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Article

Six month follow-up of two Bulk-fill composites in non-carious cervical lesions: Double blind randomized clinical trial.

Evaluación clínica a 6 meses de restauraciones cervicales en lesiones no cariosas con resinas compuestas Bulk-fill: Estudio aleatorio doble ciego.

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Abstract: Objective: To assess the six-month clinical outcome of restorations of non-carious cervical lesions (NCCL) with two composite resins: Bulk-Fill and nanohybrid resin. Materials and methods: Fifty-one patients, with three NCCLs each, were randomly allocated into three restoration groups: Tetric-N-Ceram Bulk-Fill (TB); Filtek Bulk-Fill (FB); y Filtek Z350XT (Z350). Adhesive techniques and restorative procedures were performed according to the manufacturers' instructions for the different materials. A 4mm increment was applied in TB and FB, and increments of ≤2mm depth were applied in Z350. Restorations were assessed by two calibrated examiners at baseline and at six months according to the FDI World Dental Federation guidelines (1: excellent, 2: acceptable, 3: sufficient, 4: unsatisfactory, 5: unacceptable) in Marginal Staining (MS), Fracture-Retention (FR), Marginal Adaptation (MA), Postoperative Sensitivity (S) and Caries (C). Wilcoxon test was used for the comparison between baseline and 6 months, and Kruskal-Wallis for the comparison of the three groups at six months (95% significance). Results: Forty-six patients with a total of 138 restorations attended a check-up at six months and were evaluated with excellent clinical outcome. In MS, 91.2% for Z350 and 97.8% for FB and TB; in FR, 97.8% for Z350 and 100% for FB and TB; in MA, 95.6% for Z350, 97.8% for FB and 100% for TN; in S, 95.6% for all three groups; and 100% for C. No statistically significant differences were found between the three groups nor in the comparison between the baseline and 6 months (p>0.05) Conclusion: No significant differences are observed between the three groups of resins in the parameters of MS, MA, S, FR and C regarding clinical outcome at six months.

Keywords: Composite resins; tooth cervix; dental restoration, permanent; randomized controlled trial; filtek bulk fill .

Resumen: Objetivo: Evaluar el comportamiento clínico a 6 meses en restauraciones de lesiones cervicales no cariosas (LCNC) con dos resinas compuestas Bulk-Fill y una resina nanohíbrida. Materiales y métodos: En 51 pacientes se restauraron 3 LCNC distribuidas aleatoriamente en 3 grupos, TB: Tetric-N-Ceram Bulk-Fill, FB: Filtek Bulk-Fill y Z350: Filtek Z350XT. Las técnicas adhesivas y procedimientos restauradores fueron realizados según las instrucciones de los fabricantes para los diferentes materiales. En TB y FB se aplicó un incremento de 4mm y en Z350 se aplicó incrementos ≤2mm de profundidad. Dos operadores calibrados evaluaron las restauraciones al baseline y 6 meses mediante los criterios clínicos FDI (1: excelente, 2: aceptable, 3: suficiente, 4: insatisfactorio, 5: inaceptable) en Tinción Marginal (TM), Fractura-Retención (FR), Adaptación Marginal (AM), Sensibilidad Postoperatoria (S) y Caries (C). Se utilizó Wilcoxon para la comparación entre baseline – 6 meses y Kruskal-Wallis para la comparación de los 3 grupos a 6 meses (significancia de 95%). Resultados: A los 6 meses asistieron 46 pacientes con un total de 138 restauraciones

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siendo evaluados con comportamiento clínico excelente; en TM 91,2% para Z350 y 97,8% para FB y TB; en FR, Z350 presentó 97,8% y en FB y TB el 100%; en AM, 95,6% para Z350, 97,8% para FB y 100% para TN; en S presentó 95,6% para los tres grupos; en C se presentó el 100%. No hubo diferencias estadísticamente significativas entre los 3 grupos y en la comparación de baseline - 6 meses (p>0.05). Conclusión: No existen diferencias significativas en el comportamiento clínico a 6 meses entre los 3 grupos de resinas en los parámetros TM, AM, S, FR Y C.

