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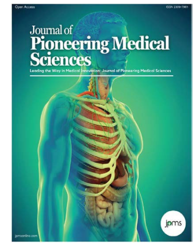

Comparative Study of Microleakage in Nano-filled and Conventional Composite Resins used in Class II Restorations

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Abstract **Background**: Microleakage at the gingival margin of Class II composite restorations remains a key failure pathway, driven by polymerization-shrinkage stress in high configuration-factor (C-factor) cavities and the lower bond-ability of dentin/cementum. **Objective**: To compare microleakage scores (primary endpoint) at gingival margins between a Nano-filled composite and a conventional micro-hybrid; secondarily, to compare score distributions and enamel-margin (occlusal) sealing as indicators of marginal sealing ability. **Methods**: Forty extracted, non-carious human molars were randomized to restoration with a Nano-filled composite (Filtek™ Supreme Ultra) or a micro-hybrid (Filtek™ Z250) using a total-etch adhesive (Adper™ Single Bond 2). Standardized Class II mesio-occlusal cavities extended 1.0 mm apical to the CEJ. After thermocycling (5000 cycles, 5-55°C), specimens were immersed in 2% methylene blue, sectioned into two halves and scored (0-4) at gingival and occlusal margins under stereomicroscopy by two blinded examiners. The worst of two sections per tooth was used a priori; sensitivity analysis using the mean of two sections was concordant. Non-parametric analyses (Mann-Whitney U; Fisher-Freeman-Halton exact test) with Holm correction for multiplicity were applied. Inter-examiner reliability was excellent (Cohen's $\kappa = 0.89$); intra-examiner $\kappa = 0.91$. **Results**: Gingival-margin microleakage was lower with Nano-filled composite: median (IQR) 1 [1-2] vs 2 [2-3] for micro-hybrid; $U = 102.5$; $Z = -2.96$; $p = 0.003$; Rosenthal's $r = 0.47$ (medium-large). Minimal/no leakage (scores 0-1) occurred in 65% of Nano-filled vs 25% of micro-hybrid restorations; severe leakage (scores 3-4) occurred in 5% vs 30%, respectively (exact $p = 0.028$). Occlusal (enamel) margins showed low leakage in both groups with no significant difference (median 0 in both; $p>0.40$). **Conclusions**: Under standardized *in vitro* conditions, the Nano-filled composite reduced gingival-margin microleakage compared with a micro-hybrid by one full score unit in the median, with a medium-large effect size ($r\approx0.47$) and excellent scoring reliability. Given method and model limitations, these findings suggest improved marginal sealing ability for Nano-filled composites in Class II restorations and warrant validation with 3D methods and clinical studies.

Key Words Class II Composite, Microleakage, Nano-filled Composite, Micro-hybrid, C-Factor, Marginal Sealing, Dye Penetration, Gingival Margin

INTRODUCTION

Microleakage, the ingress of fluids, ions and bacteria between tooth and restoration, remains a leading cause of sensitivity, marginal staining and secondary caries in posterior composites [1-4]. The challenge is amplified at gingival margins located in dentin/cementum, where bond strengths are lower and substrates are more permeable than enamel [5-7]. Critically, the configuration factor (C-factor) in Class II boxes is high, constraining composite flow during polymerization and raising shrinkage stress, which promotes interfacial gap formation [8].

Advances in filler technology have produced Nano-filled composites with densely packed nanoscale fillers and nanoclusters, designed to improve mechanical behaviour and potentially reduce shrinkage-related debonding compared to micro-hybrids [9-12]. However, methodological heterogeneity complicates interpretation: dye-penetration scoring provides ordinal 2D surrogates of leakage, whereas micro-computed tomography (micro-CT) quantifies 3D gap volumes; results can diverge across techniques and adhesive strategies [13-15]. Recent reviews emphasize that laboratory marginal metrics correlate only imperfectly with clinical outcomes and that study design, including substrate, adhesive and thermomechanical aging, critically affects findings [2,4,16].

Research Hypothesis (Alternative)
A Nano-filled composite exhibits lower gingival-margin microleakage scores than a conventional micro-hybrid under standardized conditions.

Null Hypothesis
There is no difference in gingival-margin microleakage scores between materials.

