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ORIGINAL ARTICLE

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Influence of viscosity and chemical composition of composite resins in non-carious cervical restorations: 12-month randomized clinical trial

Influência da viscosidade e composição química das resina compostas em restaurações de lesões cervicais não-cariosas: resultados de 12 meses de uma pesquisa clínica randomizada

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ABSTRACT

Objective: The objective of this double-blind, randomized controlled clinical trial was to evaluate the clinical performance of two methacrylate-based flowable composite and ormocer-based flowable composite in non-carious cervical lesions (NCCLs) of adult patients. **Material and Methods**: 183 restorations were performed on NCCLs using the Futurabond U adhesive system, applied in the selective enamel etching mode in all cavities. After the adhesive application, the cavities were restored with one out of the three evaluated flowable composites (n = 61 per group): ormocer-based flowable composite (Admira Fusion Flow, ORM), low viscosity methacrylate-based composite (GrandioSO Flow, LV) and high viscosity methacrylate-based composite (GrandioSO Heavy Flow, HV). After 12 months of clinical performance, these restorations were evaluated according to FDI and USPHS criteria in the following items: retention/fracture, marginal adaptation, marginal staining, postoperative sensitivity and caries recurrence. **Results:** eight restorations were lost/fractured after 12 months of clinical evaluation (1 in the ORM and 7 in the HV group). The retention rates for 12- months (95% confidence interval) were 98.4% (91.3%-99.7%) for the ORM group, 100% (94.5%-100%) for the LV group and 88.5% (78.1%-94.3%) for the HV group, with no statistical difference identified between any pair of groups ($p > 0.05$). Five restorations presented small marginal adaptation defects at the 12-months evaluation recall, and all of them were considered clinically acceptable. **Conclusion:** The clinical performance of the universal adhesive associated to ormocer-based or methacrylate-based flowable composite were found to be promising after 12-month of clinical evaluation.

KEYWORDS

Dental bonding; Dental restoration; Clinical trial.

RESUMO

Objetivo: O objetivo deste estudo clínico duplo-cego randomizado foi comparar as taxas de retenção de um compósito fluido à base de Ormocer versus dois compósitos fluidos à base de metacrilato quando utilizados em lesões cervicais não cariosas (LCNCs) de pacientes adultos. **Material e Métodos:** 183 restaurações foram realizadas em LCNCs utilizando o sistema adesivo Futurabond U, aplicado no modo de condicionamento seletivo do esmalte em todas as cavidades. Após a aplicação do adesivo, as cavidades foram restauradas com um dos três compósitos fluidos avaliados (n = 61 por grupo): compósito fluido à base de ormocer (Admira Fusion Flow, ORM), compósito à base de metacrilato de baixa viscosidade (GrandioSO Flow, LV) e compósito à base de metacrilato de alta viscosidade (GrandioSO Heavy Flow, HV). Após 12 meses de desempenho clínico, essas restaurações foram avaliadas de acordo com os critérios FDI e USPHS nos seguintes itens: retenção / fratura,

adaptação marginal, coloração marginal, sensibilidade pós-operatória e recorrência de cárie. **Resultados:** oito restaurações foram perdidas / fraturadas após 12 meses de avaliação clínica (1 no grupo ORM e 7 no grupo HV). As taxas de retenção por 12 meses (intervalo de confiança de 95%) foram 98,4% (91,3% -99,7%) para o grupo ORM, 100% (94,5% -100%) para o grupo LV e 88,5% (78,1% -94,3%) para o grupo HV, sem diferença estatística identificada entre nenhum par de grupos (p> 0,05). Cinco restaurações apresentaram pequenos defeitos de adaptação marginais no período de avaliação de 12 meses, e todas foram consideradas clinicamente aceitáveis. **Conclusão:** O desempenho clínico do adesivo universal associado ao compósito fluido à base de ormocer ou metacrilato mostrou-se promissor após 12 meses de avaliação clínica.

PALAVRAS-CHAVE

Adesão dentária; Restauração dentária; Ensaio clínico.

INTRODUCTION

Non-carious cervical lesions (NCCLs) are usually described as the loss of dental structure at the cement-enamel junction that is not caused by dental caries [1]. This type of lesion is very common in the adult population [2]. For instance, in the middle-aged and elderly populations of China, the prevalence of these lesions was reported to be 76.8 and 81.3% respectively [2]. Such numbers may differ among different studies, but usually they exceed 50% of the studied populations [3,4]. Several risk factors such as age, location (more common in premolars, canines and second premolars), frequency of tooth brushing, bruxism and family income were found to be associated with NCCLs [5].

