Bulk-Fill Ormocer versus Methacrylate-Based Resin Composite Restorative Systems: The Effect of Flowable Lining on Two-Year Clinical Performance in Class II Cavities

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Abstract

Objective   The aim of this study was to assess and compare the impact of bulk-fill flowable resin composite liners (BFFL) on the 2-year clinical performance of bulk-fill ormocer (BORC) in comparison to methacrylate-based resin composites (BMRC) in Class II cavities.

Materials and Methods   Thirty participants, each aged between 18 and 30 years, were included in the study, each presenting four class II cavities. A total of 120 restorations were placed, with participants randomly assigned to one of four restorative systems through a blind drawing: Admira Fusion X-Tra (AFX) alone, AFX after lining with Admira Fusion Xtra-Base (AFB), X-Tra Fill (XF) for complete cavity filling, and XF after lining with Xtra-Base (XB). The universal adhesive system (Futura U bond Voco, Germany) was consistently applied for all restoration techniques using selective enamel etching. A single operator, following the manufacturer's instructions for each material, performed all restorations, and finishing/polishing occurred immediately after placement. Clinical evaluation, based on World Dental Federation (FDI) criteria, was conducted by two blinded examiners at baseline (7 days) and at 6, 12, and 24 months postoperatively.

Keywords
► bulk-fill ormocer
► methacrylate
► composite liners
► FDI criteria
► clinical trial

Results   The chi-squared test was used to compare the four applied restorative systems within each follow-up period, while the marginal homogeneity test was employed to assess changes over time. No statistically significant differences were observed among the four restorative systems at any evaluation period.

Conclusions   After 2 years, the clinical performance of BFFL or complete bulk-fill technique remained similar, regardless of the material composition.

Introduction

Resin composites have become the predominant material choice for both anterior and posterior teeth.[1] However, polymerization shrinkage and the associated stresses remain significant factors contributing to their failures.[2] These stresses are known to be influenced by the material's placement techniques. The conventional approach to mitigate the clinical impact of polymerization stress is incremental layering. Nevertheless, this method has drawbacks, including the

potential for voids or contaminants between layers, prolonged seating time, and challenges in filling conservative cavities.

In addressing this concern, bulk-fill resin composites have been developed, allowing placement in increments of up to 5 mm.[3] These composites come in two viscosities: bulk-fill packable (high viscosity) and bulk-fill flowable (low viscosity) resin composites, akin to conventional resin composites. Bulk-fill packable types can be applied in 5 mm increments without requiring a veneering layer. On the other hand, bulk-fill flowable resin composites serve as liners and stress absorbers in class I and class II cavities, necessitating a final layer of high-viscosity resin composite.[4] The enhanced curing depth of these materials is attributed to monomers acting as chemical modulators in the polymerization reaction.[5] Additionally, their increased material translucency, achieved by reducing filler loading and increasing filler size, enables deeper light penetration.[6]

Additionally, incorporating specific monomers, prepolymerized fillers, and photoinitiators into the composition of certain bulk-fill materials has been effective in reducing polymerization shrinkage, a crucial characteristic.[7] Regarding their clinical performance, studies on bulk-fill resin composites have shown heterogeneous behavior, primarily dependent on their chemical composition. While most studies reported results similar to conventional resin composites, the intermediate use of bulk-fill flowable resin composite liners (BFFL) demonstrated an ability to reduce stress in posterior resin composite restorations with a high level of clinical efficacy.[8,9] The low elastic modulus of BFFL provides an elastic cavity wall, helping alleviate the polymerization stress associated with subsequent regular viscosity composites. Moreover, in a randomized controlled trial (RCT), one of the restorative systems utilizing BFFL liner demonstrated the lowest surface staining. However, conflicting evidence has reported decreased adaptation and higher polymerization shrinkage stress compared with the high-viscosity counterpart.[10] It remains unclear whether these restorative systems would be susceptible to proximal contact defects similar to those reported in glass ionomer restoratives.[11]

The resin matrix plays a crucial role in determining the shrinkage behavior of resin composite restorations.[12] To address clinical issues associated with methacrylate-based resin composites, ormocers were developed.[13] These materials claimed to exhibit lower polymerization stress owing to their reduced amount of organic resin. However, the initial generations of ormocers did not show clear progress compared with methacrylate-based resin composites.[14] A possible explanation for these findings was the inclusion of methacrylate monomers serving as diluents.[15] Subsequently, pure ormocer-based resin composites were introduced to the market and applied using conventional layering techniques.[16]

Additionally, ormocer-based resin composites have been utilized for bulk-filling with two viscosities similar to methacrylates (high viscosity and low viscosity). Bulk-fill ormocer-based resin composites (BORC) may represent a superior alternative to the standard layering method, offering comparable clinical performance with the added benefit of simplified procedures.[17] However, information regarding lining BORC is limited. Torres et al[18] reported in a RCT that lining BORC had no influence on their clinical performance.