Palabras Clave: *Resinas compuestas; cuello del diente; restauración dental permanente; ensayo clínico controlado aleatorio; materiales dentales.*

INTRODUCTION.

The life expectancy of the world population has increased over the last few years, resulting in an increase in multiple oral pathologies. Non-carious cervical lesions (NCCL) can be found among these pathologies, with a prevalence of 38-81%.[1,2] NCCLs are characterized by a loss of hard dental tissue at the cervical level of the tooth, and their etiology seems to be related to different factors. NCCLs are classified as: abrasion, derived from a mechanical action such as brushing, abfraction, brought about by a concentration of mechanical stress, and biocorrosion, caused by chemical biodegradation of intra and extra oral acids.[3]

Furthermore, NCCL restoration present a great challenge for dentists[4] with a 21% failure rate reported annually. The difficulty in managing soft tissue and isolating fluids such as saliva, blood, and gingival crevicular fluid, contribute to the complexity of directly restoring the cervical area.[5]

Composite resin (CR) is the first-choice restorative material in NCCLs but it presents multiple clinical problems, such as: gap formation, marginal staining with cosmetic implications, adjacent caries, and restoration failure caused primarily by polymerization contraction, that along with other factors influence polymerization contraction stress (PCS).[6] In order to counteract PCS, CR must be applied using multiple increments up to 2mm in thickness. The use of the incremental technique, however, have some disadvantages, including: bubbles trapped inside between each layer, adhesive failure due to the possibility of contaminating each layer, and the longer clinical time that must be used in the application and polymerization of each incremental layer.[7]

Bulk-Fill composite resins (BFR) were introduced a few years ago. They can be applied in a single increment of up to 4mm. This technique is simpler than the one of multiple increments used for conventional CR.[8] BFRs have been shown to have good conversion level and micro-hardness, low volume of volumetric contraction and a high depth of cure when used in layers greater than 4mm in thickness. As manufacturers have explained, these characteristics are the result of the modification of their components in comparison with conventional CR. The modifications include the addition of monomers with PCS modulator functional bonds, photoinitiators of greater reactivity and modification of inorganic filler, which allows for an increase in the translucency of the CR.[9,10] A recent *in vitro* study of Correia *et al.,*[11] found that the restorative technique may influence PCS, and that the best outcome for NCCL was observed with BFRs applied in one single increment. This can be explained because PCS not only depends on the C factor but also on the mechanical characteristics of the material, polymerization contraction level, volume and geometry of the cavity, and the technique of placement in the cavity.[12] Recently Canali *et al.,*[5] published a double-blind randomized clinical trial about BFR in NCCL, in which they compared a bulk-fill flowable composite resin and a conventional nanohybrid CR of the same brand. The results showed that both composite resins have an acceptable clinical behavior in an assessment period of 6 and 12 months according to the USPHS criterion. Nonetheless, there are still few clinical studies regarding BFRs,[13] and most have been performed on occlusal and approximal caries lesions (14)(15)(16). Therefore, the aim of this study was to assess a six-month clinical outcome in restorations of NCCL with two brands of BFR (Tetric N-Ceram Bulk-Fill and Filtek Bulk-Fill) and a conventional nanohybrid CR (Filtek Z350). The null hypothesis stated that there were no significant differences in the clinical outcome of NCCL restorations using two BFRs and a nanohybrid CR at 6 months follow-up, assessed according to the FDI criteria of restorations

MATERIALS AND METHODS.

This study was conducted based on the Consort 2010 guidelines for clinical trials. The design was clinical experimental, controlled, randomized and double-blind and was performed between March 2017 and January 2018. The study was approved by the local ethics committee (authorization number: #PROPRGFO_002017.40) and was registered at *www.clinicaltrial.gov* with the code NCT03230604.

