

TWO-YEAR FOLLOW-UP STUDY OF REPAIRS USING CONVENTIONAL RESINS AND BULK-FILL IN PROXIMAL RESTORATIONS. A DOUBLE-BLIND RANDOMIZED CLINICAL TRIAL

Dos años de seguimiento con resina convencional y Bulk-fill en restauraciones proximales. Estudio clínico aleatorio doble ciego

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ABSTRACT

Introduction: Currently, composite resins (CRs) are the material of choice for direct restorations, and in cases of partial deterioration, repair is often recommended, as it significantly increases their lifespan. Bulk-fill resins (BFRs), on the other hand, are restorative materials that can be applied in single increments, thereby simplifying the procedure and reducing clinical time. The objective of this study was to evaluate the two-year clinical performance of repairs of proximal posterior composite resin restorations performed using BFRs and conventional nanohybrid CRs.

Materials and Methods: Thirty-six volunteer patients from the clinic of the Faculty of Dentistry at the Universidad de Chile participated in this study. It had an experimental, controlled, randomized, double-blind clinical design, in which the experimental unit was the repair of proximal CR restorations. The groups evaluated were as follows: Group 1, repair with Tetric EvoCeram Bulk Fill® resin (TEVO); and Group 2, repair with Filtek Z350 XT® resin (Z350). Repairs were evaluated at baseline and at 24 months using the FDI World Dental Federation evaluation system (1: clinically excellent/very good, 2: clinically good, 3: clinically sufficient/satisfactory, 4: clinically unsatisfactory, 5: clinically poor) for the following clinical properties: marginal integrity (MI), surface texture (ST), marginal staining (MS), sensitivity (S), fracture and retention (RT), proximal and occlusal anatomy (AN), and caries (C).

Results: A total of 72 restorations were followed up. Excellent clinical performance was observed in the following parameters: MI: Z350 86.1% and TEVO 83.3%; ST: Z350 77.8% and TEVO 80.6%; MS: Z350 63.9% and TEVO 66.6%. For both fracture and retention (RT) and anatomy (AN), excellent performance was observed for Z350 (86.1%) and TEVO (88.8%). For sensitivity (S) and caries (C), both groups showed 100% excellent outcomes. No statistically significant differences were found between the two groups ($p>0.05$).

Conclusion: There were no statistically significant differences in two-year clinical performance between repairs of proximal posterior composite resin restorations performed using BFR and conventional composite resin.

Keywords: Composite resins; Filtek bulk fill; Dental restoration; Controlled clinical trial; Dental caries; Treatment outcome

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RESUMEN

Introducción: Actualmente las resinas compuestas (RC) son el material de elección para realizar restauraciones directas y ante el deterioro parcial de estas restauraciones la recomendación puede ser la reparación, permitiendo aumentar significativamente su vida útil. Por otro lado las resinas Bulkfill (RBK) son materiales de restauración que se pueden aplicar en mono incrementos, simplificando y reduciendo el tiempo clínico. El objetivo de este estudio fue evaluar el comportamiento clínico a 2 años de reparaciones de restauraciones de resina compuesta posteriores proximales realizadas con RBK y con RC nano híbrida convencional.

Materiales y Métodos: Participaron 36 pacientes voluntarios de la clínica de la Facultad de Odontología de la Universidad de Chile. Este estudio tuvo un diseño clínico experimental, controlado, randomizado y doble ciego, donde la unidad experimental fue la reparación de restauración de RC proximal. Los grupos evaluados fueron: Grupo 1: Reparación con resina Tetric EvoCeram Bulkfill® (TEVO) y Grupo 2: Reparación con resina Filtek Z350 XT® (Z350). Las reparaciones fueron evaluadas al baseline y a los 24 meses mediante el sistema FDI World Dental Federations (1: excelente, 2: aceptable, 3: suficiente, 4: insatisfactorio, 5: inaceptable) en las propiedades clínicas de: integridad marginal (IM), textura superficial (TS), tinción marginal (T), sensibilidad (S), fractura y retención (RT), anatomía proximal y oclusal (AN), y caries (C).

Resultados: Se controlaron un total de 72 restauraciones, siendo evaluados con comportamiento clínico excelente en los parámetros IM: Z350 86,1% y TEVO 83,3%; TS: Z350 77,8% y TEVO 80,6%; TM Z350 63,9% y TEVO 66,6%; para ambos RT y A: Z350 86,1% y TEVO 88,8%; y para S y C ambos grupos fueron 100%. No hubo diferencias significativas entre los 2 grupos ($p>0,05$).

Conclusión: No existe diferencia estadísticamente significativa en el desempeño comportamiento clínico a 2 años entre las reparaciones efectuadas de restauraciones de resinas compuesta proximales posteriores con RBK y resina compuesta convencional.