Hence, the objective of this randomized, split-mouth clinical trial was to assess and compare the impact of BFFL on the 2-year clinical performance of bulk-fill ormocer-based resin composites (BORC) versus methacrylate-based resin composites (BMRC) in class II cavities. The study's null hypotheses were as follows: (1) Different types of matrix structures (ormocer versus methacrylate) have no effect on the clinical performance of restorations; (2) A layer of BFFL of the same category would not affect the clinical parameters being evaluated.

Materials and Methods

The clinical trial was designed as a prospective, randomized, double-blind study involving both volunteers and examiners. It followed a split-mouth model and adhered to the Consolidated Standards of Reporting Trials (CONSORT) statement, ensuring rigorous methodology.[19] Ethical approval was obtained from the local committee of Mansoura University under the code M 11120520. Additionally, the study was registered on clinical-trials.gov with the identifier NCT06032689.

Sample Size Calculations
Sample size calculations were conducted based on the clinical success rate observed in a previous study for posterior class II composite restorations (97.5% at 24 months). The estimate determined a sample size of 23 teeth per group, considering a significance level of 0.05, power of 80%, and an equivalency limit of 15%. To account for potential dropouts, a total of thirty patients were selected, resulting in a total of 120 restorations (30 for each group) after eligibility criteria were met.

Recruitment
Patients were recruited from those seeking treatment at the outpatient clinic of the Conservative Dentistry Department in the Faculty of Dentistry, Mansoura University. A convenience sampling method was employed, and no advertisements were utilized for recruitment to maintain the nature of the sample. Informed consent was obtained from all participants before their inclusion in the study.

Eligibility Criteria
A group of 30 patients, comprising 21 females and nine males, was selected from a pool of ninety-two participants, following a thorough assessment against inclusion and exclusion criteria. Inclusion criteria encompassed good oral hygiene, a minimum of four posterior teeth exhibiting mild-to-moderate proximal carious lesions (score 3 or 4 according to ICDAS (International Caries Detection and Assessment System)), an age range of 18 to 30 years, and normal occlusion. The cervical margins of the approximal boxes were situated in enamel.

General exclusion criteria involved severe chronic periodontitis, the presence of orthodontic appliances, abnormal occlusion, parafunctional habits, or any allergic reaction to

the materials employed in the study. Specific exclusion criteria for teeth included irreversible pulpitis or nonvital status, fractured or cracked teeth, previously restored teeth, and cavities with isthmus larger than the intercuspal distance or teeth with deep sub-gingival cavity margins.

Study Design

A total of 120 class II restorations were conducted in 30 patients, each receiving four restorations. Of these, 73 restorations were performed in molars, and the remaining 47 were in premolars. The selected patient group consisted of 9 males and 21 females. Restorative techniques were assigned to each patient through blind drawing: the first involved applying Admira Fusion X-Tra (AFX) alone, the second restored cavities with AFX after lining with Admira Fusion X-Base (AFB), the third utilized X-Tra Fill (XF) to completely fill cavities, and the fourth restored cavities with XF after lining with Xtra-Base (XB). All materials utilized in the study, along with their respective manufacturers, compositions, and filler content, are detailed in ▶Table 1. The operator meticulously documented patient data, teeth numbering codes, the chosen restorative system for each tooth, and follow-up evaluation scores using follow-up sheets provided by blinded assessors after each follow-up period.

Randomization

Numbers corresponding to each restored tooth, using the World Dental Federation (FDI) two-digit numbering system, were documented on four separate and identical sheets of paper. These sheets were then placed inside opaque, securely closed envelopes, which were inserted into another opaque box. Simultaneously, the names of the four distinct restorative systems were written down, enclosed in corresponding opaque envelopes, and placed inside a separate opaque box.

Randomization was performed through a blind drawing process, involving the selection of an envelope for the tooth's number and another for the restoration system.