Participants selection

Fifty-one voluntarily patients who attended the Dental Clinic of Universidad Andrés Bello, Santiago, were selected through a check-up conducted by two examiners according to the inclusion and exclusion criteria. (Figure 1)

Inclusion criteria

Patients ≥18 years of age, healthy, with at least 20 teeth in occlusion, NCCL with ≥1.5mm depth, ≥2.5mm occluso-cervical height and mesiodistal width, and presence of enamel along the occlusal cavosurface margin of the lesion.

Exclusion criteria

Patients with chronic periodontitis, bruxism, dry mouth, psychomotor disturbances, allergy to resin, removable dental prosthesis or prosthesis abutment tooth, endodontically treated teeth, tooth isolation, or pregnant and breastfeeding patients.

Sample size

In order to calculate the sample size, a statistical power (1-β) of 80% with a Type I error (α)=0.05 was initially considered, resulting in approximately 46 restorations per group, and increasing to 51 because of a potential loss of 10% patients in one year.[15]

Calibration and training of examiners

Before the restoration process, the clinical procedure was calibrated. For this purpose, the manager of the study, a specialist in oral rehabilitation, demonstrated the clinical steps of the restoration of NCCLs following each manufacturer's instructions for each studied composite resin.

Two specialist examiners with more than 10 years of professional experience performed four restorations under the supervision of the manager. Possible errors and deficient restorations that were observed were discussed and corrected using a check list. Both operators who performed the restorations were calibrated using the FDI criterion with an intra and inter observer Kappa coefficient ≥0.8

Restorative process

Before restoration, prophylaxis with water and pumice stone was performed, and the lesions surfaces were washed and dried. The dimensions of each lesion were measured with a probe (Hu-Friedy, North Carolina, Chicago, US).

Absolute isolation (hemiarcade) was carried out for all restorations. The color of the dental dam was chosen prior to its placement, 2% mepivacaine (Scandonest 2% special, Septodont, France) was used as anesthesia, and a retraction cord was placed. No preparation or bevel was done.

Following the manufacturer's instructions, each patient received restorations with two Bulk-Fill composite resins: Tetric N-Ceram Bulk-Fill (TN) (with universal adhesive Adhese Vivapen), Filtek Bulk-Fill (FBK), and a Filtek XT Z350 (Z350) restoration (both with Single Bond Universal adhesive). All lesions were prepared with phosphoric acid (Gel Etchant, Kerr, USA) on enamel for 20 seconds. The polymerization process was performed using a light-emitting diode with a minimum irradiance of 1100mW/cm^2 (Bluephase Style, Ivoclar Vivadent, AG,Schaan, Liechtenstein), measured with a radiometer in all procedures (LEDEXTM CM4000, Dentmate technology Co., Ltd. Taiwan). The materials as well as the adhesive and restorative procedures are described in Table 1.

High speed fine diamond grain burs were used for the finishing (JotaG, Rüti, Switzerland), and flexible discs (Softlex 3M ESPE, St. Paul, US) and Enhance (Dentsply, Petrópolis, RJ, Brazil) for the polishing.

Randomization and assignment

The randomization process of each restoration was performed using a table designed by a computer from an examiner external to the project. The allocation of each tooth to its corresponding restoration group was registered in a numbered, opaque and sealed envelope by a member external to the project.

The envelope was opened when the restorations were carried out. The examiner was not blinded due to procedural differences that existed for each material; however, the patient and the evaluators did not know to which restoration each group fell.

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Clinical assessment

Two different blinded examiners (who did not know the allocation of each group) assessed all restorations at two weeks (baseline) and at 6 months according to the FDI criteria[17] (Table 2 and Table 3) in N¡Marginal Staining (MS), Marginal Adaptation (MA), Fracture-Retention (FR), Postoperative Sensitivity (S) and Caries (C). Both examiners were calibrated for the FDI criteria and presented an intra-and interexaminer Kappa coefficient ≥0.8.

The examination of the restorations was conducted using a 23 mouth mirror (Hu-Friedy Mfg. Co. Inc. Chicago, Il. US) with illumination and at 3.5x magnification (Bio Art, Brazil), according to the FDI criteria. The probs recommended by the FDI were used to assess marginal adaptation (Deppeler, Switzerland). The assessments were carried out independently. In case of disagreement, the examiners reassessed the restoration until a final agreement was reached.