Data collected on placement of 1,301 restorations, due to non-carious tooth defects by 178 dentists from the Dental Practice-Based Research Network, showed that composite resins are the material of choice for the restorative treatment of these lesions in 94% of the cases [6]. The restoration with composite resins does not treat the etiology of this condition, but it replaces the lost tissue, restores the dental structural integrity, reduces further wear, can relieve dentin hypersensitivity and also improves esthetics [7].

Among all types of available composite resins, flowable composites are low viscosity restorative materials that differ from regular viscosity resin composites by having lower filler load and less viscous resin content [8]. As a result, these materials are less rigid and have an elastic modulus 20% to 30% lower than that of regular viscosity composites [8,9]. This reduced low elastic modulus can theoretically absorb the stresses generated during the polymerization shrinkage of composites and during mechanical loading in which the teeth are subjected during function [10,11].

Although one recent systematic review of clinical trials has not detected any significant difference on the retention rates of flowable or regular composite resins when placed in NCCLs after 3-year of clinical evaluation [11], flowable composites carry the advantages of being user-friendly and being very popular among clinicians [9]. Recently, a new type of flowable composite has been developed: high viscosity materials (G-aenial Universal Flo; GC, Tokyo, Japan; GrandioSO Heavy Flow, Voco, GmbH, Cuxhaven, Germany). The manufacturers asserted that these materials have improved mechanical properties not dissimilar from regular composite restorative materials, as reduction in polymerization shrinkage and increase in abrasion resistance [9,12] on the same time that the flowability was maintained. Although, these new flowable generations have achieved a very satisfactory clinical performance in posterior restorations [13,14], no clinical studies were found using these materials in non-carious cervical lesions.

On the other side, almost all of the flowable composites used today in dental practice are still based on the dimethacrylate resins introduced in the 1960s and 1970s. Which means that several concerns, as polymerization shrinkage and lower degree of conversion are still present. Moreover, factors associated to the water sorption lead to the release of unreacted monomers, that may cause cytotoxicity to gingival and pulp living cell [15].

Therefore, some other alternatives were created and are available on the market. One of them is the ORganically MOdified CERamics (Ormocer). It's a combination of inorganic-organic co-polymers with inorganic silanated filler particles [16]. These restorative materials

replaced all methacrylate backbone resins. Recently, a new ormocer, Admira Fusion (VOCO), was introduced to composite technology and they have improved biocompatibility compared to resin-based dental restorative materials [17].

The pure silicate matrix technology combined with nano-hybrid fillers resulted in nano-ormocers that have showed a promising clinical performance in posterior restorations [18], but the impact of such chemical changes into clinical performance of restorations placed in non-carious cervical lesions has not been evaluated yet. Therefore, this double-blind randomized controlled clinical trial evaluated the clinical performance of two methacrylate-based flowable composite and ormocer-based flowable composite in NCCLs of adult patients.

MATERIAL AND METHODS

Study design

The description of the experimental design followed the Consolidated Standards of Reporting Trials (CONSORT) statement [19].

Ethics approval

The State University of Ponta Grossa (protocol 3.604.611; 2019) Ethics Committees reviewed and approved the protocol and issued a consent form for this study. Written informed consent was obtained from all participants prior to starting the treatment.

Protocol registration

This clinical trial was registered in the Brazilian Clinical Trial Registry (REBEC) under number RBR-998R5B.

Trial design, settings and location of data collection

This was a double-blind, split-mouth randomized controlled clinical trial. The study was performed in the clinics of the School of Dentistry of the State University of Ponta Grossa (Ponta Grossa, Paraná, Brazil) between June 2019 and November 2019.

Recruitment

Patients were recruited as they seek for treatment in the clinics of the university. Patients were recruited in the order in which they reported for screening session, forming a sample of convenience.

Eligibility criteria

All participants were examined by two calibrated dental residents to check if they met the inclusion and exclusion criteria. The evaluations were performed using a mouth mirror, an explorer, and a periodontal probe. Participants needed to be in good general health, be at least 18 years old, have an acceptable oral hygiene level, and present at least 20 teeth under occlusion. Participants were required to have at least three comparable NCCLs (in size, format and dimensions) to be restored. These lesions had to be non-retentive, deeper than 1 mm, and involve both the enamel and dentin of vital teeth without mobility.