Objective
To compare gingival-margin microleakage scores (primary) and score distributions (secondary) between Filtek™ Supreme Ultra and Filtek™ Z250 and to report enamel-margin performance for clinical context.

METHODS

Study Design and Reporting
Randomized, controlled *in vitro* laboratory study following CRIS/STROBE guidance for bench research.

Sample Selection and Storage
Forty extracted, intact, non-carious human molars (posterior teeth; no restorations/cracks/hypoplasia) were collected under institutional tissue-use policy. Teeth were debrided and disinfected in 0.1% thymol for 24 h, then transferred to 0.9% saline at 4°C and used within 8 weeks (uniform storage window). Periodontally compromised teeth and teeth with caries were excluded using visual and transillumination plus fibre-optic and explorer probing; suspect lesions were screened under 10× magnification.

Randomization and Blinding
Teeth were randomized (1:1) to Nano-filled (NF) or micro-hybrid (CH) groups using a computer-generated list (opaque sequential envelopes). Specimens were coded; examiners and the statistician were blinded to allocation. Disagreements were resolved by third-party arbitration.

Cavity Preparation and Standardization
Standardized mesio-occlusal Class II cavities were prepared with water-cooled diamond burs (ISO #806 314 014 524 018; new bur every five preparations to control bur wear).

Dimensions
Occlusal isthmus 1.5 mm; buccolingual width 2.0 mm; occlusal depth 2.0 mm; proximal box extended 1.0 mm apical to CEJ; flat gingival seat 1.0 mm; 90° Cavo surface; rounded internal angles. Dimensions were verified using callipers and a periodontal probe.

Operator Calibration
Ten pilot preparations were measured for reproducibility (all dimensions within ±0.2 mm tolerance).

Restorative Protocol
Adhesive: Adper™ Single Bond 2 (total-etch). 35% phosphoric acid for 15 sec (enamel/dentin), rinse 15 sec, gentle air-dry to moist dentin, two coats of adhesive, air-thin 5 sec, cure 10 sec (LED ≥1200 mW/cm², radiometer-verified).

Composites

- NF: Filtek™ Supreme Ultra, A2B
- CH: Filtek™ Z250, A2

Matrix/Contacts
Pre-contoured sectional matrix with separation ring and wooden/anatomic wedge to optimize proximal adaptation.

Placement
Incremental technique, gingival increment ≈1.5 mm, two occlusal increments ≤2 mm each; each increment cured 20 s with light tip in close proximity.

Aging and Leakage Protocol
Thermocycling 5000 cycles (5±1°C / 55±1°C; 30-s dwell; 10-s transfer). Entire tooth surface was coated with nail varnish leaving a 1-mm window around restoration margins. Following 2% methylene blue (pH 7.0) immersion for 24 h at 37°C, teeth were rinsed, varnish removed and sectioned mesiodistally under water (low-speed diamond saw). Both sections were assessed; a priori primary analysis used the worst score; a sensitivity analysis using the mean of two sections was concordant.

Scoring and Reliability
Under stereomicroscope (40×), blinded examiners scored dye penetration (0-4) at gingival and occlusal margins: 0 = none; 1 = ≤1/3 gingival wall; 2 = >1/3-≤2/3; 3 = >2/3 (not axial); 4 = to axial wall.

Seal Quality Control
Margins were inspected at 20× before dye immersion to confirm absence of external defects that could bias leakage. Inter-examiner $\kappa = 0.89$; intra-examiner $\kappa = 0.91$ (10% repeat after 2 weeks).

Sample Size and Statistics
Power (two-tailed Mann-Whitney) targeted detection of a one-unit median difference ($r \approx 0.45$), $\alpha = 0.05$, power = 0.80 → n = 20/group. Normality was not assumed. Primary: Mann-Whitney U (gingival margin). Secondary: Fisher-Freeman-Halton exact test (5×2 table) and Mann-Whitney for occlusal margins. Effect size (Rosenthal's $r = Z/\sqrt{N}$) reported. Holm correction applied to secondary endpoints. Exploratory Spearman correlations probed associations with measured cavity dimensions (targeted to near-zero given standardization).

RESULTS

Descriptive Statistics

Gingival Margin (Primary):

- Nano-filled (NF): median 1 [IQR 1-2]; mean±SD 1.25±0.79
- Micro-hybrid (CH): median 2 [IQR 2-3]; mean±SD 2.15±0.81

Group Comparison

U = 102.5; Z = -2.96; p = 0.003; r = 0.47 (medium-large).