Palabras clave: Resinas compuestas; Filtek bulk fill; Restauración dental; Ensayo clínico controlado; Caries dental; Resultado del tratamiento

INTRODUCTION

Composite resins (CRs) have become the material of first choice for direct posterior restorations due to their aesthetic and mechanical properties, which have demonstrated more than acceptable longevity in several clinical studies.^{1,2} In the past, when a restoration was deemed deficient, the traditional recommendation was replacement, a procedure that involves removing all restorative material and may cause additional wear or weakening of healthy tooth structure, thereby reducing the longevity of the restored tooth.³⁻⁶

Repairing a restoration is an alternative treatment that consists of removing only the par-

tially affected material and subsequently applying new restorative material in its place.⁷ This approach has been explored in numerous *in vitro* and clinical studies, demonstrating scientific support, and has even been defined as a first-line treatment recommendation in indicated cases.⁷⁻⁹ Among its advantages, literature reviews describe repair as a procedure that requires less clinical time than replacement and presents a lower probability of side effects or collateral damage, such as loss of pulp vitality.^{10,11}

Furthermore, bulk-fill resins (BFRs) are restorative materials designed to be applied in a single 4- to 5-mm increment without compromising the degree of conversion or

depth of cure. These characteristics allow for adequate mechanical performance in the oral environment. In addition, BFRs reduce the likelihood of bubble inclusion during the clinical procedure, as they require fewer increments than conventional composite resins.^{12,13} This improvement is attributed to the greater translucency of these materials, resulting from increased filler particle size, as well as the incorporation of more efficient photoinitiator systems, such as Ivocerin (present in Tetric EvoCeram Bulk Fill).¹⁴ *In vitro* studies have shown that BFRs exhibit performance comparable to conventional composite resins (CRs) in terms of bond strength, shear strength, polymerization efficiency, and shrinkage stress control caused by polymerization.¹⁵

Moreover, a clinical study by Balkaya *et al.*,¹⁶ reported no clinical differences between BFR-based composites and conventional CRs according to Ryge criteria after 2 years of follow-up. Similarly, Hoffmann *et al.*,¹² concluded in 2021 that BFRs demonstrated acceptable clinical performance comparable to nanohybrid resins over a 2-year period. These findings are further supported by a clinical study conducted by Loguercio *et al.* in 2023, which reported acceptable clinical performance of BFRs after 5 years of evaluation.¹⁷ Likewise, a comparative meta-analysis by Arbildo-Vega *et al.* found no significant differences between BFRs and conventional CRs, although the authors emphasized the need for additional long-term clinical studies.¹⁸

Regarding the repair of composite resins using BFRs, some *in vitro* studies have demonstrated high bond strength between nanofilled CRs and BFRs.¹⁹ However, to date, no clinical studies have evaluated the clinical performance of repairs performed with BFR-containing composite resins. Therefore, the main objective of this study was to

compare the 2-year clinical performance of posterior proximal composite resin repairs using a BFR and a conventional composite resin, according to the FDI criteria,²⁰ with respect to marginal integrity (MI), surface texture (ST), marginal staining (MS), sensitivity (S), material retention (RT), proximal and occlusal anatomy (AN), and caries (C). The hypothesis was that, over a 2-year follow-up period, there would be no significant differences in clinical performance between proximal restoration repairs performed with a conventional nanohybrid composite resin and those performed with a BFR.

MATERIALS AND METHODS

This was an experimental, controlled, randomized, double-blind (patient and examiner) study. It was designed in accordance with the 2010 CONSORT guidelines for clinical research and the Declaration of Helsinki, and was registered at clinicaltrials.gov under the code NCT05013866.

The study was conducted between March 2017 and January 2020 and was approved by the Ethics Committee of the Faculty of Dentistry, Universidad de Chile (CEC 2016/13).

Sample size calculation and participant selection

For the calculation of the sample size, a statistical power of $(1 - \beta)$ 80% was considered, with a type I error (α) = 0.05, resulting in an approximate total of 41 restorations per study group according to the type of restorations (41 restorations for the control group and 41 restorations for the experimental group) (n both groups = 82) (Figure 1).

Participant eligibility

Inclusion criteria: Patients aged ≥ 18 years, with 20 or more teeth in functional occlusion

and availability to attend follow-up visits. Teeth with at least two proximal restorations presenting defects with an indication for repair according to FDI criteria, including proximal anatomical form, marginal staining, surface staining or color change with aesthetic compromise, marginal adaptation, and/or caries.

Restorations involving less than one third of the intercuspal distance, with a proximal box depth greater than 2 mm in the cervico-occlusal direction, a supragingival enamel floor, normal radiographic appearance, and a positive response to vitality testing, and with no periodontal disease.