Statistical analysis

SPSS 21.0 software for Windows (SPSS, Chicago, IL, US) was used for the statistical data analysis. The categories for each clinical parameter in the groups were organized and arranged together. Wilcoxon test (α=0.05) was used to evaluate the same group as a function of time (baseline and at 6 months) for all clinical parameters. Kruskal Wallis test was used to compare the parameters between the three groups at 6 months (α=0.05). The statistical analysis was carried out by a person external to the project.

Figure 1. Consort Flow Diagram.

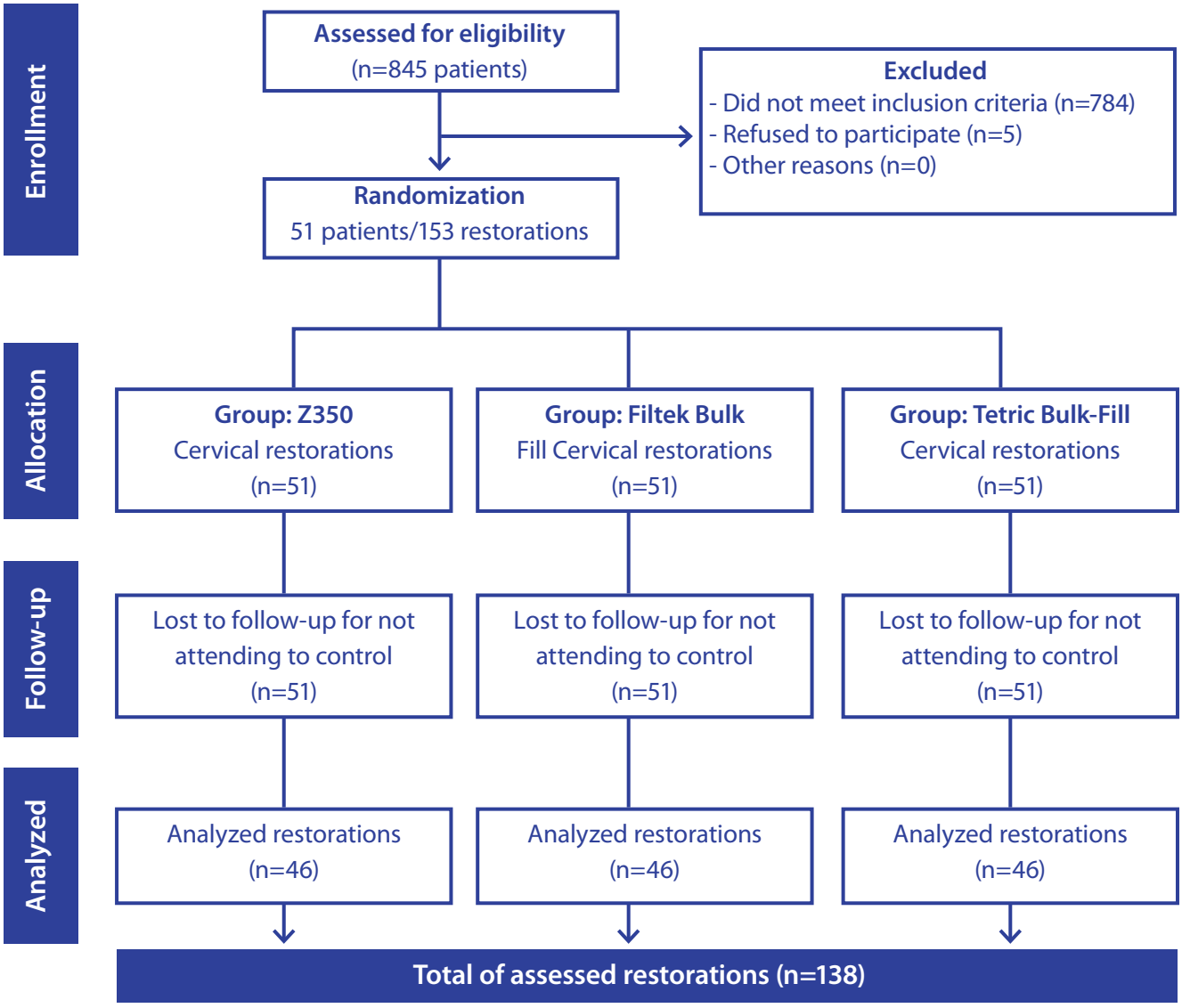

Table 1. Materials, components and restoration techniques employed in the present study.