Interventions (Clinical Procedures)

The study interventions encompassed a series of clinical procedures meticulously performed by a singular operator who was not blinded to the materials or techniques. Shade selection was intentionally omitted, under the presumption of a chameleon effect for the resin composites' universal applicability. However, XB, available in both universal and A2 shades, was specifically utilized in the universal shade to ensure color standardization across all resin composites, acknowledging the potential influence on the light-curing procedure. Comprehensive preoperative documentation included photographs and digital bite-wing radiographs for the teeth involved in the study. Vitality testing was conducted using a pulp testing device (Kerr Vitality Scanner; Kerr, Peterborough, United Kingdom).

Operative procedures were performed under local anesthesia (Artinibsa 4%, 1: 100,000, Inibsa Dental S.L. U, Spain) with rubber dam isolation. Round carbide burs (#1015–1017, KG Sorensen, Barueri, Brazil) were utilized in a high-speed handpiece (Sirona T3, Bensheim, Germany) with a generous air–water spray. Smooth spherical carbide burs (#1/2–4, DENTSPLY Maillefer, Ballaigues, Switzerland) were employed for carious tissue removal in a slow-speed handpiece (NAC-EC, NSK, Japan). The cavity preparation adhered to established guidelines for moderate-to-large class II adhesive resin composite restorations, involving the meticulous removal of residual infected carious dentin with a hand excavator (#52, DENTSPLY Maillefer, Switzerland).[20]

The prepared cavities exhibited specific characteristics: no cusp reduction, supragingival placement of gingival

Table 1 Materials used in this study

Material	Type	Manufacturing company	Resin matrix composition	Filler content	Lot. no.
X-Tra Fill	Bulk-fill high-viscosity methacrylate-based resin composite (BHMRC) (high viscosity).	VOCO, Cuxhaven, Germany	Bis-GMA, UDMA, TEGDMA	Barium aluminum silicate, fumed silica, and pigment Filler Content (wt.%): 86	2E + 06
XTra Base	Bulk-fill low-viscosity (flowable) methacrylate-based resin composite (BLMRC).	VOCO, Cuxhaven, Germany	Bis-GMA, Bis-EMA, UDMA		2E + 06
Admira Fusion X-Tra	Bulk-fill high-viscosity Ormocer based resin composite (BHORC).	VOCO, Cuxhaven, Germany	Ormocer matrix	Aluminum, and barium silicate	2E + 06
Admira Fusion X-Base	Bulk-fill low- viscosity ormocer-based resin composite (BLORC).	VOCO, Cuxhaven, Germany	Ormocer matrix	Filler Content (wt.%): 75	2E + 06
Futura Bond U Universal (single dose)	Universal dual cure self-etching adhesive.	VOCO, Cuxhaven, Germany	HEMA, Bis-GMA, HEDMA, acidic adhesive monomer, UDMA, catalyst, silica nanoparticle, and ethanol		
Total N-Etch	Acid -etchant	Ivoclar, Vivadent	Phosphoric acid (37%), thickness agent and color pigments		N010612

margins, including sound enamel with approximately 4 mm pulpal depth, and rounded cavity walls without beveling. The pulpal depth of cavities varied among patients, with each cavity having a minimum of 2 mm for the overlaying composite and 1 mm for the liner. Consequently, cavities shallower than 3 mm (which did not occur in the current study) were excluded. Also, remaining dentin thickness (RDT) throughout the study was ensured by bitewing radiographs, and extensively deep cavities with RDT less than or equal to 0.5 mm were excluded. After applying 37% phosphoric acid gel (Total-Etch; Ivoclar Vivadent, Schaan, Liechtenstein) and air-drying, the dentin surface was protected by Teflon. The self-etching universal adhesive (Futura U bond Voco, Germany) was actively applied to the cavity surfaces using a microbrush, left undisturbed for 10 seconds, and air-dried for 5 seconds with oil-free air under maximum air pressure. Light curing was performed for 10 seconds, adhering to the manufacturer's specifications.

Both adhesives and resin composites underwent light curing using a Valo curing light (Ultradent Products Inc., South Jordan, Utah, United States) in the standard application mode with an output of 1200 mW/cm^2, adhering to the manufacturer's guidelines. This approach aimed to closely simulate a clinical scenario, mirroring the common practice among clinicians who light-cure their composite restorations following the manufacturers' recommendations. The intensity of the light-curing unit was consistently monitored throughout the entire study period using a radiometer (Optilux, Kerr, Orange, California, United States) to ensure a consistent output. The light curing times for various bulk-fill resin composites, as per the manufacturers' recommendations, were 10 seconds for XF, XB, and 20 seconds for AFX, AFB.

