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ARTICLE

CLINICAL FOLLOW-UP AT 18 MONTHS OF TWO BULK FILL OCCLUSAL COMPOSITE RESINS. A DOUBLE-BLIND RANDOMIZED CLINICAL STUDY.

Seguimiento clínico a 18 meses de dos resinas compuestas oclusales Bulk Fill . Estudio clínico aleatorio doble ciego.

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ABSTRACT:

Objetive: To compare the clinical behavior of two types of Bulk Fill composite resins and a nanohybrid resin at 18 months in occlusal restorations.

Material and Methods: Three occlusal restorations were performed in each one of the 55 participants. They were randomly distributed into three groups, TN: Tetric-N-Ceram Bulk-Fill, FK: Filtek Bulk-Fill, and Z350: Filtek Z350XT. Adhesive techniques and restorative procedures were performed according to the manufacturer's instructions for each restorative material used. In TN and FK an increment of 4mm was applied, and in Z350 increments of ≤2mm depth were applied. Two calibrated operators evaluated the restorations at baseline and at 18 months using the FDI World Dental Federations system (1: excellent, 2: good, 3: satisfactory, 4: unsatisfactory, 5: poor) for clinical marginal staining (MS) properties, fracture-retention (FR), superficial texture (ST), marginal integrity (MI), postoperative sensitivity (PS) and caries (C). Kruskal-Wallis and Wilcoxon were used to compare the 3 groups at 18 months (5% significance).

Results: 38 patients with a total of 114 restorations were assessed, being evaluated with excellent clinical behavior; MI, 78.9% in Z350, 89.51% in TN and 81.6% in FK; ST 73.5% in Z350, 86.8% in TN, and 84.2% in FK; MS 84.2% in Z350, 84.2% in TN, and 91.2% in FK; PS 100% in Z350 and 97.3% in TN and FK; in C and FR, 100% in the 3 groups. There were no significant differences between the three groups (p>0.05).

Conclusion: The three resins studied presented a good clinical performance at 18 months without showing significant differences in the clinical properties evaluated.

KEYWORDS:

Composite resins; bulk fill resin; clinical trial; dental restoration wear; adhesives; randomized controlled trial.

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RESUMEN:

Objetivo: Comparar el comportamiento clínico a 18 meses en restauraciones oclusales entre dos tipos de resinas compuestas Bulk Fill y una resina nanohíbrida.

Material y Métodos: En 55 participantes se realizaron 3 restauraciones oclusales en cada paciente, distribuidas aleatoriamente en 3 grupos, TN: Tetric-N-Ceram Bulk-Fill, FK: Filtek Bulk-Fill y Z350: Filtek Z350XT. Las técnicas adhesivas y procedimientos restauradores fueron realizados según las instrucciones de los fabricantes de cada material restaurador utilizado. En TN y FK se aplicó un incremento de 4mm y en Z350 se aplicó incrementos ≤ 2 mm de profundidad. Dos operadores calibrados evaluaron las restauraciones al baseline y a los 18 meses mediante el sistema FDI World Dental Federations (1: excelente, 2: aceptable, 3: suficiente, 4:insatisfactorio, 5: inaceptable) en las propiedades clínicas de tinción marginal (TM), fractura-retención (FR), textura superficial (TS), integridad marginal (IM), sensibilidad postoperatoria (SP) y caries (C). Se utilizó Kruskal-Wallis y Wilcoxon para la comparación de los 3 grupos a 18 meses (significancia de 5%).

Resultados: Se controlaron 38 pacientes con un total de 114 restauraciones, siendo evaluados con comportamiento clínico excelente; IM, 78.9% en Z350, 89.51% en TN y 81.6% en FK; TS 73.5%, en Z350, 86.8% en TN y 84.2% en FK; TM, 84.2% en Z350, 84.2% en TN y 91.2% en FK; SP 100% en Z350 y 97,3% en TN y FK; en C y FR 100% en los 3 grupos. No hubo diferencias significativas entre los 3 grupos (p>0,05).

Conclusión: Las 3 resinas estudiadas presentaron un buen desempeño clínico a 18 meses sin mostrar diferencias significativas en las propiedades clínicas evaluadas.

PALABRAS CLAVE:

Resinas compuestas; resina bulk fill; ensayo clínico; alisadura de la restauración dental; adhesivos; ensayo clínico controlado aleatorio.

INTRODUCTION.

