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# Bulk Fill Composite Resin for Non-carious Cervical Lesions: A 24-Month Randomized Clinical Study

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***Authors' contributions***

*This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.*

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## ABSTRACT

**Objective:** To clinically evaluate for 24 months the restorations of caries-free cervical lesions (CFCL) made with bulk-fill composite resin.
**Materials and Methods:** Sixty CFCL were selected and divided into two experimental groups: Filtek Z350 (control with conventional composite resin) and Filtek BF (Bulk Fill composite resin). The restorations were evaluated according to the USPHS criteria - marginal adaptation, anatomic form, marginal discoloration, caries formation, postoperative sensitivity, and retention - at the following periods: initial, 7, 30, 180, and 720 days. The results were statistically analyzed using the Friedman ANOVA test ($p < 0.05$) followed by the Durbin-Conover post-test ($p < 0.05$). For intra-group analysis, the Wilcoxon non-parametric test was used ($p < 0.05$).

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**Results:** Significant differences were observed between the groups, with Bulk Fill resin showing superior clinical performance in terms of marginal adaptation, restoration discoloration, anatomic form, and especially dentin sensitivity. Regarding caries formation and retention, both groups presented similar results.
**Conclusion:** Bulk-fill composite resins demonstrated superiority in various USPHS criteria in the treatment of caries-free cervical lesions, proving to be a promising material for this treatment context.

*Keywords: Cervical caries; dentistry; composite resin.*

## 1. INTRODUCTION

Non-carious cervical lesions (NCCLs) refer to modifications in the cervical region of teeth resulting in the loss of dental structure unrelated to caries. They are characterized by the presence of gingival recessions associated with enamel loss, leading to the exposure of dentin and cementum, resulting in Class V cavities [1]. The etiology is multifactorial, including stress, friction, biocorrosion, or a combination of these factors. Stress involves both endogenous factors like bruxism and occlusion, and exogenous factors like nail biting and object biting. Friction involves only exogenous factors such as abrasion from excessive brushing and abrasive toothpaste. Biocorrosion involves both endogenous and exogenous factors, occurring from gastric acids in patients with gastric diseases or from the ingestion of acidic foods and beverages [2].

In treating these lesions, restorative procedures can be indicated to prevent lesion progression and restore lost dental structure. Direct adhesive restorations are commonly used for their good aesthetic and functional results [3]. However, Class V cavities have lower durability compared to other classes, with high rates of retention loss, marginal excess, and secondary caries. These problems are associated with difficulties in isolation, resin insertion, contouring, finishing, and polishing of the restorative material [4].

Additionally, traditional composite resins available on the market exhibit notable technical sensitivity, which is a significant disadvantage. Among these challenges, polymerization shrinkage stands out as the most critical issue, potentially resulting in the formation of gaps and fissures. This can lead to marginal disadaptation and microleakage, ultimately resulting in treatment failure and reduced longevity [5]. Such failures can contribute to postoperative sensitivity, secondary caries, and gingival inflammation. Furthermore, restoration durability can be compromised by chemical degradation, masticatory stress, and reduced adhesion in NCCLs due to the presence of sclerotic dentin [6]. To reduce these failures, the incremental technique was developed, consisting of inserting the composite resin in oblique increments of up to 2 mm thick, reducing the stress caused by polymerization by reducing the cavity configuration factor (C-Factor). However, this increased the clinical time required for restorative procedures [7].

The dental industry developed Bulk Fill composite resins to optimize procedures, allowing for the insertion of single increments of 4 to 6 mm, reducing clinical time [8]. These resins are classified by viscosity, with high viscosity suitable for posterior restorations due to their moldability and resistance, and low viscosity ideal for irregular surfaces and as a base in deep cavities [9]. They are also indicated for the treatment of NCCLs, reducing failures such as restoration loss and microleakage, decreasing postoperative sensitivity, and increasing restoration longevity while simplifying the technique and saving clinical time [5].