The cavo-surface margin could not involve more that 50% of enamel. Patients with extremely poor oral hygiene or using orthodontic devices, severe or chronic periodontitis, or heavy bruxism habits were excluded from the study as they need to receive other treatments before restorative intervention. Also, participants with known allergy to resin-based materials or any other material used in this study, pregnant or breastfeeding women, or participants under chronic use of anti-inflammatory, analgesic, and psychotropic drugs were not included in the study.

Sample size calculation

The annual retention rate of flowable composites at 3-years is approximately 80% [11]. With an α of 0.05, a power of 90%, and an equivalence trial of 25%, a minimum sample size of 60 restorations per group was necessary, in order to detect a difference of 25% among the tested groups.

Random sequence generation and allocation concealment

The randomization was done on an intra-individual basis so that each subject ended up with three restorations. These randomization schemes were performed using tools available at the website http://www.sealedenvelope.com.

A staff member not involved in the research protocol performed the randomization process. Details of the allocated groups were recorded

on cards contained in sequentially numbered, opaque, sealed envelopes. Opening the envelope only on the day of the restorative procedure ensured the concealment of the random sequence. In all cases, the tooth with the highest tooth number (FDI numbering system) received the first described treatment, while the tooth with the next number in sequence received the second mentioned treatment, with placement continuing in a similar manner until the third tooth.

Interventions: restorative procedure

All the patients selected for this study received dental prophylaxis with a suspension of pumice and water in a rubber cup. The degree of sclerotic dentin from the NCCLs was measured according to the criteria described by Swift et al. [20] (Table I). The cavity dimensions in millimeters measured with the aid of a millimeter probe (height, width, and depth), the geometry of the cavity (evaluated by profile photograph and labeled at $<45^{o}$, 45^{o}-90^{o}, $90^{o}<135^{o}$, and $>135^{o}$) [21], the presence of an antagonist, and the presence of attrition facets were observed and recorded. Pre-operative sensitivity was also evaluated by applying air for 10 s from a dental syringe placed 2 cm from the tooth surface and with an explorer. These features were recorded to allow comparison of the baseline features of the dentin cavities among experimental groups.

To calibrate the restorative procedure, the study director placed one restoration of each group to identify all steps involved in the restorative technique. Then, other two operators, residents in the dental school, with more than five years of clinical experience, placed three restorations in a clinical setting, one of each group, under the supervision of the study director. The restoration failures were shown to the operators prior to starting the study. At this point, the operators were considered calibrated to perform the restorative procedures. The operators restored all teeth.

Before restorative procedures, the operators anesthetized the teeth with a 3% mepivacaine solution (Mepisv, Nova DFL, Rio de Janeiro, RJ, Brazil) and cleaned all lesions with pumice and water in a rubber cup (ref #8040RA and #8045RA, KG Sorensen, Barueri, SP, Brazil), followed by rinsing and drying.

Then, shade selection was made using a shade guide. Rubber dam was placed and the universal adhesive system Futurabond U (Voco), applied in the self-etch mode associated to selective enamel etching (Vococid; 35% Phosphoric acid, VOCO GmbH, Cuxhaven, Germany) was applied according to the manufacturer's directions in all cavities. The adhesive was light-cured with an irradiance of 1200 mW/cm^2 (Bluephase N, Ivoclar Vivadent, Schaan, Liechtenstein) for 10 s each. The compositions, application modes, and batch numbers are described in Table II. Then the cavities were restored with one out of the three flowable composites described below:

- Ormocer-based flowable composite (Admira Fusion Flow, Voco) was placed in increments of 2 mm maximum, followed by light-curing with an irradiance of 1200 mW/cm^2 (Bluephase N, Ivoclar Vivadent, Schaan, Liechtenstein) for 20 s 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.

Table I - Dentin sclerosis scale used (*)

Dentin sclerosis scale	
CATEGORY	CRITERIA
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

(*) Adapted from Swift et al. [20]

Table II - Application mode of the adhesive system and composite resin in the different groups