Composite resins (CRs) have become the material of choice when performing restorations in posterior teeth, mainly due to their excellent functional and aesthetic properties.[1]

However, the main disadvantage of using CRs when restoring is stress due to polymerization contraction, this being more relevant in lesions or occlusal cavities due to the high stress factor or factor C that they have,[2] which can bring about complications such as postoperative sensitivity, marginal staining and, in the long term, the possibility of developing new caries lesions.[3]

It has been established that to counteract the stress caused by contraction, ensuring complete polymerization of the CR, it is necessary to use a technique with increments of up to 2 mm, a process that has the possible disadvantages of incorporating air bubbles or contaminating the material in each increase, and a greater use of clinical time.[4]

The constant search to improve the restoration technique with CR, maintaining its optimal clinical behavior, has encouraged the industry to incorporate Bulk Fill resins (BKR), which are indicated to be used in a single increment or monoblock of up to 4 mm deep thanks to the translucency of the material resulting from the quantity and size of the filler particles.[5]

Despite promising laboratory findings, certain studies have reported that the use of CR in these thicknesses could increase cusp deflection and cause stress in the adhesive interface, even though the meta-analysis performed by Cidreira *et al.*,[6] suggested that the application technique may not influence stress due to polymerization contraction at the adhesive interface.

On the other hand, clinical studies reveal the real behavior of materials in the mouth. There are some publications related to BKR, with 12-month reports suggesting acceptable clinical behavior in posterior teeth.[7] However, there is still a lack of randomized clinical studies providing greater evidence of the performance of the different commercial brands of BKRs,[8] so it is of interest and important to evaluate their clinical behavior by comparing them with each other.

For this reason, the main objective of the present study was to compare at 18 months the clinical performance of occlusal restorations performed with two BKRs (Tetric N-Ceram Bulk-Fill and Filtek Bulk-Fill), and a conventional nanohybrid CR (Filtek Z350), proposing as a null hypothesis the non-existence of significant differences in clinical behavior between the three resins evaluated.

MATERIALS AND METHODS.

Study design

This experimental, controlled, randomized, double-blind (patient and operator) study follows the Consort 2010 clinical trial guideline.[9]

The study was carried out between March 2017 and January 2019 and approved by the ethics committee of the School of Dentistry of Universidad Andrés Bello number #PROPRGFO_002017.40 and registered at *https://clinicaltrial.gov* with the code NCT03230604. Each participating patient was informed of the details of the study and asked to sign an informed consent.

Sample Size Calculation and Selection of Participants

To calculate the sample size, a statistical power of (1-β) =80% was initially considered with a type I error (α) =0.05, resulting in an approximate total of 46 restorations per group, increased to 55 per group due to a possible 20% loss of patients in one year. Using G.Power software version 3.1, the following formula was calculated: non-centrally δ= 2.5248762, critical t= 1.6602343, d_f=51 and power= 0.8058986.

Through a clinical examination carried out by two operators according to the inclusion and exclusion criteria, 55 patients who voluntarily attended the Dental Clinic of the School of Dentistry of Universidad Andrés Bello-Santiago were selected. (Figure 1)

Eligibility of participants

Inclusion criteria: Patients ≥18 years old, healthy, ≥24 teeth in occlusion, with availability of time for follow-up, and with high cariogenic risk. Teeth with 3 caries lesions and/or indication for replacement of occlusal restorations in molars or premolars, with a depth greater than 3 mm, with a thickness not > 1/3 of the intercuspal distance, and with at least one occlusal contact and proximal contact on a natural tooth.

Exclusion criteria: Patients with active periodontal disease, with severe bruxism or temporomandibular disorder, with evidence of xerostomia, pregnant or lactating women, with psychomotor problems that prevent hygiene, history of allergy to resin. Abutment teeth for prosthesis, endodontically treated or with pulp problems, with cracks in dentin and impossibility of absolute isolation.

Calibration and training of operators

Two operators with more than 10 years of professional experience performed all the restorations. Prior to the restoration process, a calibration of the clinical procedure was carried out. An oral rehabilitation specialist demonstrated the entire clinical sequence for each material, which is detailed in the clinical protocol column of Table 1.

Then each operator performed four restorations under the supervision of the lead researcher. Errors and defects in restorations were observed, discussed, and corrected through a checklist. Both operators were calibrated according to the FDI criteria with an intra- and inter-operator Cohen's Kappa of ≥ 0.8.

Clinical Procedure

Patients were anesthetized using the corresponding technique depending on the tooth. Then only the carious tissue or of restoration replacement was removed conservatively using high-speed diamond spherical burs (1010 to 1014-

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KG Sorensen, SP, Brazil) and under abundant cooling with water. The measurements of the biological preparation were recorded with a millimeter probe (HuFriedy®, North Carolina, Chicago, USA), in three directions (mesio-distal, vestibular-lingual, and cervical-occlusal). Each restorative process was performed with absolute isolation.