The restoration procedures were executed as follows: for reconstructing the missing proximal wall and achieving proper contact and contour, an adequately sized metal sectional matrix band (TOR VM, Russia) and a separating ring (Palodent V3, DENTSPLY/Caulk, Milford, Delaware, United States) were meticulously positioned. A correctly sized wooden wedge (TOR VM, Russia) was thoughtfully inserted interproximally. A proximal wall, approximately 1 mm thick, was then built using the veneering bulk-fill high-viscosity resin composite.

Following that, in cavities without added liners, the entire restoration depths were filled in bulk (utilizing the complete bulk-fill technique) using manual filling instruments and burnishers, and then cured in accordance with the manufacturer's recommendations. For cavities employing BFFL, a 1 mm thick layer of bulk-fill flowable resin composite was applied to the pulpal floor and light-cured as per the manufacturer's instructions. Subsequently, they were overlaid occlusally with a surface layer of the utilized high-viscosity resin composites, ensuring a thickness of at least 2 mm. Upon removal of the metal band, light curing was performed from the mesial sides at a distance of 1 mm for 20 seconds.

Occlusal adjustments were performed utilizing fine grit yellow-coded tapered diamond stones with a round end and flame-shaped design (Komet, United States). Polishing procedures were conducted using polishing points (Jiffy, Ultradent Products Inc., South Jordan, Utah, United States) and polishing brushes (Occlubrush, Kerr, Switzerland) operated with a low-speed contra-angle handpiece (NAC-EC, NSK, Japan), maintaining a maximum speed of 20,000 rpm under water coolant and applying minimal pressure.

Evaluation Procedures

Calibration Procedures for Clinical Evaluation
Two independent and calibrated examiners, who did not attend the restorative procedures, were responsible for the evaluation process. Calibration was conducted using an online tool (www.e-calib.info). An interexaminer and intra-examiner agreement of at least 90% was required before the beginning of the evaluation.[21]

Blinding
The study was classified as double-blind since both patients and examiners, who were not involved in the restoration procedures, were unaware of the type of intervention.

Clinical Evaluation
Evaluation procedures were conducted at 1 week (baseline), 6 months, 12 months, 18 months, and 24 months using the FDI criteria. Clinical intraoral photographs were captured during all recall periods, and a standardized case report for each patient was utilized to document the FDI parameters at each evaluation. Cotton roll isolation was employed to maintain dry fields throughout all evaluation periods. The parameters requiring clinical visibility were assessed using a 4X dental loupe (Univet, Italy) with strong illumination from a corresponding LED light source.

Only the FDI criteria relevant to class II restorations using similar bulk-fill resin composite materials were selected for evaluation (►Table 2). In terms of esthetic properties, marginal staining, color match, and translucency were considered. For functional properties, fracture of material, retention, marginal adaptation, and contact point/food impact were evaluated. Among the biological properties, postoperative sensitivity and recurrent decay were assessed. Clinical parameters were assigned the following scores: clinically very good (1), clinically good (2), clinically satisfactory (3), clinically unsatisfactory (4), and clinically poor (5) (►Table 3).

Postoperative sensitivity and tooth vitality were assessed using the visual analogue scale (VAS).[22] The VAS consists of a 10-cm-long horizontal line labeled at two ends. The initial label is "no pain at all" (score 0), while the final label is "pain as severe as it could be" (score 10). Patients were instructed to mark the line to indicate their level of tooth sensitivity, and categorical scores were assigned: none (0), mild (1–3), moderate (4–6), and severe. All patient readings (marks) were recorded, and the severity of pain was then evaluated. Interproximal contacts were assessed using waxed dental floss. If the contact was weak, 25, 50, and 100 μm metal blades were placed in the interdental space to determine the thickest one that could access.