Exclusion criteria

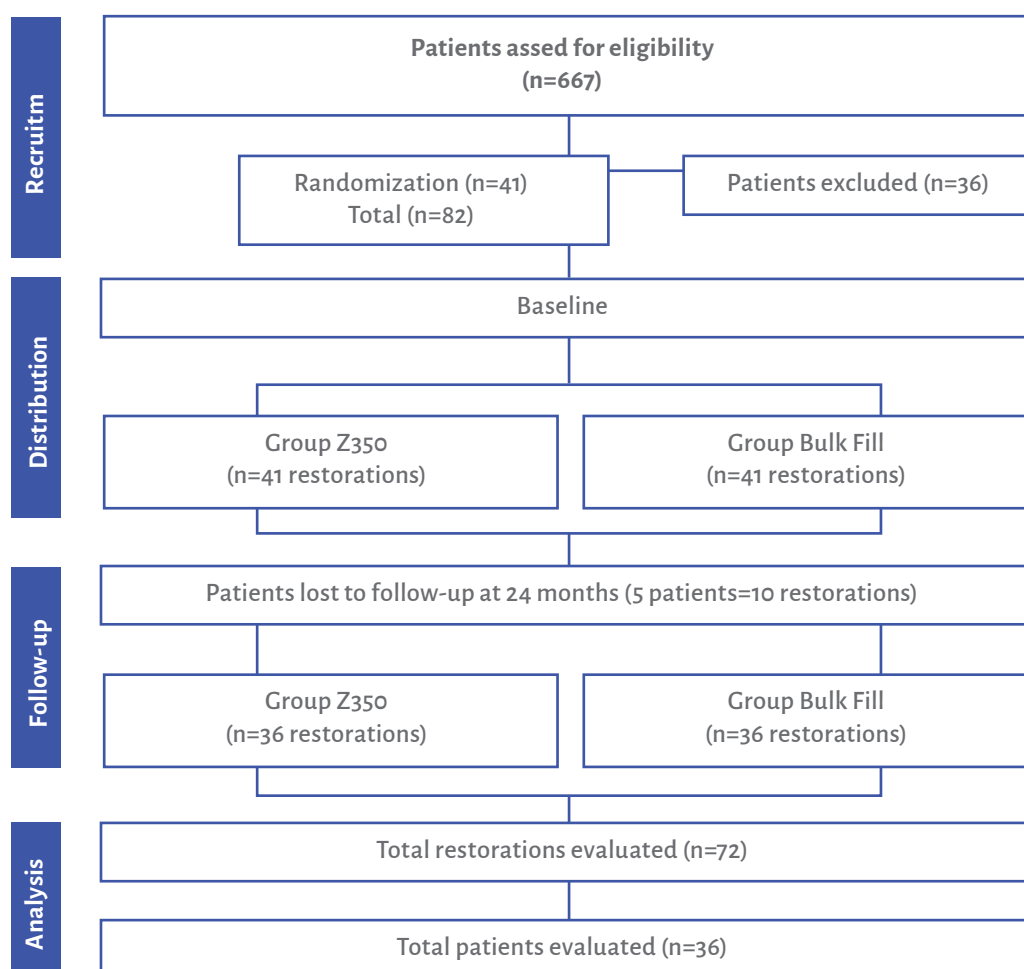
Patients with altered or reduced salivary flow; psychomotor disorders that impair oral hygiene; pregnant or breastfeeding women; patients with severe bruxism; prosthesis wearers; a history of failed restoration repairs; inability to achieve absolute isolation; and teeth that were endodontically treated, with tooth and/or restoration fractures, and/or the presence of cracks.

Examiner/operator calibration and training

Prior to the restorative procedure, calibration of the clinical protocol was performed. An oral rehabilitation specialist demonstra-

Figure 1

Consort Flow Diagram.



ted the complete clinical sequence for each material (Table 1). Subsequently, two operators, each with more than 10 years of professional experience, performed four resin repairs under the supervision of the study coordinator.

Errors and defects in the restorations were observed, discussed, and corrected using a checklist. For intra- and inter-examiner calibration, a Cohen's kappa coefficient ≥ 0.8 was required at the beginning of the study and prior to evaluation.

Clinical procedure

Blinding of the study was applied to the examiners who performed the clinical evaluations of the restorations and to the patients at the beginning of the study. Two operators carried out all restorations at baseline and were aware of the treatment allocation due to the clinical protocols required for the use of both materials.

They recorded the reasons for indicating repair (Table 4) and the dimensions of each biological preparation (Table 3).