In each patient, the three groups of composite resin FK, TN and Z350 were performed, using the adhesive of the same commercial brand. The materials, adhesive, and restorative procedures are explained in Table 1. The light-curing process was carried out with an LED unit with a minimum irradiance of 1,100 mW/cm^2 (Bluephase Style, Ivoclar Vivadent, AG, Schaan, Liechtenstein), being checked throughout the process with a radiometer (LEDEXTM CM4000, Dentmate technology Co., Ltd. Taiwan.) Fine-grained high-speed diamond burs (JotaG, Rüti, Switzerland) were used for finishing, and Enhance-style polishing cups were used for polishing (Dentsply, Petrópolis, RJ, Brazil) and rubber polishing burs for composite (Jota-Suiza) at low speed.

Randomization and assignment

The randomization process of each restoration was carried out using a spreadsheet designed in Excel by an external operator. The assignment of each tooth to its corresponding group was recorded in an opaque, sealed, and numbered envelope. At the time of restoration, the operator opened the envelope, ensuring randomization. The operators were not blinded due to the procedural differences that exist between each material; however, the patient and the evaluators did not know which restoration each group corresponded to.

Clinical Evaluation

Two blinded examiners (they did not know the distribution of each group) different from those who performed the restoration, evaluated at 15 days (Baseline), and 18 months (18m) all the restorations using the FDI criteria (10) (Table 2) with the parameters marginal staining (MS), marginal integrity (MI), fracture and retention (FR), superficial texture (ST), postoperative sensitivity (PS) and caries (C), being classified as excellent=1, good=2, satisfactory=3, unsatisfactory=4, and poor=5. Both examiners were calibrated intra and inter-examiner (Cohen Kappa ≥ 0.8).

The evaluations were carried out with a flat buccal mirror number 23, respectively (Hu-Friedy Mfg.Co.Inc.Chicago, Il. USA) with lighting and a 3.5x magnifying glass (Bio Art, Brazil). In the evaluation of marginal adaptation, the probes recommended by FDI (Deppeler Swiss Dental, Rolle, Switzerland) were used. The evaluations were carried out independently and in case of disagreement, the examiners re-evaluated the restoration, reaching a consensus before the patient left the room

Statistical analysis

For the statistical analysis of the data, the SPSS 21.0 software for Windows (SPSS, Chicago, IL, USA) was used. The categories obtained for each clinical parameter in the groups were arranged and ordered. The Wilcoxon test was used to evaluate the same group as a function of time (baseline and 18 months) for all the clinical parameters, and the Kruskal Wallis test was used for the comparison of the parameters between the three groups at 18 months. A level of significance of 5% was considered for both tests. Statistical analysis was performed by an external operator.

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RESULTS.

Of the total of 55 patients, 38 attended the 18-month check-up, of which 24 were females (63.2%) and 14 males (36.8%), with a mean age of 23 years (ranging between 18-45 years). The detail of the distribution of the restorations is explained in Table 3, highlighting that 38.6% (44 teeth) were in the upper teeth and 64.4% (70 teeth) in the lower teeth. Mean measurements and the standard deviation of the dimensions of each preparation are described in Table 4, highlighting that the average depth in the cervical-occlusal direction was 3.35mm for Z350, 3.28mm for FK, and 3.27mm for TN.

The comparisons of the different groups between Baseline and 18 months are represented in

Table 5. At 18 months (18m) the results qualified as excellent in each group were: MI, 78.9%[30] in Z350, 89.51%[34] in TN, and 81.6%[31] FK. In MS they were qualified excellent for Z350 (73.5%)[28] 86.8%[33] in TN, and 84.2%[32] for FK. In MS, it was excellent for Z350 84.2%[32] 84.2%[32] in TN, and 91.2%[35] in FK. There was no PS at 18m in Z350 and TN, and there was only 1 case qualified as good in the FK group. In the C and FR parameter, 100% of the cases were excellent in the 3 groups studied. In the comparison of the 3 groups at 18m, there were no significant differences in all the parameters ($p>0.05$). When evaluating the clinical behavior by group between baseline and 18 months (intragroup), it is highlighted that there were statistically significant differences in the MI, ST, and MS parameters ($p<0.05$).

Figure 1. P¿Study CONSORT flowchart.[9]