Table 2 Evaluation methods for World Dental Federation (FDI) criteria

1. Marginal staining	• Minor discoloration: requires visual inspection with a mirror and operating light • Severe discoloration: visual inspection at a speaking distance of 60 to 100 cm
2. Color match/stability and translucency	• The operator light was switched off and proper evaluation of color match was done at 60 to 100 cm
3. Fracture of restorative material and restoration retention	• A magnifying aid (loupe 4 x) with powerful light source was used for evaluation
4. Marginal adaptation	• A magnifying aid (loupe 4 x) with powerful light source was used for evaluation • Two special probes with different blunt tips (150 and 250 μm) and dental floss were used
5. Radiographic examination	• Digital periapical radiographs were taken at different follow-up periods
6. Patient's view	• A structured interview with the patient on his/her satisfaction/dissatisfaction with the restoration using a visual analogue scale (VAS)
7. Postoperative (hyper-) sensitivity and tooth vitality	• Intensity was assessed with VAS • Postoperative sensitivity was evaluated by blowing a stream of compressed air for 3 seconds at 2–3 cm from the restoration • Vitality was tested with application of cold (dry ice) and compared the reaction with the adjacent vital teeth
8. Recurrent caries	• Diagnosis of caries was performed according to ICDAS using loupe, mirror and the same two special probes
9. Tooth integrity (enamel cracks and tooth fractures)	• Evaluation was performed using loupe with the help of the blunt probes.
10. Contact point/food impact	• Metal blades *25-/50-/100-μm*

Statistical Analysis

The kappa index was utilized to measure the degree of agreement between evaluators. The chi-squared test was employed for comparison between the four groups within every follow-up period, while the marginal homogeneity test was used to compare the changes within each group over time. All analyses were conducted using SPSS (IBM SPSS v20, IBM Corp., Armonk, New York, United States). The VAS was the chosen method for analyzing postoperative sensitivity.

Results

The restorative procedures were executed precisely as planned, with no modifications made. Throughout all evaluation periods, 100% of patients attended recall evaluations. Following normality tests, the clinical evaluation scores did not exhibit a normal distribution pattern ($p < 0.05$). Therefore, the chi-squared test was utilized for comparison between the four groups within each follow-up period, while the marginal homogeneity test was used to compare changes over time within individual groups, judged at the ($p < 0.05$) level of significance. In general, there were no statistically significant differences observed between class II restorations concerning the selected FDI criteria at baseline, 6, 12, 18 months, and 2-year recall visits (►**Table 4**).

Marginal Staining, Marginal Adaptation, Recurrent Caries, and Tooth Integrity (Enamel Cracks and Tooth Fractures)

A nonsignificant difference was detected by the chi-squared or marginal homogeneity tests among restorations at any evaluation time or between evaluation times ($p > 0.05$).

Color Match and Translucency

At all follow-up periods, only two restorations that used the XF system and one in the XB system showed a minor deviation in shade and translucency, which was clinically considered good (score 2).

Fractures

At the end of the 12-month evaluation period, eight restorations showed minor fractures (one tooth with the XF system, two teeth with XB, three with AFX, and two restorations in the AFB groups). However, these fractures did not necessitate the replacement of the restoration. The fractured portions were repaired using the same process and materials that were used initially.

Contact Point/Food Impact

When assessing contact point and food impact, eight restorations (one in the XF group, two in the XB system, three in AFX, and two in AFB) were slightly too strong. However, this did not pose any significant disadvantage, and there were no statistical differences at the end of the 24-month recall visit.

Postoperative Sensitivity and Tooth Vitality

At the baseline (1-week) recall visit, minor hypersensitivity for a limited period with normal vitality (score 1) was reported in one tooth restored with the XF system and two restorations with the AFX restorative system.

Discussion

In class II cavities, the loss of marginal ridges, considered strategic tooth structures, leads to a notable reduction in