Materials	Composition	Application Mode
Futurabond U	35% Phosphoric acid (Vococid): 35% Phosphoric Acid Adhesive: HEMA, Bis-GMA, HEDMA, acidic adhesive monomer (*), urethane dimethacrylate, catalyst, silica nanoparticles and ethanol	1. Apply Etchant only on enamel for 15 s (selective enamel etching)
(VOCO GmbH, Cuxhaven, Germany)		2. Rinse for 10 s; 3. Air dry to remove excess of water 4. Keep dentin dry, do not overdry 5. Apply the adhesive for 20 s with vigorous agitation. 6. Gently air thin for 5 s. 7. Light-cure for 10 s. (Bluephase N, 1200 mW/cm^2)
GrandioSO Flow (LV; VOCO GmbH, Cuxhaven, Germany)	Organic matrix: Bis-GMA, Bis-EMA, TEGDMA, HDDMA, canforquinone, amine and butylhydroxytoluene	1. Placed in increments of 2 mm maximum
	Inorganic fillers: barium aluminum borosilicate glass ceramic filler, silicon dioxide nanoparticles (0.02-1 µm)	2. Light-curing for 20 s each layer (Bluephase N, 1200 mW/cm^2)
	Filler content: 87% w/w	
GrandioSO Heavy Flow (HV, VOCO GmbH, Cuxhaven, Germany)	Organic matrix: Bis-GMA, Bis-EMA, TEGDMA, HDDMA, canforquinone, amine and butylhydroxytoluene	1. Placed in increments of 2 mm
	Inorganic fillers: barium aluminum borosilicate glass ceramic filler, silicon dioxide nanoparticles (0.02-0.04 µm)	2. Light-curing for 20 s each layer (Bluephase N, 1200 mW/cm^2)
	Filler content: 89% w/w	
Admira Fusion Flow (ORM; VOCO GmbH, Cuxhaven, Germany)	Organic matrix: organically modified ceramic (Ormocer)	1. Placed in increments of 2 mm
	Inorganic fillers: barium aluminum borosilicate glass ceramic filler, silicon dioxide nanoparticles (0.02-1 µm)	2. Light-curing for 20 s each layer (Bluephase N, 1200 mW/cm^2)
	Filler content: 83% w/w	

Abbreviations: HEMA: 2-hydroxyethyl methacrylate; Bis-GMA: Bisphenol-A-glycidyl dimethacrylate; HEDMA: 1,6-hexanediol dimethacrylate; Bis-GMA –bisphenol A-glycidyl methacrylate, Bis-GMA –bisphenol A polyethylene glycol diether dimethacrylate, TEGDMA – triethylene glycol methyl ether methacrylate, HDDMA – 1,6-hexanediol dimethacrylate, (*) *Acidic adhesive monomer in the composition of Futurabond U is* 10-MDP: 10-methacryloyloxydecyl dihydrogen phosphate according to personal communication with Dr. Martin Danebrock (VOCO).

A radiometer (Bluephase meter II, Ivoclar Vivadent, Schaan, Liechtenstein) 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, Barueri, SP, Brazil) and polished with OptraPol NG (Ivoclar Vivadent, Schaan, Liechtenstein) under constant water-cooling.

Blinding

The examiners were not involved with the restoration procedures and therefore they were blinded to the group assignment. Patiens were blinded to group assignment in a double-blind randomized controlled trial.

Clinical evaluation

Two experienced and calibrated dentists who were not involved with the restoration procedures performed the clinical evaluation. 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 2 consecutive days. These subjects had cervical restorations and they did not participate in this project. An intraexaminer and interexaminer agreement of at least 85% was necessary before the beginning of the evaluation [21].

An individual standardized paper case report form was used for each evaluator at each recall time (baseline, 6 and 12-months) so that evaluators were kept blinded to earlier

evaluations during the follow-up recalls. The restorations were evaluated by World Federation criteria (FDI) [22,23] and the classical United States Public Health Service (USPHS) criteria (adapted by Bittencourt et al., 2005 and Perdigão et al., 2012) [24,25]. The primary clinical endpoint was restoration retention/ fracture, but the following secondary endpoints were also evaluated: marginal staining, marginal adaptation, postoperative sensitivity, color match and recurrence of caries. The evaluation of the spontaneous postoperative sensitivity was performed one week after the restorative procedure by asking the patient if he experienced any pain during the period.

These variables were ranked according to FDI criteria into clinically very good, clinically good, clinically sufficient/ satisfactory, clinically unsatisfactory but repairable, and clinically poor (replacement required) [22,23] and in the USPHS criteria into alfa, bravo, and charlie [24]. Both examiners evaluated all the restorations once and independently. When disagreements occurred during the evaluations, they had to reach a consensus before the participant was dismissed.