Therefore, the purpose of this prospective randomized clinical study was to examine the clinical performance of direct restorations comparing Bulk Fill composite resin with conventional resin in terms of retention over two years in NCCLs. The hypothesis investigated was whether Bulk Fill resin used to restore NCCLs offers clinical performance over time comparable to conventional composite resins.

## 2. MATERIALS AND METHODS

### 2.1 Eligibility Criteria

**Inclusion Criteria:**

- Adults aged 18 to 60 years.
- Lesions near gingival tissue present in structurally compromised teeth (Class V).

- Teeth with occlusal contact with the antagonist.
- Occlusal balance and absence of premature contacts.

**Exclusion Criteria:**

- Active periodontal disease.
- Dental mobility grades I, II, and III.
- Uncontrolled caries activity.
- Xerostomia.
- Undergoing orthodontic treatment.
- Temporomandibular dysfunction.
- Parafunctional habits.
- Use of muscle relaxant appliances.
- History of systemic diseases affecting gingival and periodontal tissues.
- History of adverse reactions to any materials used in this study.
- Pregnancy or lactation.

## 2.2 Study Design

Prospective randomized double-blind split-mouth study. Randomization was performed by drawing the dental element and composite resin for unrestricted randomization.

The restorations were divided into two groups as shown in Table 1.

## 2.3 Sample Calculation

The number of restorations sample calculation based on an F distribution (analysis of variance) for a repeated measures design with two experimental groups. Assuming an analysis power of 0.90, an effect size of 0.25, and a type I error of 0.05 with nine measurements over time, a total sample size of 30 restorations per group was defined. This calculation was performed using the GPower 3.1.9 program. The distribution and composition of the experimental groups are shown in Table 2.

**Patient Recruitment:** Patients were selected through social media outreach and posters at the State University of Western Paraná (Unioeste).

**Clinical Procedures:** Patient anamnesis was followed by clinical and radiographic exams to prepare the treatment plan. Subjects were randomly assigned to one of the treatment groups.

The description of the materials used is shown in Table 2.

**Restoration Technique:** The restoration procedures were performed by a single trained operator following these clinical steps: initial prophylaxis with pumice and water using a rubber cup, color selection, absolute isolation, application of the adhesive system according to the manufacturer's instructions, light activation with an LED light (Bluphase, Ivoclar Vivadent, Barueri, SP, Brazil) with a power density of 1200 mW/cm² for both groups, restorations with Filtek Z350 composite resin (3M-ESPE, Sumaré, SP, Brazil) using the incremental technique

**Table 1. Distribution of groups (n=60)**

| Group | Description |
|---|---|
| CZ350 | Control group - Filtek Z350 conventional composite resin with Single Bond adhesive system |
| Filtek BF | Experimental group - Filtek Bulk Fill composite resin (3M ESPE) with Single Bond adhesive system |

**Table 2. Description of materials**

| Material/Brand | Manufacturer | Composition | Instructions for Use |
|---|---|---|---|
| Single Bond Adhesive System | 3M ESPE | BisGMA, HEMA, dimethacrylates, ethanol, water, and a photoinitiator | Apply with brush for 15 seconds, evaporate solvent, light-cure for 10 seconds |
| Filtek Bulk Fill Composite Resin | 3M ESPE | AUDMA and AFM | Single increment of up to 5 mm |
| Filtek Z350 Composite Resin | 3M ESPE | Organic matrix: BisGMA, BisEMA; Inorganic matrix: Zirconia-silica 0.6 to 1.4 µm | Incremental technique (2 mm) |

and light-cured for 40 seconds, or restorations with Filtek Bulk Fill composite resin applied in a single increment of up to 5 mm and light-cured for 40 seconds. Immediate finishing involved removing excess composite resin with a high-speed diamond bur under adequate cooling, and polishing the restorations was performed 7 days after the restorative treatment.

## 2.4 Longitudinal Analysis of Restorations

Restorations were clinically evaluated according to the United States Public Health Services (USPHS) criteria described by Cvar and Ryge in 1971 (Table 3) at initial, 7, 30, 180, and 720 days.