Table 3 World Dental Federation (FDI) criteria and grading

A. Esthetic properties	1. Clinically excellent / very good	2. Clinically good (after polishing probably very good)	3. Clinically sufficient / satisfactory (minor shortcomings, no unacceptable effects but not adjustable without damage to the tooth)	4. Clinically unsatisfactory (but reparable)	5. Clinically poor (replacement necessary)
1. Marginal staining	1.1 No marginal staining	1.2 Minor marginal staining, easily removable by polishing	1.3 Moderate marginal staining, not esthetically unacceptable	1.4 Pronounced marginal staining; major intervention necessary for improvement	1.5 Deep marginal staining, not accessible for intervention
2. Color match and translucency	2.1 Good color match, no difference in shade and/or translucency.	2.2 Minor deviations in shade and/or translucency	2.3 Distinct deviation but acceptable. Does not affect aesthetics: 2.3.1 More opaque 2.3.2 More translucent 2.3.3 Darker 2.3.4 Brighter	2.4 Localized clinically deviation that can be corrected by repair: 2.4.1 Too opaque. 2.4.2 Too translucent 2.4.3 Too dark. 2.4.4 Too bright	2.5 Unacceptable. Replacement necessary
B. Functional properties					
3. Fracture of material and retention	3.1 No fractures / cracks	3.2 Small hairline crack	3.3 Two or more or larger hairline cracks and/or material chip fracture not affecting the marginal integrity or approximal contact	3.4.1 Material chip fractures which damage marginal quality or approximal contacts 3.4.2 Bulk fractures with partial loss (less than half of the restoration)	3.5 (Partial or complete) loss of restoration or multiple fractures
4. Marginal adaptation	4.1 Harmonious outline, no gaps, no white or discolored lines	4.2.1 Marginal gap (<150 µm), white lines. 4.2.2 Small marginal fracture removable by polishing 4.2.3 Slight ditching, slight step/flashes, minor irregularities.	4.3.1 Gap <250 µm not removable. 4.3.2. Several small marginal fractures 4.3.3 Major irregularities, ditching or flash, steps	4.4.1 Gap >250 µm or dentine/base exposed 4.4.2. Severe ditching or marginal fractures 4.4.3 Larger irregularities or steps (repair necessary)	4.5.1 Restoration (complete or partial) is loose but in situ 4.5.2 Generalized major gaps or irregularities
5. Radiographic examination (when applicable)	5.1 No pathology, harmonious transition between restoration and tooth	5.2.1 Acceptable material excess present. 5.2.2 Positive/negative step present at margin <150 µm	5. 3.1 Marginal gap < 250 µm 5. 3. 2 Negative steps visible <250 µm No adverse effects noticed 5.3.3 Poor radiopacity of filling material	5.4.1 Marginal gap >250 µm 5.4.2 Material excess accessible but not removable 5.4.3 Negative steps >250µm and reparable	5.5.1 Secondary caries, large gaps, large overhangs 5.5.2 Apical pathology 5.5.3 Fracture/loss of restoration or tooth

Table 3 (*Continued*)

6. Patient's view	6.1 Entirely satisfied with aesthetics and function	6.2 Satisfied. 6.2.1 Aesthetics 6.2.2 Function, e.g., minor roughness	6.3 Minor criticism but no adverse clinical effects 6.3.1 Esthetic shortcomings. 6.3.2 Some lack of chewing comfort 6.3.3 Unpleasant treatment procedure	10.4 Desire for improvement 10.4.1 Aesthetics 10.4.2 Function, e.g., tongue irritation. Reshaping of anatomic form or refurbishing is possible	6.5 Completely dissatisfied and / or adverse effects, including pain
C. Biological properties					
7. Postoperative (hyper-)sensitivity and tooth vitality	7.1 No hypersensitivity, normal vitality	7.2 Minor hypersensitivity for a limited period, normal vitality	7.3.1 Moderate hypersensitivity 7.3.2 Delayed/mild sensitivity; no subjective complaints, no treatment needed	7.4.1 Intense hypersensitivity 7.4.2 Delayed with minor subjective symptoms 7.4.3 No clinical detectable sensitivity. Intervention necessary but not replacement	7.5 Intense, acute pulpitis or non-vital tooth. Endodontic treatment is necessary, and restoration must be replaced
8. Recurrence of caries (CAR), erosion, abfraction	8.1 No secondary or primary caries	8.2 Small and localized 1.Demineralization 2. Erosion or 3. Abfraction	8.3 Larger areas of 1. Demineralization 2. Erosion or 3. Abrasion/abfraction on, dentine not exposed Only Preventive measures are necessary	8. 4.1 Caries with cavitation and suspected undermining caries 8.4.2 Erosion in dentine 8.4.3 Abrasion/ abfraction in dentine Localized and accessible can be repaired	8.5 Deep caries or exposed dentine that is not accessible for repair of restoration
9. Tooth integrity (enamel cracks, tooth fractures)	9.1 Complete integrity	9.2.1 Small marginal enamel fracture (<150 μm) 13.2.2 Hairline crack in enamel (<150 μm)	9.3.1 Marginal enamel defects <250μm 9.3.2 Crack <250μm. 9.3.3 Enamel chipping. 9.3.4 Multiple cracks	9.4.1 Major marginal enamel defects; gap >250 μm or dentine or base exposed 9.4.2 Large cracks >250 μm, probe penetrates 9.4.3. Large enamel chipping or wall fracture	9.5. Cusp or tooth fracture
10. Contact point/food impact	10.1 Normal contact point (floss or 25 μm metal blade of can be inserted but not 50μm blade).	10.2. Slightly too strong but no disadvantage	10.3. Slightly too weak, no indication of damage to tooth, gingiva, or periodontal structures (50 μm metal blade can pass easily but not 100 μm)	10.4 Too weak (100 μm metal blade can pass) and possible damage (food impaction). Repair possible	10.5 Too weak and/or clear damage (food impaction) and/pain/ gingivitis. Requires replacement