Statistical analysis

The statistical analyses followed the intention-to-treat protocol according to CONSORT (Consolidated Standards of Reporting Trials) suggestion [19]. Descriptive statistics were used to describe the distributions of the evaluated criteria. Statistical analysis for each individual item was performed for each evaluation criteria (FDI and USPHS criteria). The differences in the ratings of the three groups in each recall time were compared two-by-two with Wilcoxon Signed Rank test ($\alpha = 0.05$). The absolute and relative risks of each criteria were calculated along with the 95% confidence interval. Cohen's kappa statistics was used to test inter-examiner agreement. In all statistical tests, we pre-set the level of significance to 5%.

RESULTS

Twenty five out of 52 patients examined for eligibility were not enrolled in the study because they did not fulfill the inclusion criteria. Thus, a total of 27 subjects (12 men and 15 women) were selected. One hundred and eighty three restorations were placed: 61 for each group (Figure 1). All baseline details relative to the research subjects and characteristics of the restored lesions are displayed in Table III. The overall Cohen *kappa* statistics showed excellent agreement between the examiners during the six months (0.94) follow-up recall. All research subjects were evaluated at baseline, six and twelve-month recall.

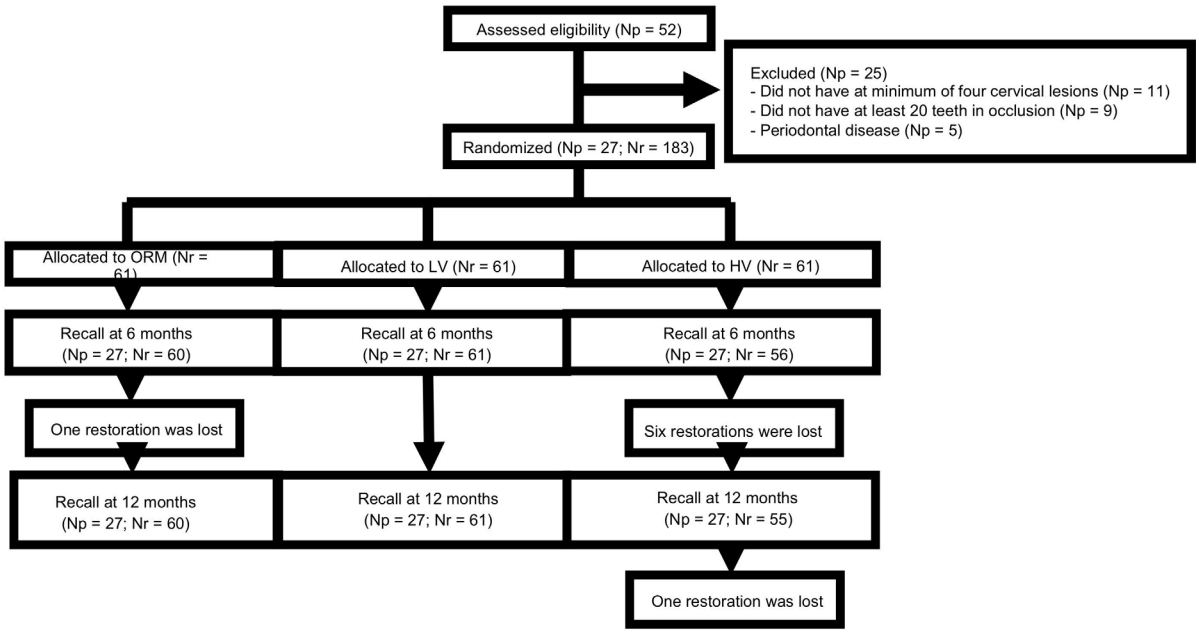

Figure 1 - Flow diagram. Np: number of patients, Nr: number of restorations. ORM= ormocer-based flowable composite; LV=low viscosity methacrylate-based composite; HV= high viscosity methacrylate-based composite.

Table III - Characteristics of the research subjects and the non-carious cervical lesions (NCCL) per each experimental **group (*).**

Characteristics of research subjects			
Gender distribution			
Male	12		
Female	15		
Age distribution (years)			
20-29	3		
30-39	2		
39-49	6		
> 49	16		
Characteristics of Class-V lesions			
	ORM	**LV**	**HV**
Shape (degree of angle)			
< 45	09	06	07
45-90	18	26	17
90-135	09	07	06
> 135	25	22	31
Cervico-incisal height (mm)			
< 1.5	13	07	10
1.5-2.5	24	21	21
2.5-4.0	19	28	24
> 4.0	04	04	05
Degree of sclerotic dentin			
1	20	18	17
2	12	14	13
3	12	12	09
4	07	07	12
Presence of antagonist			
Yes	61	61	61
No	00	00	00
Attrition facet			
Yes	16	12	11
No	45	49	50
Pre-operative sensitivity (spontaneous)			
Yes	61	61	61
No	00	00	00
Pre-operative sensitivity (air dry)			
Yes	23	23	17
No	37	38	45
Tooth distribution			
Anterior			
Incisor	16	06	09
Canines	09	14	08
Posterior			
Premolar	26	34	29
Molar	08	12	12
Arc distribution			
Maxillary	29	33	31
Mandibular	32	28	30

(*) ORM: Admira Fusion Flow; LV: GrandioSO Flow; HV: GrandioSO Heavy Flow.