Treatment randomization was performed by coin toss and recorded in an Excel spreadsheet by an external operator. Participants were randomly allocated into two groups: the TEVO group, with 41 Bulk-fill Tetric Evo-Ceram® restorations (Ivoclar Vivadent), and the Z350 group, with 41 Filtek Z350® restorations (3M ESPE). Partial removal of the old composite resin was performed in relation to the defect according to FDI criteria, using round diamond burs (SS White®). The dimensions of the biological preparations were recorded in the three spatial directions (mesiodistal, buccolingual, and cervico-occlusal) using a North Carolina periodontal probe (Hu-Friedy UNC156®). The restorative procedure was performed under absolute isolation. Details of each material and clinical protocol are described in Table 1.

Table 1

Materials, manufacturer, composition, and clinical protocol of the materials used

Material	Manufacturer	Composition	Clinical protocol
Gel Etchant	Kerr Co. Orange, CA USA	37% phosphoric acid	Application to enamel for 20 seconds, followed by rinsing for twice the application time and drying
Optibond FL	Kerr Co. Orange, CA USA	Primer: HEMA, GPDM, ethanol, water, CQ, BHT, PAMA. Adhesive: bis-GMA, HEMA, GDM, CQ, ODMAB, barium aluminoborosilicate, Na ₂ SiF ₆ , fumed silica, γ -methacryloxypropyltrimethoxysilane	Active application of one coat of primer for 20 seconds, followed by air-drying for 20 seconds; application of the bond, air-drying, and light curing for 20 seconds
Tetric EVO CERAM Bulkfill (TEVO)	Ivoclar Vivadent AG, Schaan, Liechtenstein shade IVA-IVB	Bis-GMA, UDMA, Ba-Al-Si glass, pre-polymerized filler (monomer, glass filler, and ytterbium fluoride), spherical mixed oxide. Filler content: 79–81 wt% / 60–61 vol%	Application in a single increment not exceeding 4 mm, followed by light curing for 20 seconds
Filtek Z350 Universal (Z350)	3M Espe St. Paul, MN, USA, shade A3-A2	UDMA, Bis-EMA, TEGDMA, Bis-GMA. Zirconia/silica. Particle size: 0.6–10 μ m. Inorganic filler: 72.5 wt% (55.6 vol%).	Application in multiple increments of less than 2 mm, followed by light curing for 20 seconds.

Table 2

Distribution of restorations according to tooth type

	MAXILLA		MANDIBLE		Total
	Premolar	Molar	Premolar	Molar	
Z350	11	7	3	15	36
FK	10	8	8	10	36
Total	21	15	11	25	72

Table 3

Dimensions of the preparations to be restored according to group

Groups	Cervico-Occlusal Depth (mm)		Mesio-Distal Length (mm)		Buccolingual/Palatal Width (mm)	
	Z350	TEVO	Z350	TEVO	Z350	TEVO
Standard deviation (mm)	0.69	0.07	0.79	0.57	1.15	0.21
Mean	3.61	3.74	2.93	2.96	3.87	3.66

Table 4

Reasons for indicating repair for each restoration

Reasons for Replacement	Z350	TEVO	TOTAL
Caries beneath the restoration	8	5	13
Inadequate proximal contact	4	11	15
Cervical discrepancy	22	19	41
Marginal staining	2	1	3
Total	36	36	72

All cavities were etched on enamel and dentin using 37% phosphoric acid, and Optibond FL® adhesive (Kerr, USA) (Primer + Bond) was applied following the manufacturer's instructions. A preformed 0.05-mm metallic sectional matrix system was used with the CompositeTight 3D® matrix holder (Garrison Dental Solutions, Spring Lake, MI, USA) and a wooden wedge.

Placement and sculpting of the Z350 resin were performed using oblique increments with a maximum thickness of 2 mm; each increment was light-cured for 20 seconds. In the case of the TEVO resin, placement

was performed in a single increment of up to 4 mm in depth. All light-curing procedures were carried out using an LED unit with a minimum irradiance of 1,100 mW/cm² (Bluephase Style®, Ivoclar Vivadent AG, Schaan, Liechtenstein), which was monitored throughout the procedure using a radiometer (LEDEX™ CM4000®, Dentmate Technology Co., Ltd., Taiwan).

Finishing was performed using fine-grit high-speed diamond burs (JotaG®, Rütli, Switzerland), flexible discs (Sof-Lex® 3M ESPE, St. Paul, USA), and Enhance® (Dentsply, Petrópolis, RJ, Brazil).