Table 4 Scores of all tested criteria and results of chi-square and marginal homogeneity tests

Category	Score	Baseline (n=30) XF	XB	AFX	AFB	a	6 Months (n=30) XF	XB	AFX	AFB	a	12 Months (n=30) XF	XB	AFX	AFB	a	18 Months (n=30) XF	XB	AFX	AFB	a	24 Months (n=30) XF	XB	AFX	AFB	a	XF[b]	XB[b]	AFX[b]	AFB[b]
Marginal staining	1	30	30	30	30	p=1.0	30	30	30	30	p=1.0	30	30	30	30	p=1.0	30	30	30	30	p=1.0	30	30	30	30	p=1.0	p1=1.0	p1=1.0	p1=1.0	p1=1.0
	2	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		p2=1.0	p2=1.0	p2=1.0	p2=1.0
	3	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		p3=1.0	p3=1.0	p3=1.0	p3=1.0
	4	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		p4=1.0	p4=1.0	p4=1.0	p4=1.0
	5	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0					
Color match and translucency	1	28	29	30	30	p=0.288	28	29	30	30	p=0.288	28	29	30	30	p=0.288	28	29	30	30	p=0.288	28	29	30	30	p=0.288	p1=1.0	p1=1.0	p1=1.0	p1=1.0
	2	2	1	0	0		2	1	0	0		2	1	0	0		2	1	0	0		2	1	0	0		p2=1.0	p2=1.0	p2=1.0	p2=1.0
	3	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		p3=1.0	p3=1.0	p3=1.0	p3=1.0
	4	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		p4=1.0	p4=1.0	p4=1.0	p4=1.0
	5	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0					
Fracture of material and retention	1	30	30	30	30	p=1.0	30	30	30	30	p=1.0	30	30	30	30	p=1.0	30	30	30	30	p=1.0	30	30	30	30	p=1.0	p1=1.0	p1=1.0	p1=1.0	p1=1.0
	2	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		p2=1.0	p2=1.0	p2=1.0	p2=1.0
	3	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		p3=1.0	p3=1.0	p3=1.0	p3=1.0
	4	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		p4=1.0	p4=1.0	p4=1.0	p4=1.0
	5	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0					
Marginal adaptation	1	30	30	30	30	p=1.0	30	30	30	30	p=1.0	30	30	30	30	p=1.0	30	30	30	30	p=1.0	30	30	30	30	p=1.0	p1=1.0	p1=1.0	p1=1.0	p1=1.0
	2	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		p2=1.0	p2=1.0	p2=1.0	p2=1.0
	3	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		p3=1.0	p3=1.0	p3=1.0	p3=1.0
	4	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		p4=1.0	p4=1.0	p4=1.0	p4=1.0
	5	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0					
Radiographic examination	1	30	30	30	30	p=1.0	30	30	30	30	p=1.0	30	30	30	30	p=1.0	30	30	30	30	p=1.0	30	30	30	30	p=1.0	p1=1.0	p1=1.0	p1=1.0	p1=1.0
	2	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		p2=1.0	p2=1.0	p2=1.0	p2=1.0
	3	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		p3=1.0	p3=1.0	p3=1.0	p3=1.0
	4	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		p4=1.0	p4=1.0	p4=1.0	p4=1.0
	5	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0					
Interproximal contact	1	30	30	30	30	p=0.288	30	30	30	30	p=1.0	30	30	30	30	p=1.0	30	30	30	30	p=1.0	29	28	27	28	p=0.784	p1=0.317	p1=0.317	p1=0.317	p1=0.317
	2	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		1	2	3	2		p2=0.157	p2=0.157	p2=0.157	p2=0.157
	3	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		p3=0.083	p3=0.083	p3=0.083	p3=0.083
	4	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		p4=0.157	p4=0.157	p4=0.157	p4=0.157
	5	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0					
Postoperative (hyper-) sensitivity and tooth vitality	1	29	30	28	30	p=0.288	30	30	30	30	p=1.0	30	30	30	30	p=1.0	30	30	30	30	p=1.0	30	30	30	30	p=1.0	p1=0.157	p1=0.157	p1=0.083	p1=0.083
	2	1	0	2	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		p2=1.0	p2=1.0	p2=1.0	p2=1.0
	3	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		p3=0.157	p3=0.157	p3=0.157	p3=0.157
	4	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		p4=1.0	p4=1.0	p4=1.0	p4=1.0
	5	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0					