Materials	Components	Mode of application
Single Bond® Universal Adhesive (3M ESPE, Neuss, Germany) N° Lote: 653245 - 652541.	MDP, dimethacrylate resin, HEMA, polyalkenoic acid copolymer methacrylate, filler,ethanol, water, starter and silane.	Acid conditioning in enamel for 20 sec. (37% orthophosphoric acid), washing for 40 sec., drying to remove excess of water, active and vigorous application of adhesive for 20 sec., gentle air drying for 5 sec. and light curing for 10 seconds.
Adhese® Universal VivaPen Adhesive (Ivoclar-Vivadent, Schaan, Liechtenstein). N° Lote: V11838.	MDP, HEMA, Bisphenol glycidyl methacrylate, carboxylic methacrylate acid, decanediol dimethacrylate, ethanol, water, silicon dioxide and camphorquinone.	Acid conditioning in enamel for 20 sec. (37% orthophosphoric acid), washing for 40 sec., drying to remove excess of water, active and vigorous application of adhesive for 20 sec., gentle air drying for 5 sec. and light curing for 10 seconds.
Filtek® Z350 XT Universal Restorative (3M ESPE, St.Paul, MN, USA). Color Body A3/ Lote: N753777-N777310 Color Body A2/ N° Lote: N767854-N767854.	UDMA, Bis-EMA, TEGDMA, BisGMA, zirconium and silica. Filler: 72% weight%55Volume	Application using incremental technique (mininum 3 layers). Light curing for 20 seconds.
Filtek® Bulk Fill Posterior Restorative (3M ESPE, St. Paul, MN,USA) Color A3-A2 Color: A3 / N° Lote: N7661149 Color: A2 / Nº Lote: N7661148.	Bis-GMA- AUDMA, DDMA, Bis-EMA, dimethacrylates. TEGDMA, diluents, ytterbium triofluoride, zirconium and silica. Filler:77%weight/59% Volume.	Single increment application up to 4 mm, photocured for 20 seconds.
Tetric® N-Ceram Bulk-fill (Ivoclar-Vivadent,Schaan, Liechtenstein). Color: IVB / N° Lote: V35951-W36853 Color: IVA / N° Lote: Q33216-W36852.	Dimethacrylates, barium glass filled prepolymers, ytterbium trifluoride, additives, Ivocerin and stabilizers. Filler:78%weight/61%Volume.	Single increment application up to 4 mm, photocured for 20 seconds.

MDP: dihydrogenated methacryloxidephosphate. **HEMA:** Hydroxyethyl methacrylate. **UDMA:** Urethane dimethacrylate. **TEGDMA:** triethylene glycol dimethacrylate. **Bis-GMA:** Bisphenol Glycidyl methacrylate. **Bis-EMA:** bisphenol A polyethylene glycol diether dimethacrylate. **AUDMA:** Aromatic urethane dimethacrylate. **DDMA:** Dodecanidiol dimethacrylate.

Table 2. Criterios World Dental Federation (FDI).[17]

Esthetics	
	1. Tinción marginal
1. Clinically excellent.	1.1 Marginal staining absence.
2. Clinically good.	1.2 Minimum marginal staining, easily removable through polish.
3. Clinically sufficient/satisfactory (insignificant deficiencies, without side effects).	1.3 Moderate marginal staining, esthetically acceptable.
4. Clinically unsatisfactory (restoration because of preventive reasons).	1.4 Marked marginal staining, greater procedure needed.
5. Clinically poor (need for replacement)	1.5 Deep marginal staining, procedure not accessible.