Score Distribution (Gingival)

See Table 2 and Figure 1. Minimal/no leakage (0-1): 65% (NF) vs 25% (CH); severe (3-4): 5% (NF) vs 30% (CH); exact p = 0.028 (Holm-adjusted significant).

Occlusal (Enamel) Margins (Secondary)

Both groups showed low scores (median 0 in each); no significant difference (p>0.40) (Table 1).

Reliability

Inter-examiner κ = 0.89; intra-examiner κ = 0.91; initial disagreement rate 12.5%, resolved by third-party arbitration.

Table 1: Descriptive Statistics of Microleakage Scores at Gingival Margin

Group	n	Mean Score±SD	Median Score	Min Score	Max Score
NF (Nano-filled)	20	1.25±0.79	1.0	0	3
CH (Micro-hybrid)	20	2.15±0.81	2.0	0	4

Table 2: Frequency Distribution of Microleakage Scores

Microleakage Score	Group NF (n=20)	Group CH (n=20)
0 (No leakage)	5 (25%)	2 (10%)
1 (≤ 1/3 height)	8 (40%)	3 (15%)
2 (1/3 - 2/3)	6 (30%)	9 (45%)
3 (> 2/3 height)	1 (5%)	4 (20%)
4 (To axial wall)	0 (0%)	2 (10%)

DISCUSSION

The primary objective of this *in vitro* study was to compare the microleakage performance of a Nano-filled composite resin and a conventional micro-hybrid composite resin at the gingival margins of standardized Class II restorations. The results demonstrated a statistically significant reduction in microleakage with the Nano-filled composite (Group NF) compared to the micro-hybrid composite (Group CH). The mean microleakage score was significantly lower for Group NF (1.25±0.79) than for Group CH (2.15±0.81) (p = 0.003). Furthermore, the distribution of scores revealed that a substantially higher proportion of teeth restored with the Nano-filled composite exhibited minimal or no leakage (65% scoring 0 or 1) compared to the micro-hybrid composite (25% scoring 0 or 1). Conversely, severe leakage (scores 3 or 4) was observed in only 5% of the Nano-filled group but in 30% of the micro-hybrid group. These findings lead to the rejection of the null hypothesis.

The observed difference in microleakage can be attributed to several factors related to the distinct composition and properties of the two composite types. Nano-filled composites, such as Filtek Supreme Ultra, incorporate a combination of discrete silica/zirconia nanofillers (approximately 20 nm) and nanoclusters (loose agglomerates of these nanofillers) within the resin matrix [17]. This unique filler technology allows for a higher overall filler loading (typically 78.5% by weight for Filtek Supreme Ultra) compared to conventional micro-hybrids like Filtek Z250 (typically 82% by weight, but with larger average particle sizes) [18]. While the filler loading by weight is similar, the Nano-filled composite achieves this with a significantly higher number of smaller particles and a reduced interparticle spacing [19].

This dense, nanoscale filler network is believed to contribute to reduced polymerization shrinkage and, crucially, lower polymerization shrinkage stress [20]. Polymerization shrinkage stress is a major driver of gap formation at the tooth-restoration interface, particularly in areas of high C-factor (configuration factor), such as the gingival seat of a Class II restoration where the bonded surface area is large relative to the free, unbonded surface area available for stress relief [21]. The lower shrinkage stress generated by Nano-filled composites likely results in better maintenance of the bond integrity at the gingival margin during polymerization and subsequent thermocycling, thereby minimizing microleakage [22]. Additionally, the smaller particle size and improved handling characteristics of Nano-filled composites may facilitate better adaptation to the cavity walls, especially in the challenging gingival seat area [23].