Table 5
FDI clinical criteria by specific parameter

Criteria		1. Clinically excellent	2. Clinically good	3. Clinically satisfactory/ sufficient (minor deficiency, without adverse effects)	4. Clinically unsatisfactory (repair for preventive reasons)	5. Clinically poor (replacement required)
Esthetic Characteristics	1. Marginal staining	1.1 No marginal staining	1.2 Minimal marginal staining, easily removable with polishing	1.3 Moderate marginal leakage, not esthetically unacceptable	1.4 Severe marginal leakage, major intervention is required to improve	1.5 Deep marginal leakage, not accessible for intervention
	2. Surface texture	2.1 Comparable to enamel	2.2.1 Slightly irregular, not noticeable from a distance during speech 2.2.2 Few isolated pores	2.3.1 Irregular surface but acceptable, covered by a saliva film 2.3.2 Multiple pores on more than one surface	2.4.1 Rough surface, not masked by a saliva film; simple polishing is insufficient 2.4.2 Voids	2.5 Very rough, unacceptable surface, plaque-retentive
	3. Fracture and Retention	3.1 Restoration intact, no fracture/cracks	3.2 Small fine cracks	3.3 Two or more large cracks and/or material loss (do not affect marginal integrity)	3.4 Material loss compromising marginal quality; fractures increase with or without partial loss (less than half of the restoration)	3.5 Partial or total loss of the restoration
Functional Characteristics	4. Marginal integrity	4.1 Harmonious contour, without gaps or dislocation	4.2.1 Marginal gap (50 µm) 4.2.2 Small marginal polishing	4.3.1 Marginal gap >5µm not restorable 4.3.2 Small enamel and dentin fractures	4.4.1 Gap >250 µm in dentin/exposed base 4.4.2 Harmful fracture of the margins	4.5 Filling is mobile but remains in place
	5. Anatomic form (proximal and occlusal)	5.a.1 Normal contact point (dental floss or 25 µm metal strip can pass)	5.a.2 Slightly tight contact, but without issues (dental floss or 25 µm metal strip passes only with pressure)	5.a.3 Slightly weak contact, with no indication of damage to teeth, gums, or periodontal structures; 50 µm strip can pass	5.a.4 Too weak, with possible food impaction damage; 50 µm strip can pass 5.b.4 Inadequate contour repair	5.a.5 Too weak and/or obvious damage due to food impaction and/or pain/gingivitis 5.b.5 Insufficient contour requires replacement
	a. Contact point b. Contour	5.b.1 Normal contour 5.1 Ideal form	5.b.2 Slightly deficient contour 5.2 Form is slightly altered.	5.b.3 Visibly deficient contour 5.3 Form deviates from normal but is acceptable.	5.4 Form is affected and esthetically unacceptable. Intervention/correction is required.	5.5 Form is unsatisfactory and/or lost. Repair is not feasible/reasonable; replacement is required.

Table 5

FDI clinical criteria by specific parameter

Criteria		1. Clinically excellent	2. Clinically good	3. Clinically satisfactory/ sufficient (minor deficiency, without adverse effects)	4. Clinically unsatisfactory (repair for preventive reasons)	5. Clinically poor (replacement required)
Biological Characteristics	6. Postoperative (hyper)sensitivity and tooth vitality	6.1 No hypersensitivity; normal vitality	6.2 Mild hypersensitivity for a limited period; normal vitality	6.3.1 Moderate hypersensitivity 6.3.2 Delayed/mild sensitivity; no subjective complaints; no treatment required	6.4.1 Severe hypersensitivity. 6.4.2 Delayed with minor subjective symptoms. 6.4.3 No clinically detectable sensitivity. Intervention required, but no replacement	6.5 Severe acute pulpitis or non vital tooth. Endodontic treatment is required and the restoration must be replaced.
	7. Absence of recurrent caries	fdi.1 Absence of recurrent caries	7.2 Small and localized demineralization. Does not require surgical treatment	7.3 Large areas of demineralization; preventive measures are required (dentin not exposed)	7.4 Cavitated caries (localized and accessible, can be restored)	7.5 Deep secondary caries or exposed dentin, not accessible for repair or restoration

Table 6

Clinical evaluation of restorations expressed as percentage (%) and number of restorations (n)