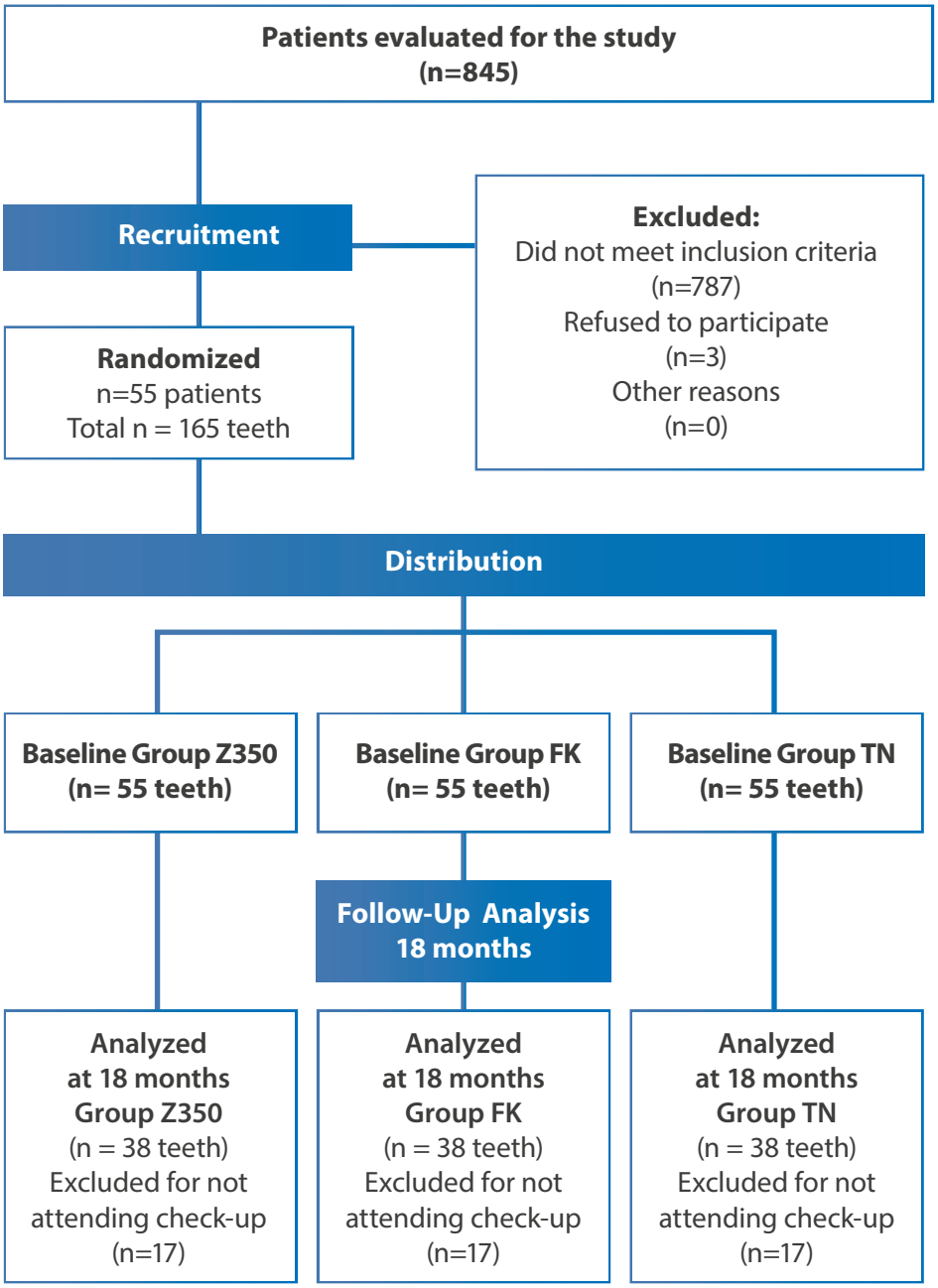

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Table 1. Materials, manufacturing, composition, and clinical protocol of the materials used.

Material	Manufacturing/Lot	Composition	Clinical protocol
Gel Etchant	Kerr Co. Orange, CA USA /5524662	37% orthophosphoric acid	Application on enamel for 20 seconds. Washing for twice the time and drying.
Single Bond Universal (SBU)	3M Espe St. Paul, MN, USA / 653245-652541	MDP: Phosphate monomer. Dimethacrylate resins, HEMA. Vitrebond copolymer, ethanol, water, and silane.	Active application of two layers of adhesive for 20 seconds, blow-dried for 25 sec. andphotopolymerization for 20 sec.
Tetric N Bond Universal (TU)	Ivoclar Vivadent AG, Schaan, Liechtenstein / V11838.	Bis-GMA.UDMA. Dimethacrylate. HEMA. Phosphonic acid acrylate. Silicon Dioxide nano filler (SiO2). Ethanol, stabilizers	Active application of two layers of adhesive for 20 seconds, blowdried for 25 sec. and photopolymerization for 20 sec.
Tetric N Ceram Bulk Fill (TN)	Ivoclar Vivadent AG, Schaan, Liechtenstein /Color IVB: V35951 Color IVA :Q33216	Bis-GMA, UDMA, Bis- EMA. Glass filled (barium aluminum silicate). 17% Isofiller (Di-methacrylates, glass filler and ytterbium fluoride). Inorganic filler: 78.6% by weight (61% volume). Initiator: Ivocerin	Application in an increment no greater than 4 mm. photopolymerization for 20 sec.
Filtek Bulk fill (FK)	3M Espe St. Paul, MN, USA / Color A3 N7661149.	Bis-GMA, AUDMA, DDDMA, Bis-EMA, Di-methacrylates, TEGDMA, diluents. Ytterbium trifluoride (particle size: 0.1 to 5 microns). Zirconium/silica (particle size: 0.01 to 3.5 µm). Inorganic filler: 76.5% by weight (58.4% by volume)	Application in an increment no greater than 4 mm. photopolymerization for 20 sec.
Filtek Z350 Universal (Z350)	3M Espe St. Paul, MN, USA/ Color A3 N753777 Color: A3.5 / N547639.	UDMA, Bis-EMA, TEGDMA, Bis-GMA. Zirconium/silica. Particle size: 0.6 – 10 µm. Inorganic filler: 72.5% by weight (55.6% volume)	Application in multiple increments less than 2 mm. photopolymerization for 20 sec.