## 2.5 Statistical Analysis

Analysis was conducted according to the intention-to-treat protocol, including all randomly divided participants. Data were tabulated in Excel, and statistical analyses were performed using JAMOVI software version 1.2.24. Data were subjected to the Friedman ANOVA test ($p < 0.05$) followed by the Durbin-Conover post-test ($p < 0.05$) for intra-group analysis, and Wilcoxon test ($p < 0.05$) for inter-group analysis.

**Incidence by Gender:** The gender of patients who underwent restorative procedures was analyzed to determine incidence rates.

## 3. RESULTS AND DISCUSSION

Overall, there was a statistically significant difference in the intra-group analysis for the Z350 group in the evaluation criteria of marginal adaptation and discoloration between the periods of 7, 30, 180, and 720 days when compared to the 720 days. No statistically significant difference was observed in the intra-group analysis for the Bulk Fill group in any of the evaluation criteria.

Regarding sensitivity, a statistically significant difference was observed between the initial period and the remaining periods for both the Z350 and Bulk Fill groups.

In the inter-group analysis, there was a statistically significant difference between the different restorative materials tested, except for retention and caries formation.

The data are presented in Tables 4 to 9.

**Table 3. USPHS evaluation criteria for direct clinical evaluation of restorations**

| Category | Acceptable/Unacceptable Scale | Criterion |
|---|---|---|
| Marginal Adaptation | A (1) Indetectable by explorer | No fossa |
| | B (2) Detectable fossa (explorer binds in both directions) | Detectable fossa |
| | C (3) Obvious fossa or fracture | Obvious fossa or fracture |
| Anatomic Form | A (1) Indetectable fossa | No detectable fossa |
| | B (2) Detectable fossa only in enamel | Fossa only in enamel |
| | C (3) Detectable fossa involving enamel-dentin interface | Fossa involving enamel-dentin |
| Marginal Discoloration | A (1) No discoloration | No discoloration |
| | B(2) Superficial stain (usually removable) | Superficial stain |
| | C (3) Deep stain | Deep stain |
| Caries Formation | A (1) No evidence of caries | No caries evidence |
| | B (2) Evidence of caries | Caries evidence |
| Postoperative Sensitivity | A (1) No postoperative sensitivity | No postoperative sensitivity |
| | B (2) Postoperative sensitivity at any point during the study | Postoperative sensitivity noted |
| Retention | A (1) Retained | Retained |
| | B (2) Partially retained | Partially retained |
| | C (3) Restoration lost | Restoration lost |

**Table 4. Percentages (%) of marginal adaptation of restorations in the Z350 and bulk fill groups at corresponding periods**

| Time (Days) | 7 | 30 | 180 | 720 |
|---|---|---|---|---|
| Z350 | A (1) | B (2) | C (3) | EI |
| Z350 | 100 | 0 | 0 | Aa |
| Bulk Fill | 100 | 0 | 0 | Aa |

**EI – Inferential Statistics**

- Different lowercase letters present significant differences with p<0.05 in intra-group analysis (row) by Friedman ANOVA test (p < 0.05) followed by Durbin-Conover post-test (p < 0.05).
- Different uppercase letters present significant differences with p<0.05 in inter-group analysis (column) by Wilcoxon test (p < 0.05).

**Table 5. Percentages (%) of discoloration of restorations in the Z350 and bulk fill groups at corresponding periods**

| Time (Days) | 7 | 30 | 180 | 720 |
|---|---|---|---|---|
| Z350 | A (1) | B (2) | C (3) | EI |
| Z350 | 100 | 0 | 0 | Aa |
| Bulk Fill | 100 | 0 | 0 | Aa |

**EI – Inferential Statistics**

- Different lowercase letters present significant differences with p<0.05 in intra-group analysis (row) by Friedman ANOVA test (p < 0.05) followed by Durbin-Conover post-test (p < 0.05).
- Different uppercase letters present significant differences with p<0.05 in inter-group analysis (column) by Wilcoxon test (p < 0.05).