Clinical property	Criterion	Z350		TEVO	
		B (%)	24m (%)	B (%)	24m (%)
Marginal integrity	1. Excellent	100 (36)	86.1 (31)	100 (36)	83.3 (30)
	2. Good	-	8.3 (3)	-	11.1 (4)
	3. Satisfactory	-	5.6(2)	-	5.6 (2)
	4. Unsatisfactory	-	-	-	-
	5. Poor	-	-	-	-
Surface texture	1. Excellent	100(36)	77.8(28)	100 (36)	80.6 (29)
	2. Good	-	16.6 (6)	-	11.1 (4)
	3. Satisfactory	-	5.6(2)	-	8.3(3)
	4. Unsatisfactory	-	-	-	-
	5. Poor	-	-	-	-
Marginal staining	1. Excellent	100 (36)	63.9 (23)	100 (36)	66.6(24)
	2. Good	-	19.4 (7)	-	16.7(6)
	3. Satisfactory	-	11.1 (4)	-	13.9 (5)
	4. Unsatisfactory	-	5.6(2)	-	2.8(1)
	5. Poor	-	-	-	-
Sensitivity	1. Excellent	100% (36)	100 (36)	100 (36)	100 (36)
	2. Good	-	-	-	-
	3. Satisfactory	-	-	-	-
	4. Unsatisfactory	-	-	-	-
	5. Poor	-	-	-	-
Fracture and retention	1. Excellent	100% (36)	86.1 (31)	100% (36)	88.8 (32)
	2. Good	-	5.6 (2)	-	5.6 (2)
	3. Satisfactory	-	8.3 (3)	-	5.6 (2)
	4. Unsatisfactory	-	-	-	-
	5. Poor	-	-	-	-
Proximal anatomy	1. Excellent	100 (36)	86.1 (31)	100% (36)	88.8 (32)
	2. Good	-	8.3 (3)	-	5.6 (2)
	3. Satisfactory	-	5.6 (2)	-	5.6 (2)
	4. Unsatisfactory	-	-	-	-
	5. Poor	-	-	-	-
Caries	1. Excellent	100 (36)	100 (36)	100 (36)	100 (36)
	2. Good	-	-	-	-
	3. Satisfactory	-	-	-	-
	4. Unsatisfactory	-	-	-	-
	5. Poor	-	-	-	-

Clinical Evaluation

The restorations were examined two weeks after placement to verify that they were in optimal condition, and the same evaluation was performed two years after placement. Two calibrated operators, with a Cohen's kappa coefficient >0.8 , independently and blindly evaluated all restorations. The evaluators were different from the recruiter, operator, and statistician. Clinical assessment was performed by direct observation using a flat mouth mirror and probes (No. 5 and No. 23, respectively; Hu-Friedy Mfg. Co. Inc., Chicago, IL, USA), under adequate illumination and 3.5x magnification loupes, in accordance with FDI criteria. Restorations were classified as:

- 1: Excellent;
- 2: Good;
- 3: Satisfactory;
- 4: Unsatisfactory; and
- 5: Poor.

The clinical parameters evaluated were MI, ST, MS, S, RT, AN, and C (Table 5). For marginal adaptation assessment, FDI-recommended probes were used (Deppeler, Switzerland). In cases of disagreement, the examiners re-evaluated the restoration and reached a final consensus. It should be noted that patients who attended follow-up visits underwent a complete oral health examination to comply with ethical requirements, and if any problems were detected, they were referred to a specialist for evaluation and treatment. Two blinded operators (unaware of group allocation), different from those who performed the restorations, evaluated all restorations at 15 days (baseline) and at 24 months using the FDI criteria (20) described in Table 6.

Statistical analysis

For statistical analysis, SPSS software version 21.0 for Windows (SPSS, Chicago, IL, USA)

was used. The categories obtained for each clinical parameter in the study groups were pooled and ranked. To evaluate changes within the same group over time (baseline and 24 months) for all clinical parameters, the Wilcoxon test was used ($\alpha=0.05$). For comparison of clinical parameters between the two groups at 24 months, the Mann-Whitney test was applied ($\alpha=0.05$). Statistical analysis was performed by an external operator.

RESULTS

Of the total initial sample (41 patients), 36 patients attended the 24-month follow-up. Of these, 23 were females (63.9%) and 13 were males (36.1%), with a mean age of 25.9 years (range: 18–60 years). Regarding tooth type, 55.5% of the repairs were performed on molars and 44.5% on premolars; 50% were in the maxilla and 50% in the mandible (Table 2). With respect to the measurements of the three dimensions (cervico-occlusal, buccolingual/palatal, and mesiodistal), shown in Table 3, the mean and standard deviation ($\pm$) of cervico-occlusal depth for each group were 3.61 mm (± 0.69) for the TEVO group and 3.74 mm (± 0.07) for the Z350 group. Regarding the main reasons for indicating repair of the restorations, in order of frequency, these were: cervical discrepancy (56.9%), inadequate proximal contact (20.8%), caries beneath the restoration (18.1%), and marginal staining (4.16%) (Table 4).

For the MI parameter, most repairs performed with Z350 (86.1%) were rated as excellent, as were those performed with TEVO (83.3%). No repairs in this category received a score of 4 or 5 (Table 5). For the ST parameter, repairs performed with Z350 were rated as excellent in 77.8% of cases, while those performed with TEVO achieved an excellent rating in 80.1%.

No repairs in this category received a score of 4 or 5 (Table 6). For the MS parameter, 63.9% of the RC Z350 resin restorations were rated as excellent with respect to marginal staining; however, two repairs received a score of 4. In the TEVO group, only one restoration was rated as unsatisfactory, and 66.6% were evaluated as excellent.