Retention/Fracture

Eight restorations were lost or fractured after 12 months of clinical evaluation for both evaluation criteria (one for ORM and seven for HV; Tables IV and V). Regarding to teeth groups of teeth, five lost restorations were in premolar (two maxillary and three mandibular) and two in maxillary incisors. The retention rates for 12 months (95% confidence interval) were 98.4% (91.3%-99.7%) for the ORM group, 100% (94.5%-100%) for the LV group and 88.5% (78.1%-94.3%) for the HV group, with statistical difference identified between ORM vs. HV ($p = 0.03$) and between ORM vs LV ($p = 0.01$; Tables IV and V).

Marginal adaptation

Five restorations were considered to have minor discrepancies in marginal adaptation at the 12 month recall using the FDI criteria (2 for ORM, 2 for LV and one for HV; Table IV). When USPHS criteria was used, only one restoration (LV group) showed signs of minor discrepancies in marginal adaptation. No significant difference was detected between any pair of groups at the 12 months recall ($p > 0.05$; Tables IV and V).

Marginal discoloration

Five restorations were considered to have minor discrepancies in marginal adaptation at the 12 month recall using the FDI criteria (1 for ORM, 1 for LV and 3 for HV; Table IV). When USPHS criteria was used, none restoration showed marginal discoloration. No significant difference was detected between any pair of groups at the 12 months recall ($p > 0.05$; Tables IV and V).

Other parameters

No restorations had postoperative sensitivity to air at the 1 week evaluation, and also at 6 and 12 months recalls using both criteria. No restoration showed recurrence of caries after 12 months of clinical evaluation for FDI or USPHS criteria. Usually, the restorations showed a very good clinical performance, which can be seen in Figure 2, after 12 months of clinical performance.

DISCUSSION

One of the objectives of the present study was to compare the clinical performance of a high viscosity methacrylate-based flowable composite in comparison with a low viscosity methacrylate-based flowable composite in non-carious cervical lesions. In the common sense, flowable composite

Table IV - Number of evaluated restorations for each experimental group (*) classified according to the World Dental Federation (FDI) criteria [22,23] (**)

Time		Baseline			06 months			12 months		
FDI Criteria	*(**)*	ORM	LV	HV	ORM	LV	HV	ORM	LV	HV
Marginal staining	VG	61	61	61	59	60	52	59	60	51
	GO	--	--	--	1	1	2	1	1	2
	SS	--	--	--	--	--	1	--	--	1
	UN	--	--	--	--	--	--	--	--	--
	PO	--	--	--	--	--	--	--	--	--
Fractures and retention	VG	61	61	61	57	60	52	57	60	51
	GO	--	--	--	1	--	1	1	--	1
	SS	--	--	--	1	--	1	1	--	1
	UN	--	--	--	1	1	1	1	1	1
	PO	--	--	--	1	--	6	1	--	7
Marginal adaptation	VG	61	61	61	60	59	54	58	59	53
	GO	--	--	--	--	1	1	2	1	1
	SS	--	--	--	--	1	--	--	1	--
	UN	--	--	--	--	--	--	--	--	--
	PO	--	--	--	--	--	--	--	--	--
Post-operative (hyper-) sensitivity	VG	61	61	61	60	61	55	60	61	54
	GO	--	--	--	--	--	--	--	--	--
	SS	--	--	--	--	--	--	--	--	--
	UN	--	--	--	--	--	--	--	--	--
	PO	--	--	--	--	--	--	--	--	--
Recurrence of caries	VG	61	61	61	60	61	55	60	61	54
	GO	--	--	--	--	--	--	--	--	--
	SS	--	--	--	--	--	--	--	--	--
	UN	--	--	--	--	--	--	--	--	--
	PO	--	--	--	--	--	--	--	--	--

(*) ORM: Admira Fusion Flow; LV: GrandioSO Flow; HV: GrandioSO Heavy Flow; (**) VG for clinically very good; GO for clinically good; SS for clinically sufficient/satisfactory; UN for clinically unsatisfactory and; PO for clinically poor.