**Table 6. Percentages (%) of anatomic form of restorations in the Z350 and bulk fill groups at corresponding periods**

| Time (Days) | 7 | 30 | 180 | 720 |
|---|---|---|---|---|
| Z350 | A (1) | B (2) | C (3) | EI |
| Z350 | 100 | 0 | 0 | Aa |
| Bulk Fill | 100 | 0 | 0 | Aa |

**EI – Inferential Statistics**

- Different lowercase letters present significant differences with p<0.05 in intra-group analysis (row) by Friedman ANOVA test (p < 0.05) followed by Durbin-Conover post-test (p < 0.05).
- Different uppercase letters present significant differences with p<0.05 in inter-group analysis (column) by Wilcoxon test (p < 0.05).

**Table 7. Percentages (%) of sensitivity of restorations in the Z350 and bulk fill groups at corresponding periods**

| Time (Days) | Initial | 7 | 30 | 180 | 720 |
|---|---|---|---|---|---|
| Z350 | A (1) | B (2) | EI | A (1) | B (2) |
| Z350 | 40 | 60 | Aa | 86.67 | 13.33 |
| Bulk Fill | 26.66 | 73.33 | Aa | 93.33 | 6.66 |

**EI – Inferential Statistics**

- Different lowercase letters present significant differences with p<0.05 in intra-group analysis (row) by Friedman ANOVA test (p < 0.05) followed by Durbin-Conover post-test (p < 0.05).
- Different uppercase letters present significant differences with p<0.05 in inter-group analysis (column) by Wilcoxon test (p < 0.05).

**Table 8. Percentages (%) of retention of restorations in the Z350 and bulk fill groups at corresponding periods**

| Time (Days) | 7 | 30 | 180 | 720 |
|---|---|---|---|---|
| Z350 | A (1) | B (2) | C (3) | EI |
| Z350 | 100 | 0 | 0 | Aa |
| Bulk Fill | 100 | 0 | 0 | Aa |

**EI – Inferential Statistics**

- Different lowercase letters present significant differences with p<0.05 in intra-group analysis (row) by Friedman ANOVA test (p < 0.05) followed by Durbin-Conover post-test (p < 0.05).
- Different uppercase letters present significant differences with p<0.05 in inter-

group analysis (column) by Wilcoxon test ($p < 0.05$).

**Table 9. Percentages (%) of caries formation associated with restorations in the Z350 and bulk fill groups at corresponding periods**

| Time (Days) | 7 | 30 | 180 | 720 |
|---|---|---|---|---|
| Z350 | A (1) | B (2) | C (3) | EI |
| Z350 | 100 | 0 | 0 | Aa |
| Bulk Fill | 100 | 0 | 0 | Aa |

**EI – Inferential Statistics**

- Different lowercase letters present significant differences with $p<0.05$ in intra-group analysis (row) by Friedman ANOVA test ($p < 0.05$) followed by Durbin-Conover post-test ($p < 0.05$).
- Different uppercase letters present significant differences with $p<0.05$ in inter-group analysis (column) by Wilcoxon test ($p < 0.05$).

The hypothesis that Bulk Fill resin used to restore non-carious cervical lesions has clinical performance comparable to traditional composite resins over 720 days was confirmed. This is evident in the study by Correia et al. [10], which analyzed polymerization shrinkage stress in different restorative techniques for non-carious cervical lesions. This study compared Bulk Fill and conventional resins, with the latter used in incremental technique with different distribution forms of increments. Results showed that bulk-fill resin exhibited the lowest stress concentration, followed by the incremental technique with the initial increment inserted in the gingival wall. This supports the hypothesis that bulk-fill resin can provide similar or superior clinical performance to conventional composite resins over a period of 720 days.