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Table 3. Materials, components and restoration techniques employed in the present study.

	World Dental Federation (FDI) criteria			
	Functional characteristics		Biological characteristics	
	2. Fracture and Retention	3. Marginal Adaptation	4. Postoperative Hypersensitivity	5. Recurent caries
1. Clinically Excellent	2.1 Preserved restoration, not fractured/cracks.	3.1 Harmonic contour without gaps or white lines.	4.1 Absent hypersensitivity.	5.1 No secondary or primary caries injury
2. Clinically good	2.2 Small fine cracks	3.2.1 Marginal gap that is a white line (<150µm). 3.2.2 Small marginal fracture removable with polishing. 3.2.3 Small gap, step or irregularity.	4.2 Low hypersensitivity for a limited period of time.	5.2 Small and localized demineralization. No surgical treament required.
3. Clinically sufficient/ satisfactory (minor deficiencies, no adverse effects)	2.3 Two or more cracks, cracks and/or material release (does not affect marginal integrity)	3.3.1 Gap <250µm not removable. 3.3.2 Several small marginal fractures. 3.3.3 Major irregularities, steps or gaps.	4.3.1 Premature/slightly more intense tenderness.	4.3. Delayed sensitivity /weak sensitivity, no subjective complaints or necessary treatment.
4. Clinically unsatisfactory (repair for prophylactic reasons)	2.4 Detachment of material that damages quality at the marginal level; fractures increase with or without partial loss (less than half of the restoration).	3.4.1 Breach >250µm not removable, dentin/exposed base. 3.4.2 Severe step or marginal fracture. 3.4.3 Irregularities or major steps (repair is necessary).	4.4.1 Premature/very intense sensitivity. 4.4.2 Extremely delayed/weak sensitivity with subjective complaints. 4.4.3 Negative Sensitivity, Necessary Intervention but No Replacement.	4.4 Cavitated caries (localized and accessible, can be resto red).
5. Clinically poor (replacement is necessary)	2.5 Partial or total loss of the restoration.	3.5.1 Partial or complete restoration is found with mobility but in situ. 3.5.2 Generalized major gaps or irregularities.	4.5 Very intense tenderness, acute pulpitis or pulp necrosis. Necessary endodontic treament and restoration replacement.	4.5 Very intense sensitivity, acute pulpitis or pulp necrosis. Necessary endodontic treatment and restoration replacement.

Table 4. Distribution of restorations by tooth.

	Maxilla			Mandible			
	Canine Incisors	Premolar	Molar	Canine Incisors	Premolar	Molar	Total
Z350	4	13	4	4	19	2	46
FB	3	13	4	4	19	3	46
TB	2	22	3	6	11	2	46
Total	9	49	11	14	48	7	138

Table 5. Clinical assessment of restorations expressed as a percentage (%) and number of restorations (n).

		Z350		FB		TB	
		Baseline	6months	Baseline	6months	Baseline	6months
Marginal Staining (MS)	1	100%(46)	91.2%(42)	100%(46)	47.8%(45)	46 (100%	45(97.8%)
	2	0% (0)	8.8% (4)	0% (0)	2.2% (1)	0% (0)	2.2%(1)
	3	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
	4	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
	5	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
Fracture and retention (FR)	1	100% (46)	97.8%(45)	100% (46)	100% (46)	100% (46)	100% (46)
	2	0% (0)	2.2%(1)	0% (0)	0% (0)	0% (0)	0% (0)
	3	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
	4	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
	5	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
Marginal Adaptation (MA)	1	100% (46)	95.6%(44)	100% (46)	97.8%(45)	100% (46)	100% (46)
	2	0% (0)	4.4%(2)	0% (0)	2.2%(1)	0% (0)	0% (0)
	3	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
	4	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
	5	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
Sensibilidad post-operatoria (S)	1	100% (46)	95.6%(44)	100% (46)	95.6%(44)	100% (46)	95.6%(44)
	2	0% (0)	4,4%(2)	0% (0)	4.4%(2)	0% (0)	4.4%(2)
	3	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
	4	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
	5	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
Caries (C)	1	100% (46)	100% (46)	100% (46)	100% (46)	100% (46)	100% (46)
	2	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
	3	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
	4	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
	5	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)

RESULTS.