MDP: Methacryloxydecylphosphate dihydrogen. **HEMA:** Hydroxyethyl methacrylate. **UDMA:** Urethane Dimethacrylate. **TEGDMA:** triethylene glycol dimethacrylate. **Bis-GMA:** Bisphenol Glycidyl Methacrylate. **Bis-EMA:** Bisphenol polyethylene glycol diether methacrylate. **AUDMA:** Aromatic urethane dimethacrylate. **DDMA:** Dodecadeniol dimethacrylate.

Table 2. System for Evaluating Restorations World Dental Federation (FDI).

	World Dental Federation (FDI) Criteria				
	Aesthetic Properties	Functional properties		Biological properties	
Criterion	1. Marginal staining	2. Fracture and Retention	3. Marginal adaptation	4. Postoperative sensitivity	5. Recurrence of caries
1. Excellent	1.1 No marginal staining	2.1 Restoration retained, no fractures or cracks	3.1 Harmonious outline, no gaps, no discoloration	4.1 No hyper sensitivity	5.1 No secondary or primary caries
2. Good	1.2 Minor marginal staining, easily removable by polishing	2.2 Small hairline cracks	3.2.1 Marginal gap that is a white line (<150µm) 3.2.2 Small marginal fracture removable by polishing 3.2.3 Small gap or irregularity	4.2 Low hypersensitivity for a limited period of time	5.2 Very small and localized demineralization area. No operative treatment required.
3. Satisfactory	1.3 Moderate marginal staining, not aesthetically unacceptable	2.3 Two or more larger hairline cracks and/or chipping (not affecting marginal integrity)	3.3.1 Gap <250 µm and non-removable 3.3.2 Several small marginal fractures 3.3.3 Major irregularities or gaps	4.3.1 Premature/slightly increased sensitivity 4.3.2 Delayed sensitivity/weak sensitivity, without subjective complaints; no treatment needed.	4.3 Large areas of demineralization, only preventive measures are necessary (with no dentin exposure).
4. Unsatisfactory	1.4 Pronounced marginal staining, major intervention is necessary	2.4 Chipping fractures that damage marginal quality, bulk fractures with or without partial loss (less than half of the restoration)	3.4.1 Gap >250 µm and non-removable, dentin/base exposed. 3.4.2 Severe marginal fractures 3.4.3 Major irregularities (treatment is necessary)	4.4.1 Premature/very intense sensitivity 4.4.2 Extremely delayed/weak sensitivity with subjective complaints 4.4.3 Negative sensitivity, intervention necessary but not replacement	4.4 Caries with cavitation (localized and accessible and can be repaired).
5. Poor	1.5 Deep marginal staining not accessible for intervention	2.5 Partial or complete loss of restoration	3.5.1 Partial or complete restoration/filling is loose but in situ 3.5.2 Generalized major gaps	4.5 Very intense sensitivity, acute pulpitis, or pulpal necrosis. Endodontic treatment is mandatory. Restoration must be replaced.	4.5 Deep secondary caries or exposed dentin, not accessible for repair or restoration.

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Table 3. Distribution of restorations according to type of operated tooth.

	MAXILLARY		MANDIBULAR		
	Premolar	Molar	Premolar	Molar	Total
Z350	3.5% (4)	2.6% (3)	9.6% (11)	17.5% (20)	33.3% (38)
FK	0%	14.9% (17)	0.8% (1)	17.5% (20)	33.3% (38)
TN	0%	17.5% (20)	0%	15.7% (18)	33.3% (38)
Total	3.5% (4)	35% (40)	10.4% (12)	50.7% (58)	100% (114)

Table 4. Dimensions of the cavities to be restored according to group.