For the S parameter, no repairs exhibited sensitivity at the 2-year evaluation. For the RT parameter, 86.1% of CR Z350 repairs and 88.8% of TEVO repairs were rated as excellent. Only two repairs received scores of 2 and 3, respectively.

For the AN parameter, 86.1% of restorations in the CR Z350 group were rated as 1, compared with 88.8% in the TEVO group. No repairs in this category received scores of 4 or 5. Restorations were evaluated at baseline and again after 24 months according to FDI criteria in both groups. A p -value >0.05 was obtained for both groups, indicating no statistically significant differences between groups in any of the clinical properties. No clinical parameter received a score of 5; a score of 4 was observed only for marginal staining. No changes were recorded for the caries and sensitivity parameters. For the MI, ST, MS, RT, and AN parameters, comparison within each group between baseline and 24 months showed statistically significant differences ($p<0.05$).

DISCUSSION

The present study aimed to evaluate the clinical performance of proximal restoration repairs performed using a BFR composite and a conventional nanohybrid resin composite. Based on the results obtained, the null hypothesis was accepted, as no statistically significant differences were observed between the study groups after 24 months of evaluation with respect to the FDI clinical properties (pa-

rameters). These findings are consistent with a study published by Ugurlu *et al.*,¹⁹ in which microtensile bond strength testing showed similar results for repairs of resin composites performed with a BFR composite and a nano-hybrid resin composite after simulated aging equivalent to two years in the oral cavity. A possible explanation for these findings is that, despite certain differences between the materials, both share a similar chemical nature in terms of their organic matrix and inorganic filler composition, allowing them to bond to the aged resin in a comparable manner.

Therefore, the use of a BFR for repairing resin composite restorations may offer the advantage of a faster and simpler procedure compared with conventional resin composites. Moreover, as reported in a meta-analysis by Arbildo Vega *et al.*,¹⁸ the properties of BFRs may even be superior to those of conventional resin composites with respect to polymerization shrinkage and shrinkage stress. This is attributed to the incorporation of filler particles and additives that modulate the elastic modulus during polymerization; by maintaining an initially low modulus, the resin can undergo slight deformation during shrinkage, thereby reducing stress at the adhesive interface, regardless of viscosity or application technique. However, this assumption requires confirmation through further long-term *in vitro* and clinical studies.

It should be noted that the evaluation period of the present study was 24 months, which is considered a medium-term follow-up in the literature and is a necessary period to report, as the first signs of restoration deterioration can be identified between 6 and 24 months.²¹ In the present study, no cases of caries development were observed. This finding may be explained by the fact that caries formation requires the presence of risk factors, which were controlled in this study, as all patients received extensive oral health education and

preventive measures aimed at maintaining a low cariogenic risk over time.

These findings are consistent with those reported by Opdam *et al.*,²² who described that the main failures occurring during the first 3 to 4 years are related to restoration fractures and endodontic problems, whereas secondary caries becomes one of the principal causes of restoration failure between 4 and 6 years. These causes are also influenced by factors such as the patient's cariogenic risk, the number of restored surfaces (indicating that a greater number of restored surfaces increases the risk of failure), the type of tooth, with maxillary molars presenting a higher risk of failure due to greater occlusal forces, and whether the dental tissue and/or restorative material is affected.²³

Regarding surface texture, the results obtained for TEVO (80.6%) and Z350 (77.8%), both rated as excellent, are consistent with those reported in other clinical studies.^{24,25} These findings can be partially explained by the natural deterioration of restorations resulting from exposure to mechanical forces such as mastication. However, this percentage may be lower than that reported in other studies, which in the present study may be partially explained by the exclusion of patients with signs of parafunction or bruxism at the start of the study.

With respect to marginal staining, both TEVO (63.9%) and Z350 (63.6%) were rated as "excellent", with no statistically significant differences between the two groups. Nevertheless, this parameter showed the greatest deterioration compared with the baseline evaluation, which is a common finding in clinical studies of resin composites.²⁶ This deterioration can be partly explained by degradation at the adhesive interface of the restoration, leading to microdefects that favor pigment accumulation. Regarding marginal integrity, no differences were observed between the two resin

groups, with "excellent" ratings of 86.1% for TEVO and 83.3% for Z350. These values may be slightly higher than those reported in another clinical study comparing a conventional resin with a bulk-fill resin from the same commercial brand (3M), which could be explained by the use of a universal adhesive system in that study.²⁷ It should be noted that, to minimize potential bias associated with the adhesive material, Optibond FL was used in the initial study design. This adhesive has extensive clinical evidence and has been supported by a recent meta-analysis conducted by van Meerbeek *et al.*,²⁸