Of the 51 patients, 46 attended the check-up at 6 months, 28 females (60.9%) and 18 males (39.1%), with a mean age of 43 years (23-64 years). A total of 153 restorations were conducted, and at six months, 138 restorations were evaluated. Approximately, 49% of restorations were conducted on the maxilla and 51% on the mandible. The details of restorations distribution is shown in Table 4. The mean depth of lesions was 1.90mm for Z350, 2.22mm for FB, and 1.77mm for TB.

At six months, they were evaluated as clinically excellent or 1 regarding TM: 91.2% for Z350 and 97.8% for FB and TB, in parameter MA 95.6% for Z350, 97.8% FB, and 100% for TN. There was only one acceptable clinical evaluation in retention and fracture parameter, which was the restoration group Z350. From each group, two restorations (4.4%) were registered as presenting postoperative sensitivity. There were no adjacent caries in any of the three groups of restorations (Table 5).

When evaluating clinical behavior of each group between baseline and 6 months in all the evaluated parameters, no statistically significant difference ($p>0.05$) was observed. Similarly, when comparing the three groups, there were no significant differences in clinical parameters at six months ($p>0.05$).

DISCUSSION.

The aim of the present study was to assess clinical outcome in restorations of NCCL with Bulk-fill composites resins, and a control group with conventional nanohybrid resin. Results confirm the proposed hypothesis, which stated that there were no significant differences at 6-months between two BFRs and one conventional CR, according to the FDI parameters of marginal staining, fracture-retention,

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marginal adaptation, postoperative sensitivity, and caries.

These results coincide with other studies conducted by Bayraktar *et al.,*[14] and Yazici *et al.,*[16] in different types of restorations Class I and II, in which differences at 6 and 12 months between BFR and conventional resins were not found. As previously mentioned, so far there is only one study conducted by Canali *et al.,*[5] that showed similar results to this study regarding the clinical outcome of NCCL restorations.

However, that study was conducted with low viscosity or fluid (base) BFR (Filtek Bulkfill Flow), contrary to the BFRs used in the present study, which were resins of high viscosity or "full-body", according to the classification of van Ende *et al.*[13]

It is important to mention that, according to some studies, fluid or base resins have to be covered by a high viscosity resin, because of their low resistance to fracture and abrasion, which does not result in a good clinical outcome in the long-term.[18] Despite this, the cervical area it is not usually subjected to occlusal loads; however, it can be subjected to other mechanical efforts such as lesions produced by abrasion, thus a fluid resin or base can have other results in the long-term, which should be studied in the future.

BFRs were applied in a single layer, which can result in a greater PCS, although this does not only depend on the application technique, but also on other factors such as the material composition. The composition of BFRs considerably vary between manufacturers, who, for obvious reasons, do not divulge technical details. With data from previous studies, the results obtained so far can be explained, since Bulk-fill resins are capable of modulating the PCS because of the mechanical properties that their different components have, besides the modification in the quality of filling when compared with conventional resins. In general, BFRs contain monomers such as UDMA, which have lower viscosity and bigger flexibility in comparison with Bis-GMA present in conventional resins. This causes an increase in the mobility of the structure that is moderated by the PCS. Another factor that can influence PCS is the higher percentage and type of filling that BFRs contain, which in the specific case of TB resin that presents the greater content of filling of the studied resins, in addition to the presence of prepolymerized particles, as confirmed by the study of Blackham *et al.*[19]

Furthermore, in the case of FB resin, the stress modulation can be explained by the presence of the high molecular weight compound aromatic dimethacrylate (AUDMA), which reduces the quantity of reactive groups in the resin, thus helping to moderate the volumetric contraction, as well as the stiffness of the polymeric matrix during development and in its final stage. It should be noted that the abovementioned factors contribute to the stress for polymerization, confirming the data of an *in vitro* study conducted by Correia *et al.,*[11] In this way, with the data and the results previously reported, it can be demonstrated that BFRs can be applied in increments up to 4mm and, as they can thus be applied in a single layer, their use simplifies the application technique in less time than conventional CR, without affecting the clinical characteristics of restorations in relation to adaptability, marginal staining and post-operative sensitivity.