	Depth C-O (mm)			Length M-D (mm)			Width V-L/P (mm)		
Groups	Z350	FK	TN	Z350	FK	TN	Z350	FK	TN
Median	3.00	3.00	4.00	5.00	5.00	4.50	3.50	4.00	3.00
SD	0,69	0.74	0.84	2.03	1.70	2.06	1.33	1.00	1.78
Mean	3.35	3.28	3.27	5.39	5.22	5.03	3.80	3.93	3.86

***C-O:** Cervical-Occlusal. ***M-D:** Mesial-Distal. ***V-L/P:** Vestibular-Lingual/Palatal. **SD:** Standard Deviation.

Table 5. Clinical evaluation of the restorations expressed in percentage (%) and frequency (f).

Clinical property	Criterion	Z350		TN		FK		Sig.
		B %(f)	18m %(f)	B %(f)	18m %(f)	B %(f)	18m %(f)	
Marginal integrity	1. Excellent	100% (38)	78.9% (30)	100% (38)	89.5% (34)	100% (38)	81.6% (31)	p>0.05
	2. Good	---	18.4% (7)	---	10.5% (4)	---	13.2% (5)	
	3. Satisfactory	---	2.6% (1)	---	---	---	5.3% (2)	
	4. Unsatisfactory	---	---	---	---	---	---	
	5. Poor	---	---	---	---	---	---	
Surface texture	1. Excellent	100% (38)	73.7% (28)	100% (38)	86.8% (33)	100% (38)	84.2% (32)	p>0.05
	2. Good	---	26.3% (10)	---	13.2% (5)	---	15.8% (6)	
	3. Satisfactory	---	---	---	---	---	---	
	4. Unsatisfactory	---	---	---	---	---	---	
	5. Poor	---	---	---	---	---	---	
Marginal staining	1. Excellent	100% (38)	84.2% (32)	100% (38)	84.2% (32)	100% (38)	92.1% (35)	p>0.05
	2. Good	---	13.2% (5)	---	10.5%(4)	---	2.6% (1)	
	3. Satisfactory	---	2.6% (1)	---	5.3 (2)	---	5.3% (2)	
	4. Unsatisfactory	---	---	---	---	---	---	
	5. Poor	---	---	---	---	---	---	
Sensitivity	1. Excellent	100% (38)	100% (38)	100% (38)	100% (38)	100% (38)	97.4% (37)	p>0.05
	2. Good	---	---	---	---	---	2.6% (1)	
	3. Satisfactory	---	---	---	---	---	---	
	4. Unsatisfactory	---	---	---	---	---	---	
	5. Poor	---	---	---	---	---	---	
Fracture and Retention	1. Excellent	100% (38)	100% (38)	100% (38)	100% (38)	100% (38)	100% (38)	p>0.05
	2. Good	---	---	---	---	---	---	
	3. Satisfactory	---	---	---	---	---	---	
	4. Unsatisfactory	---	---	---	---	---	---	
	5. Poor	---	---	---	---	---	---	
Caries	1. Excellent	100% (38)	100% (38)	100% (38)	100% (38)	100% (38)	100% (38)	p>0.05
	2. Good	---	---	---	---	---	---	
	3. Satisfactory	---	---	---	---	---	---	
	4. Unsatisfactory	---	---	---	---	---	---	
	5. Poor	---	---	---	---	---	---	

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DISCUSSION.

The objective of this study was to evaluate the clinical behavior of occlusal restorations made with two BKRs and a control group of restorations made with a nanohybrid CR. According to the results obtained, the null hypothesis is not rejected, with no significant differences at 18 months of evaluation between the groups studied, according to the FDI clinical properties.

Similar results were found in 2017, where a clinical evaluation was carried out at 6 years of restorations of class I and II caries lesions, performed with conventional CR and a BKR, also carrying out an intermediate evaluation at 3 and 5 years, whose findings indicated that there was no significant difference between the two restoration groups, using the USPHS criteria.[11]

In the clinical property of fracture and retention, there were no defects in the 3 groups studied, being practically 100% evaluated as excellent. This result could suggest that both BKRs have adequate initial mechanical properties, which makes them resistant to the usual occlusal forces, having a behavior similar to conventional CR.

Comparable retention rates have been reported in other clinical studies.[8,12,13] However, it should be noted that patients with signs of bruxism or occlusal instability were excluded, a factor that could influence the behavior of these materials. It would be advisable to incorporate these factors in future research to evaluate the resistance of resins more extensively in an even more demanding clinical context from the biomechanical point of view.

Even though occlusal lesions may have a high SPC factor depending on the size of the cavity, in terms of PS, these were not present at baseline and at 18 months, except in one case in the FK group, an unusual occurrence that has been partly explained by cusp deflection (14) or by some type of adhesive failure (15). It should be noted that there were no significant differences between the groups, which agrees with the same systematic review carried out by Hardan *et al.*,[14] in 2021.