However, another meta-analysis focusing on cervical lesions restored with Optibond FL identified marginal staining as one of the most frequent defects in composite resin (CR) restorations. This finding was also supported by Mahn *et al.*,²⁶ who reported that 20% of restorations exhibited marginal staining at the 2-year follow-up. Bonding between a new and an aged composite resin restoration presents clinical challenges, particularly with regard to adhesion and marginal staining. Over time, composite resin restorations undergo degradation due to water absorption and a reduction in unpolymerized double bonds, which diminishes their capacity for chemical adhesion with new resin layers. In addition, the absence of an oxygen-inhibited layer in aged restorations restricts the formation of bonds with newly applied resin. According to current evidence on improving adhesion in resin composite repairs, mechanical surface treatments, such as the use of diamond burs or air abrasion, followed by the application of multicomponent adhesive systems are recommended.^{29,30}

It would be of interest to conduct further studies on repairs performed with BFRs in combination with different adhesive systems, particularly considering that universal adhesives have been widely used in recent years due to

their favorable clinical outcomes, with evaluations of up to five years reported in clinical trials.^{17,31} Regarding the fracture and retention parameters, no restorations exhibited clinically relevant defects requiring intervention according to FDI criteria. This may indicate that both materials are able to withstand the biomechanical forces to which proximal restorations are subjected, as demonstrated by several clinical and laboratory studies published by Demarco *et al.*,³² and Heintze *et al.*³³ In this respect, it should be noted that no specific surface treatment was performed other than roughening of the aged resin surface, such as air abrasion, sandblasting, or chemical surface treatment with silane application. This decision was made because, to date, there is no strong clinical evidence supporting the superiority of these protocols. An example is a study that evaluated the effect of different surface treatment protocols by measuring the shear bond strength of bulk-fill resin composites repaired with either BFRs or CRs.¹⁹

The results showed that although different surface treatments influenced shear bond strength, there were no differences in bond strength between the resin composites used for repair.³⁴ The current explanation is that once the material has been polymerized, the potential for bonding through new polymer linkages formed after light curing is significantly reduced after 24 hours. At present, there is controversy on this topic. In an *in vitro* study by Gutiérrez *et al.*,³⁵ comparing repairs performed with and without silane application in combination with an adhesive system, the authors observed that the addition of silane reduced bond strength between resin composites, suggesting that it is not a recommended alternative when combined with adhesive systems.

However, a scoping review conducted by Neto *et al.*,³⁶ indicated that the combination

of surface roughening, adhesive systems, and silane application could improve the adhesive strength of resin composite repairs, also concluding that higher-quality *in vitro* studies and clinical trials are still needed to confirm this assumption.

Finally, it should be highlighted as a limitation of the present study that data regarding the age of the resin composite restorations were not collected, due to the heterogeneity of the patient population. This aspect represents a valuable opportunity to be addressed in future research. Regarding postoperative sensitivity, no cases were reported. This may be explained by the standardization of the adhesive technique and by the fact that, as a CR repair, the degree of dentin exposure is lower compared with complete replacement or treatments involving dentinal caries lesions.

This represents an important advantage of CR repair therapy. In this regard, a clinical study by Correia *et al.*,²⁸ reported no statistically significant differences in postoperative sensitivity at one year between BFRs and nanohybrid resin composites. However, further clinical studies are required to confirm this finding with greater certainty.

As limitations of the present study, it should be noted that although the number of restorations was calculated based on the total initial sample, the proportion of patients available for evaluation decreased at the 2-year follow-up. Therefore, increasing the sample size, both at baseline and at the final evaluation, taking potential losses into account, is clearly necessary.

In addition, this study was conducted under near-ideal conditions, as it was carried out in a university clinic under the supervision of experienced faculty members. This suggests the need for further studies performed under conditions closer to real-world clinical practice, such as in primary health care centers or private clinics, in order to allow comparison of

results. Despite the limitations of the present study, there is still limited clinical evidence regarding repairs performed with BFRs over a 24-month follow-up period.

Therefore, it would be of interest to evaluate these repairs over longer observation periods to detect potential significant changes which, if confirmed, would further support the findings of this investigation. In conclusion, no statistically significant differences were observed

in the 2-year clinical performance between repairs of posterior proximal resin composite restorations performed with bulk-fill resin composites and those performed with conventional resin composites. Repair using BFRs represents an additional treatment option when indicated and may offer a simpler and faster technique compared with conventional resin composites.

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CONFLICT OF INTERESTS

The authors declare that they have no conflicts of interest.

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

Sara Rodríguez Dueri: Research procedure regarding the execution and evaluation of restorations in study participants.

Daniela Vásquez Pereira: Data collection from study participants.

Eduardo Fernández Godoy: Data collection from study participants.

Osmir Oliveira Junior: Conceptualization, development, and methodology.

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