Although most of NCCLs have a minor factor of cavity configuration or C factor (adhered cavity walls divided by free walls),[20] the abovementioned ideas have been clinically related to PCS produced between tooth and CR, besides of the influence of chemical degradation and zones of stress concentration during mastication that finally affects the longevity of restorations in NCCL.[21,22] Because of this, it would be interesting to further study the clinical outcome of BFR, classifying NCCLs according to their cavity geometry, for example, include only wedge type abfractions, since these depend on the depth and extension (point that was not characterized in this study) and suffer a bigger stress due to contraction.

The retention and fracture is a condition that has been studied many times in NCCLs, which due to their characteristics, most of the time do not possess macromechanical retention,[23] like occlusal or proximal-occlusal lesions.

Even though this study only presented one restoration rated 2 according to FDI, it is necessary to continue with a longer term evaluation, since there are other factors that can have an influence on retention, such as the adhesive and the adhesive technique used.[13] Even though some authors have suggested that the adhesive is the most significant factor in the adhesive behavior

of a CR restoration. We used the corresponding universal adhesives suggested by the manufacturer of the adhesives tested in this study (Single Bond Universal and Adhese Universal), which in clinical studies of universal adhesives in NCCLs have demonstrated a similar rate of annual retention over 94%.[24] This is mainly explained because their chemical composition contains the functional monomer MDP, which is responsible for creating a steady chemical bonding with the calcium of hydroxyapatite of the dental tissue.[25] Because of this, we believe that in a future study it would be necessary to include a fourth group with a conventional nanohybrid resin of the same commercial brand, so that, a comparison of retention and fracture between RBK and conventional nanohybrid CR would be made more accurately, as there may be differences in the composition of adhesive and restorative materials, not often informed by manufacturers.

In terms of preparation of NCCL before restoration, it should be mentioned that beveling was not conducted, because there are still controversies regarding its benefits in the retention of NCCL restorations.[26,27] On the other hand, acid conditioning of the enamel in NCCL was done before the application of adhesives, since Szesz *et al.*,[28] have described that application of acid on enamel before self-etching or universal adhesive in NCCL may result in better esthetical results and marginal adaptation, even though other studies have indicated that there are no significant differences in reconditioning or not the enamel.[24,29]

The FDI evaluation criteria correspond to a method of clinical evaluation that presents a wider categorization, and it is defined with a higher number of evaluated parameters, being more sensitive for the detection of possible differences in the different clinical characteristics of a restoration.[30] For this reason, this study chose this system of evaluation, although the comparison with other types of studies with similar characteristics that have used the USPHS (US Public Health Service) criterion could be more complex.

Within the limitations of the study, it can be mentioned that although each NCCL was measured, a detailed characterization of each NCCL, such as the quantification of enamel on the periphery, quantification of sclerotic dentine, type of NCCL, characteristics of wear facets and type of occlusion of each tooth, was not performed. These aspects can influence adhesion, and thus the clinical behavior of restorations over time.[23] Another limitation of the study is the short-term evaluation. Therefore, it would be necessary to conduct a longer monitoring to evaluate the real clinical behavior of BFRs in NCCL. Finally, it would be interesting to measure the time saved for performing each restoration using BFRs.

CONCLUSION.

The clinical outcome of restorations of NCCL with two brands of BFRs (Tetric N-Ceram Bulk-Fill and Filtek Bulk-Fill) and a conventional nanohybrid CR (Filtek Z350), do not show significant differences at 6 months, demonstrating that the use of BFRs can result in a good clinical outcome in the short term, probably allowing time saving.

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