The findings of this study align with those of Bagis *et al.* [16], who utilized micro-CT to quantify gap formation and reported significantly less gap volume at the gingival margins of Class II restorations with a Nano-filled composite compared to a micro-hybrid. Their quantitative approach provides strong evidence supporting the superior marginal adaptation of Nano-filled composites. However, our results contrast with the study by Al-Hiyasat *et al.* [15], which found no significant difference in microleakage between Nano-filled and micro-hybrid composites in Class II cavities using dye penetration. This discrepancy could be attributed to several methodological differences: Al-Hiyasat *et al.* [15] used different composite brands (a different Nano-filled and a different micro-hybrid), a different adhesive system (a self-etch adhesive) and a different thermocycling protocol (1000 cycles vs. 5000 cycles in our study). The increased number of thermocycling cycles in our study may have subjected the restorations to greater stress, potentially amplifying differences in material performance and marginal seal integrity [24]. Furthermore, the specific filler technology and resin matrix formulation vary significantly between different composite brands, even within the same category (Nano-filled or micro-hybrid), which can influence shrinkage behaviour and bond strength [25].

The clinical significance of reduced microleakage at the gingival margin of Class II restorations cannot be overstated.

The gingival margin is the most critical area for marginal seal failure due to its location in dentin/cementum and the challenges of access, isolation and polymerization [5]. Microleakage at this site provides a pathway for bacteria and oral fluids, increasing the risk of secondary caries development along the gingival floor [26]. Secondary caries is the most common reason for the replacement of composite restorations [27]. Therefore, the significantly lower microleakage observed with the Nano-filled composite in this study suggests a potential clinical advantage in terms of improved restoration longevity and reduced risk of recurrent caries at the vulnerable gingival margin.

This study rejects the null hypothesis, demonstrating a one-unit median improvement and fewer severe leaks at the gingival margin with a Nano-filled composite versus a micro-hybrid under standardized conditions. The effect size (r≈0.47) indicates a clinically meaningful shift in the ordinal leakage distribution. Mechanistically, high C-factor conditions and dentin/cementum bonding make gingival margins susceptible to shrinkage-stress-induced gaps [8,21,22]. Nano-filled systems, with densely packed nanoscale fillers/nanoclusters and favourable rheology, may better maintain interfacial integrity, thereby improving marginal sealing ability [1,10-12,25].

Methodological Context

Our findings concur with micro-CT reports showing reduced gap formation for Nano-filled materials at Class II gingival margins [16], but differ from dye-based studies reporting parity [15]; such discrepancies likely reflect differences in adhesives, brands, thermomechanical aging and measurement modality (2D ordinal vs 3D quantitative). We used total-etch at dentin/cementum, a choice known to influence outcomes versus self-etch strategies; enamel-margin parity observed here underscores substrate dependence.

Caution on Inference

We did not measure shrinkage stress directly; attributing causality to stress reduction remains hypothesized rather than demonstrated. Dye penetration is semi-quantitative and 2D, with imperfect correlation to clinical caries incidence; micro-CT or fluid filtration would add mechanistic depth. Moreover, materials were from a single manufacturer, limiting generalizability across formulations.

Clinical Relevance

The pronounced reduction in severe leakage (3-4) at dentin/cementum suggests a potential for improved longevity in high-risk margins; however, *in vitro* effects require validation under mechanical fatigue and in clinical trials to confirm translation to secondary-caries reduction.

CONCLUSIONS

The Nano-filled composite exhibited lower gingival-margin microleakage than the micro-hybrid by one ordinal unit in the median (r≈0.47), with excellent examiner reliability. Occlusal (enamel) margins showed low leakage for both materials without between-group differences. The null hypothesis was rejected. Findings are constrained by *in vitro* design, dye-penetration methodology and single-brand materials; conclusions should be interpreted cautiously and not generalized to all Nano-filled or micro-hybrid composites. Future work should include 3D methods (micro-CT/fluid filtration), mechanical fatigue, diverse manufacturers and clinical studies.

Strengths

Standardized preparations with bur-wear control; blinded scoring with third-party arbitration; thermocycling; prespecified worst-section rule plus sensitivity analysis; effect size and reliability reported; enamel-margin context included.

Limitations

Single-brand comparison; dye-based ordinal metric; absence of mechanical loading; *in vitro* setting; and potential sampling bias mitigated (two sections assessed; worst-score rule). Storage transitioned from thymol disinfection to saline to minimize dentin alterations.

Recommendations

- Compare across multiple manufacturers and adhesive strategies at dentin/cementum margins
- Incorporate mechanical fatigue and prolonged aging to simulate occlusal stress
- Measure polymerization stress (e.g., tensiometry) and correlate with leakage
- Head-to-head dye vs micro-CT vs fluid-filtration on identical samples
- Conduct randomized clinical trials with validated caries endpoints

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