Table V - Number of evaluated restorations for each experimental group (*) according to the modified United States Public Health Service (USPHS) criteria [24]

Time		Baseline			06 months			12 months		
USPHS Criteria		ORM	LV	HV	ORM	LV	HV	ORM	LV	HV
Marginal staining	Alfa	61	61	61	60	61	55	60	61	54
	Bravo	--	--	--	--	--	--	--	--	--
	Charlie	--	--	--	--	--	--	--	--	--
Retention	Alfa	61	61	61	60	61	55	60	61	54
	Bravo	--	--	--	--	--	--	--	--	--
	Charlie	--	--	--	1	--	6	1	--	7
Fracture	Alfa	61	61	61	58	60	53	58	60	52
	Bravo	--	--	--	2	1	2	2	1	2
	Charlie	--	--	--	--	--	--	--	--	--
Marginal adaptation	Alfa	61	61	61	60	60	55	60	60	54
	Bravo	--	--	--	--	1	--	--	1	--
	Charlie	--	--	--	--	--	--	--	--	--
Post-operative sensitivity	Alfa	61	61	61	60	61	55	60	61	54
	Bravo	--	--	--	--	--	--	--	--	--
	Charlie	--	--	--	--	--	--	--	--	--
Recurrence of caries	Alfa	61	61	61	60	61	55	60	61	54
	Bravo	--	--	--	--	--	--	--	--	--
	Charlie	--	--	--	--	--	--	--	--	--

(*) ORM: Admira Fusion Flow; LV: GrandioSO Flow; HV: GrandioSO Heavy Flow.

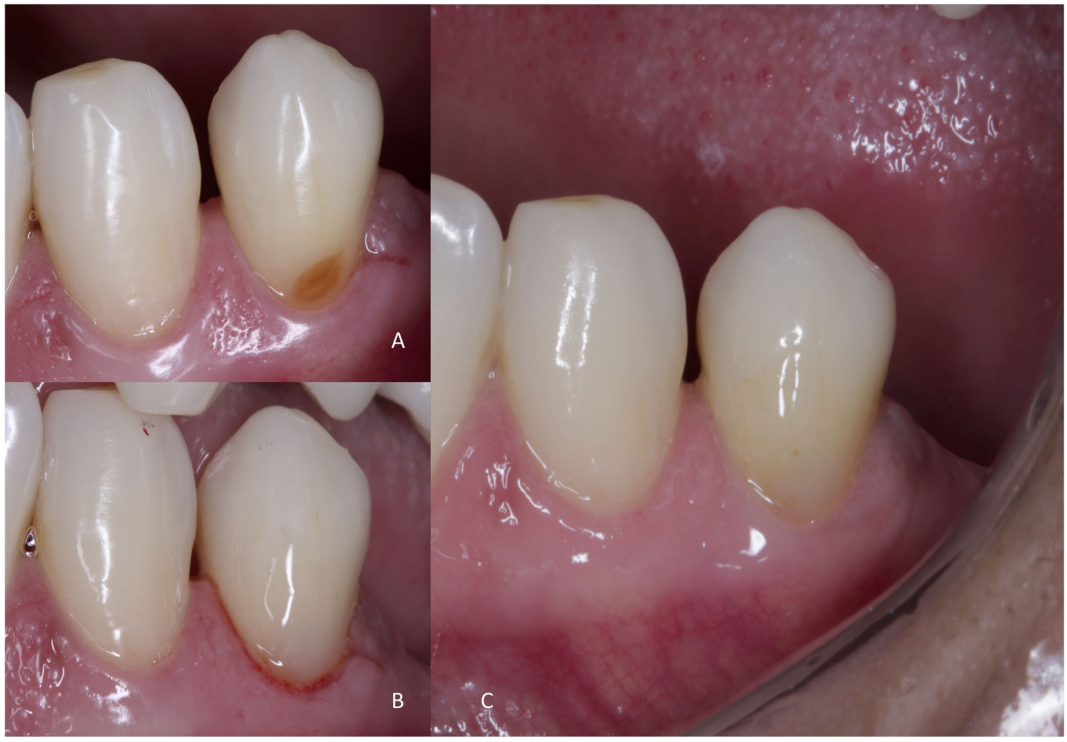

Figure 2 - (A) Initial aspect of non-carious cervical lesion; (B) Restoration finished; Immediate aspect; Vestibular view; (C) Restoration after 12 months of clinical evaluation. Vestibular view.

has a lower filler content and higher volume of resin matrix when compared with non-flowable composite [10,26]. This allows a more intimal adaptation to the cavity walls, greater flow and flexibility. Therefore, the first generation of flowable composite was applied as a cavity liner or in Class V restorations due to the low elastic modulus [10,26].