There was no presence of secondary caries in the evaluated period, which coincides with other reports, mainly because all the patients, for ethical reasons, were treated to lower their initial cariogenic risk. In addition, and even though it has been shown that the main factor for the development of caries is the oral environment,[7] local factors also play a role, such as the marginal integrity of the restorations[16] a characteristic that should be ruled out in this study as an etiological factor, since characteristics between excellent and satisfactory were found in this aspect in the three groups studied.

In T, MI, and MS there was a significant deterioration of the 3 groups between baseline and 18 months. This can be explained by the degradation of the adhesive at the interface between tooth and restoration, noting that this has been related to unfavorable effects of the SPC, because it can produce failures in the marginal sealing of the restoration, with gaps and subsequent accumulation of plaque and stains. A recent study carried out by Yazici *et al.*,[17] shows the 6-year clinical result of two CRs, Tetric Evoceram Bulkfill and Filtek Ultimate (different from the one used in the present study), reporting that in the case of BKR the deterioration in MS was practically minimal, with significant differences with the conventional resin group. Despite this, the study by Yazici is not comparable because it was evaluated using the USPHS criteria and was carried out with another type of adhesive (etch-rinse). It is worth mentioning that in the present study universal adhesives were used, carrying out a selective conditioning of the enamel with 37% orthophosphoric acid, as recommended, since the ordinary action of the acid monomers of the universal adhesives does not allow an adequate etching pattern that maintains the sealing properties between the tooth-restoration interface.[18]

Some studies suggest that the type of adhesive used can directly affect the MI parameters and marginal staining, so using different brands of

adhesives could produce certain discrepancies, mainly due to the different compositions between them. This finding was reported in the last review by Dreweck and collaborators.[19] Despite the aforementioned aspects, there were no differences between the three groups at 18 months in the follow-up period reported in this study, results that would agree with similar studies in classes I carried out by Suneelkumar *et al.*,[20] and Durão *et al.*[21]

It is important to note that the evaluation time may still be insufficient to be able to observe any significant difference in these clinical properties, as was indicated in the study by Yazici *et al.*,[17] who found differences from 24 months onwards. It can also be mentioned that in a future design it would be advisable to use a single adhesive to avoid the possible confounding factor of the adhesive.

The present study was carried out using the FDI evaluation system, with the aim of detecting the possible differences between the restoration materials with greater precision, since a study carried out by[21] found significant differences using the USPHS evaluation system, especially in ST and MI. The FDI restoration evaluation system corresponds to a clinical evaluation method that presents a broader categorization and multiple clinical properties, being more sensitive and detailed in the detection of possible defects in restorations.[10]

However, it must be mentioned that this same point could be a limitation because there is another clinical evaluation system such as the USPHS or Ryge, the most used method in the past and one that could make comparison with other clinical studies of the same nature more difficult.

The following aspect can be mentioned as a limitation of the study: the initial total number of restorations, which indicated a reliable statistical power, was not obtained, because, as in all clinical studies, there was a significant percentage of patients (approximately 30%) who did not attend subsequent check-ups, and in which it was not possible to standardize the preparations, due to the diversity of carious lesions and/or restorations.

Finally, this study suggests that, in the medium term, Bulk Fill resins had an acceptable clinical behavior, and they can be considered the material of choice due to the potential saving of clinical time, which preserves the properties of conventional restorative materials. However, these results must be interpreted with some caution, and must be confirmed in a long-term follow-up study, to verify whether Bulk Fill resins have a better clinical behavior compared to conventional resins.

CONCLUSION.

When comparing the occlusal restorations performed with two types of Bulk Fill resins and a conventional nano-hybrid resin, the three groups of resins presented an acceptable clinical performance, finding no significant differences in clinical behavior during the 18-month evaluation period.

When evaluating the MS, MI, and ST parameters, significant differences were found between the baseline and the end of the follow-up period in the three resins studied.

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The authors declare no conflict of interest.

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Authors' contributions:

Vildósola P: Conceptualization, development, methodology, and supervision of the study. Critical review of the manuscript.

Rodriguez S: Investigation procedure in the execution of the restorations in the study participants.

Carrión J: Collection of results as an evaluator of the study participants.

Saez C: Collection of results as of the study participants.

Nakouzi Momares J: Edition of the manuscript.

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REFERENCES.

