longevity, but the repaired one can be considered a relative failure, being further evaluated as an integral part of restoration.[38] The previously outcome definition led the authors to have clear results of failed and relative failed restorations.

Regarding the secondary outcomes, no significant differences were observed when different materials were compared, and comparable results to those presented in the literature were observed. However, despite some differences observed in the present study, the majority of restorations were rated, using FDI and USPHS criteria, as clinically acceptable, resulting in no significant differences between the tested materials or in the other clinical secondary outcomes: marginal staining, recurrence of caries, and postoperative sensitivity. Therefore, the second null hypothesis was accepted.

It is worth mentioning that previous studies have shown that FDI criteria were more sensitive and precise in detecting minor failures during the clinical evaluation of direct restorations than modified USPHS criteria.[54-56] This difference may lead to an increase in the quality of assessments, mainly in studies assessing NCCL restorations and for "marginal adaptation" and "marginal staining" criteria,[57] as observed in the present study. Various research centers continue using USPHS criteria,[17,18,51] therefore it is better to conduct such evaluations using two sets of criteria to allow for the future comparison of the present study's results to those of all clinical studies published on NCCLs.

However, as Schwendicke and Opdam[58] noted, FDI and USPHS criteria, although well described, are difficult to use, mainly because these criteria added to the subjective process of clinical diagnosis can be susceptible to different interpretations. These authors suggested the use of intraoral digital photography as an alternative to evaluate the quality of restorations, reducing the risk of reporting bias. This method was recently validated by Opdam et al[59] and was used in the present study as an additional tool to record and evaluate the restorations at baseline and at each recall to allow for permanent recording of comparisons over time, providing detailed information and improving the level of evidence in the clinical research.[60]

Although the lower viscosity of flowable composite resins could increase the volume of residual monomers[61] and reduce the biocompatibility to gingival tissues[62] by inducing an increased inflammatory response from host,[63] mainly when used in cervical lesions,[64] no signs of periodontal or gingival inflammation were observed during the follow-ups in the present study (results not shown), and there were no signs of new NCCLs detected around the restored teeth. The gingival inflammation observed at baseline may be related to the use of clamps for rubber dam isolation and the finishing and polishing procedure, resulting later in the recovery of the connective tissue.[65] Longer follow-up needs to be performed to critically evaluate the biocompatibility or periodontal health regarding NCCL restorations with low-viscosity composites.

It is important to mention that some participants' characteristics may have influenced the failure of some restorations, mainly because three participants lost three restorations each. The most influential factor for clinical failure is the presence of occlusal wear facets,[66] which is related to high stress and occlusal forces concentrated in the cervical area, leading to a higher incidence of NCCL progression.[67] However, none of those three participants showed any NCCL progression during the follow-ups, and they maintained at least one more restoration of each group. Further long-term studies are necessary to evaluate the participant effect on cervical restorations.

New types of flowable composites are now available: self-adhesive and self-adhesive bulk fill resin composites as a simplified proposal for NCCL restoration. A systematic review and meta-analysis of in vitro studies reported lower bond strength values to dental tissues compared to conventional flowable composites.[68] Notwithstanding, short-term[69-71] and a recent long-term[72] clinical studies in NCCLs have reported acceptable clinical performance similar to the conventional flowable composites. Even so, further in vitro and long-term clinical studies should be performed to assess the advantages of these new materials compared to other flowable composites.

Finally, the limitations of the present study should be mentioned. One of them is the number of restorations by participant (three or more), which may have caused a clustering effect in the results. Even though this is a common situation in the dental literature,[10,30,39,40,70] the influence of the clustering effect should be considered in future studies. In the present study no cavity preparation was performed before placement of the restorations. At the time that the present study was started, the evidence regarding this topic was unclear,[73-75] or thought to be clinically insignificant.[55] However, more recently, a long-term clinical study[76] showed that NCCL restorations without any cavity preparation resulted in a higher retention loss when compared to a group in which the dentin was prepared. Therefore, future clinical studies should be conducted to test the clinical performance of the restorative materials tested in the present study when associated with dentin preparation. Another potential limitation of this study is the mid-term evaluation (2 years of clinical performance). Future trials with longer-term follow-up are needed to get more accurate outcomes and to identify the baseline characteristics of NCCLs associated with failure, using proper statistical analysis.

## Conclusion

The clinical performance of the universal adhesive associated with ormocer-based or methacrylate-based flowable composites was found to be promising after 24 months of clinical evaluation. However, the high-viscosity composite restorations showed significantly more failures. The clinical behavior of resin composites in NCCLs was dependent on their flowability.

## Disclosure

The authors have no conflicts of interest to declare.

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