However, with the advent of nanotechnology, it's possible to increase significantly the percentage of filler in the composite, maintaining their handling properties (flowability). Based on this, it was possible to produce a flowable composite that has a filler content of more than 80% w/w [27], similar to regular viscosity composite materials. Actually, several studies showed that highly filled flowable composites showed mechanical properties that are comparable to those of regular viscosity composite [8,9,28,29].

Nevertheless, according to the manufacturer, both methacrylate-based (GrandioSO Flow and GrandioSO Heavy Flow) flowable composites showed high filler weight. Actually, Jager et al. [29] evaluated the rheological properties of various flowable composites, among them, GrandioSO Flow and GrandioSO Heavy Flow. The authors showed that, although a very similar amount of filler in both materials was found, GrandioSO Flow showed a significant lower viscosity when compared to GrandioSO Heavy Flow. The authors described that other factors as the type and shape of fillers, along with the quality of silanization, probably have a greater influence here than the filler content itself, as well as previously observed by Beun et al. [30]. It seems that, the higher viscosity of GrandioSO Heavy Flow affected their ability to 'moist' and adapt well to cavity margins and wall in non-carious cervical lesions and, consequently, significantly increased the loss of retention/fracture of GrandioSO Heavy Flow restorations after 12 months of clinical evaluation.

The second objective of the present study was to compare the clinical performance of a low viscosity methacrylate-based flowable composite (GrandioSO Flow) in comparison with ormocer-based flowable composite (Admira Fusion Flow) in non-carious cervical restorations. As described in the introduction section, the first generation of ormocer-based composites showed a poor long-term clinical behavior of restorations carried out with these materials, when compared to methacrylate-based composites [16,31].

However, only a few number of clinical studies that evaluated both materials were found [32,33]. For instance, Celik et al. [31]

showed that the ormocer-based flowable composite (Admira Flow, Voco) showed similar clinical performance when compared to a methacrylate-based flowable composite (Filtek Flow, 3M Oral Care, St. Paul, MN, USA) after 2-year recall rate. In other study [32], the authors didn't observe any significant difference between an ormocer-based flowable composite (Ceram.X Duo, Dentsply, Dentsply DeTrey, Konstanz, Germany) and a methacrylate-based flowable composite (EsthetX, Dentsply) after 8 years of clinical evaluation.

These restorative materials replaced all methacrylate backbone resins as well as the methacrylate-based viscosity reducers, cross linking agents and hydrophilic acrylics commonly present in composite failures [34]. However, due to several problems in handling properties, methacrylate-based monomers had to be added to the ormocer matrix of the first commercial products, diminishing the initial promising advantages [15]. This could be consider the main reason to the controversial results when first generation of ormocer-based composite are compared to methacrylate-based composite in posterior and anterior restorations [16,31].

As this new generation of pure silicate matrix technology combined with nano-hybrid fillers resulted in nano-ormocer, it will be expected a better clinical performance when compared to a methacrylate-based composite. Due to the short-term follow-up shown in the present study, it was not possible to detect any significant difference. However, future long-term evaluations need to be done to evaluate this hypothesis.

In the present study, the authors included all groups of teeth in the experimental design. Although, due to occlusal forces, it would be expected a different clinical behavior when molars are compared to incisor, with the lower retention rate for the former, this was not observed by Heymann et al. [35]. In that study, no significant difference in terms of retention rate was observed when molars, premolars or anterior teeth (incisors and canines) were compared [35]. In the present study, the same results were observed, given that, five lost restorations were in premolar (two maxillary and three mandibular) and two in maxillary incisors in agreement with Heymann's results [35]. This seems to be the reason that explains why, in many studies in which clinical follow-up of adhesive restorations in NCCL was performed, both anterior and posterior teeth were included [36-41].

CONCLUSIONS

The clinical performance of a ormocer-based or low viscosity methacrylate-based flowable composite were found to be promising after 12-month clinical evaluation. The Heavy Flow restorations showed significantly more failures.

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Conflict of Interest

The authors 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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Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subject's oversight committee guidelines and policies of The State University of Ponta Grossa. The approval code for this study is: 3.604.611; 2019.

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