1. Lynch CD, Opdam NJ, Hickel R, Brunton PA, Gurgan S, Kakaboura A, et al. Guidance on posterior resin composites: Academy of Operative Dentistry - European Section. J Dent. 2014;42(4):377-83.
2. Feilzer AJ, de Gee AJ, Davidson CL. Setting stresses in composites for two different curing modes. Dent Mater. 1993;9(1):2-5.
3. Kaisarly D, Meierhofer D, El Gezawi M, Rösch P, Kunzelmann KH. Effects of flowable liners on the shrinkage vectors of bulk-fill composites. Clin Oral Investig. 2021;25(8):4927-40.
4. Sabbagh J, McConnell RJ, McConnell MC. Posterior composites: Update on cavities and filling techniques. J Dent. 2017;57:86-90.
5. Bucuta S, Ilie N. Light transmittance and micro-mechanical properties of bulk fill vs. conventional resin based composites. Clin Oral Investig. 2014;18(8):1991-2000.
6. Cidreira Boaro LC, Pereira Lopes D, de Souza ASC, Lie Nakano E, Ayala Perez MD, Pfeifer CS, et al. Clinical performance and chemical-physical properties of bulk fill composites resin -a systematic review and meta-analysis. Dent Mater. 2019;35(10):e249-e64.
7. Veloso SRM, Lemos CAA, de Moraes SLD, do Egito Vasconcelos BC, Pellizzer EP, de Melo Monteiro GQ. Clinical performance of bulk-fill and conventional resin composite restorations in posterior teeth: a systematic review and meta-analysis. Clin Oral Investig. 2019;23(1):221-33.
8. Arbildo-Vega HI, Lapinska B, Panda S, Lamas-Lara C, Khan AS, Lukomska-Szymanska M. Clinical Effectiveness of Bulk-Fill and Conventional Resin Composite Restorations: Systematic Review and Meta-Analysis. Polymers (Basel). 2020;12(8).
9. Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. Int J Surg. 2011;9(8):672-7.
10. Hickel R, Peschke A, Tyas M, Mjör I, Bayne S, Peters M, Hiller KA, Randall R, Vanherle G, Heintze SD. FDI World Dental Federation: clinical criteria for the evaluation of direct and indirect restorations-update and clinical examples. Clin Oral Investig. 2010;14(4):349-66. doi: 10.1007/s00784-010-0432-8. Epub 2010 Jul 14. PMID: 20628774.
11. van Dijken JWV, Pallesen U. Bulk-filled posterior resin restorations based on stress-decreasing resin technology: a randomized, controlled 6-year evaluation. Eur J Oral Sci. 2017;125(4):303-9.
12. Yazici AR, Antonson SA, Kutuk ZB, Ergin E. Thirty-Six-Month Clinical Comparison of Bulk Fill and Nanofill Composite Restorations. Oper Dent. 2017;42(5):478-85.
13. Vildósola P, Nakouzi J, Rodriguez S, Reyes A, Reyes J & Conejeros C. Six month follow-up of two Bulk-fill composites in non-carious cervical lesions: Double blind randomized clinical trial. J Oral Res. 2019;8(3):9.
14. Hardan L, Sidawi L, Akhundov M, Bourgi R, Ghaleb M, Dabbagh S, et al. One-Year Clinical Performance of the Fast-Modelling Bulk Technique and Composite-Up Layering Technique in Class I Cavities. Polymers (Basel). 2021;13(11).
15. Perdigão J. Current perspectives on dental adhesion: (1) Dentin adhesion - not there yet. Jpn Dent Sci Rev. 2020;56(1):190-207.
16. Dennison JB, Sarrett DC. Prediction and diagnosis of clinical outcomes affecting restoration margins. J Oral Rehabil. 2012;39(4):301-18.
17. Yazici AR, Kutuk ZB, Ergin E, Karahan S, Antonson SA. Six-year clinical evaluation of bulk-fill and nanofill resin composite restorations. Clin Oral Investig. 2021.
18. Van Meerbeek B, Yoshihara K, Van Landuyt K, Yoshida Y, Peumans M. From Buonocore's Pioneering Acid-Etch Technique to Self-Adhering Restoratives. A Status Perspective of Rapidly Advancing Dental Adhesive Technology. J Adhes Dent. 2020;22(1):7-34.
19. Dreweck FDS, Burey A, de Oliveira Dreweck M, Loguercio AD, Reis A. Adhesive strategies in cervical lesions: systematic review and a network meta-analysis of randomized controlled trials. Clin Oral Investig. 2021;25(5):2495-510.
20. Suneelkumar C, Harshala P, Madhusudhana K, Lavanya A, Subha A, Swapna S. Clinical performance of class I cavities restored with bulk fill composite at a 1-year follow-up using the FDI criteria: a randomized clinical trial. Restor Dent Endod. 2021;46(2):e24.
21. Durão MA, Andrade AKM, Santos MDCM, Montes MAJR, Monteiro GQM. Clinical Performance of Bulk-Fill Resin Composite Restorations Using the United States Public Health Service and Federation Dentaire Internationale Criteria: A 12-Month Randomized Clinical Trial. Eur J Dent. 2021;15(2):179-92.

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