This study, based on the findings of Canali et al. [11], examined the clinical evolution of restorative treatments for non-carious cervical lesions (NCCLs) over 720 days, comparing the performance of conventional composite resins with bulk-fill composite resins. The results obtained between both groups were similar, indicating that both types of resin composites demonstrated acceptable results in the treatment of NCCLs. However, it is important to highlight that a significant difference between this study and Canali's study was the evaluation period. While Canali's study had a one-year evaluation, the present study extended the evaluation to two years. This difference in follow-up time may partially explain why the results of Bulk Fill resin in this study were especially favorable, demonstrating better performance over this period.

Regarding the observed results in terms of marginal discoloration of the restorations performed in the study, it is noted that only the group in which NCCLs were treated with conventional composite resin showed changes, and this was only observed after 720 days of the restorative procedure. Conversely, a study by Correia et al. [12] analyzing the clinical performance of restorations in NCCLs over 30 months showed that all groups, including those treated with Bulk Fill and conventional composite resins, presented changes in marginal discoloration. Thus, it is possible to highlight that longer evaluations are necessary for a better understanding of the effect of time on the materials used in restorative treatments.

In analyzing the results of this study, it is observed that the criterion showing the greatest discrepancy between the two resin composites was dentin sensitivity. Dentin hypersensitivity is generally characterized as a short and sharp pain caused by the exposure of dentinal tubules following dental structure loss. Teixeira et al. [2,13] conducted a study aiming to evaluate the risk factors associated with NCCLs, dentin hypersensitivity, and gingival recession. The study concluded that there is a positive correlation between the three factors and further verified that lesion depth and morphology contribute to high levels of dentin sensitivity and the severity of gingival recessions.

In a study by Vidósola et al. (2019), the clinical evolution of NCCL restorations with two bulk-fill composite resins and one conventional composite resin was analyzed over 6 months. The study observed that all three resin composites showed similar results in terms of postoperative sensitivity, with 95.6% of restorations scoring excellent and 4.4% good after 6 months. In contrast, the present study observed that both groups showed improvement in dentin sensitivity, but this result was more stable and enduring in procedures performed with bulk-fill resin. In treatments with conventional composite resin Z350, dentin sensitivity after 720 days almost equaled the initial analysis result before the restorative treatment.

In this study, the most frequent gender was male, representing 55.5% of the cases. Conversely, an observational study by Pontes et al. [4,14] showed a higher frequency of NCCLs in females (51.4%). It is noted that gender is not directly related to the appearance of these lesions, but rather the age group of affected individuals. This is related to a longer exposure time to etiological factors associated with NCCLs.

Thus, bulk-fill composite resins, allowing the polymerization of increments up to 4 mm, reduce the number of steps to perform a restoration, minimizing the chance of technical errors and the clinical time required. Due to their recent market availability, further research and extensive clinical follow-up are necessary to ensure clinical success and treatment longevity.

## 4. CONCLUSION

The use of Filtek Bulk Fill composite resin for the restoration of caries-free cervical lesions demonstrated superior clinical performance compared to Filtek Z350 (conventional) resin in the evaluated aspects – marginal adaptation, restoration discoloration, anatomic form, and dentin sensitivity; and similar results to Filtek Z350 in the criteria of caries formation and retention. The restorations were in good condition according to USPHS evaluation criteria at the evaluated intervals. However, a longer follow-up period is necessary to verify comparative clinical performance over the long term, ensuring greater reliability of the results.

## DISCLAIMER (ARTIFICIAL INTELLIGENCE)

Author(s) hereby declare that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc) and text-to-image generators have been used during writing or editing of manuscripts.

## CONSENT

All authors declare that 'written informed consent was taken from the patient (or other approved parties) for publication of this research'.

## ETHICAL APPROVAL

This study was approved by the research ethics committee involving human beings of the state university of western Paraná - Unioeste / Brazil under the number 2.414.995 and registered at rebec under the number u1111-1224-0300. Clinical procedures were performed at the dental clinic of Unioeste.

## COMPETING INTERESTS

Authors have declared that no competing interests exist.

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