Table 4 (*Continued*)

Category	Score	Baseline (n=30) XF	XB	AFX	AFB	a	6 Months (n=30) XF	XB	AFX	AFB	a	12 Months (n=30) XF	XB	AFX	AFB	a	18 Months (n=30) XF	XB	AFX	AFB	a	24 Months (n=30) XF	XB	AFX	AFB	a	XF^b	XB^b	AFX^b	AFB^b
Recurrent caries	1	30	30	30	30	p=1.0	30	30	30	30	p=1.0	30	30	30	30	p=1.0	30	30	30	30	p=1.0	30	30	30	30	p=1.0	p1=1.0	p1=1.0	p1=1.0	p1=1.0
	2	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		p2=1.0	p2=1.0	p2=1.0	p2=1.0
	3	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		p3=1.0	p3=1.0	p3=1.0	p3=1.0
	4	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		p4=1.0	p4=1.0	p4=1.0	p4=1.0
	5	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0					
Tooth integrity (enamel cracks and tooth fractures)	1	30	30	30	30	p=1.0	30	30	30	30	p=1.0	30	30	30	30	p=1.0	30	30	30	30	p=1.0	30	30	30	30	p=1.0	p1=1.0	p1=1.0	p1=1.0	p1=1.0
	2	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		p2=1.0	p2=1.0	p2=1.0	p2=1.0
	3	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		p3=1.0	p3=1.0	p3=1.0	p3=1.0
	4	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		p4=1.0	p4=1.0	p4=1.0	p4=1.0
	5	0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0		0	0	0	0					

Abbreviations: AFB, Admira Fusion Xtra-Base; AFX, Admira Fusion X-Tra; XB, Xtra-Base; XF, X-Tra Fill.

a)USED test: Chi-squared test for comparing between groups (XF, XB, AFX, and AFB).

b)USED test: Marginal homogeneity test for comparing between different follow-up times as compared with baseline value.

tooth strength and increased cusp flexure. The use of the universal adhesive (Futura U bond, Voco) was standardized across all systems, applicable in both etch-and-rinse and self-etch modes. Studies have shown no significant difference in its clinical behavior between different applied strategies.[23]

However, in this study, enamel was selectively etched based on reports of the formation of longer resin tags and thicker hybrid layers.[24] Sectional matrix systems were chosen for their ability to produce tighter proximal contacts compared with circumferential matrix systems.[25] The type of matrix used in class II restorations can also influence the degree of proximal contact. Clinical evaluation in this study utilized FDI criteria, considered more sensitive, reliable, and precise.[26]

Based on the results of this RCT, no significant differences were observed among all restorations during the 24-month periodic follow-ups based on the selected FDI criteria. As a result, the first null hypothesis, stating that different types of matrix structures (ormocer versus methacrylate) would not have an effect on the marginal integrity of restorations, was accepted. Additionally, the second part of the hypothesis was accepted, indicating that the use of BFFL did not affect the evaluated clinical parameters.

Nonsignificant differences in aesthetic properties were observed among all restorations. This could be attributed to the fact that both AFX and XF contained nanohybrid particles with nearly similar filler content. The size and distribution of fillers are crucial factors influencing surface properties like roughness and gloss after polishing.[27]

Moreover, nanoparticles, being smaller than the visible light wavelength (0.1–100 nm), enhance material translucency and opalescence, improving aesthetic characteristics. However, approximately three restorations using the XF approach, whether with BFFL or not, showed minimal color deviation from the baseline up to 24 months. This could be attributed to enhanced material translucency, which may compromise some aesthetic features of the restorations. A previous in vitro study reported a high likelihood of color change in this type of BMRC after polymerization.[28] Contrarily, prior clinical studies assessing various BMRCs used in this study reported no aesthetic issues in the baseline evaluation. However, the observed good color stability in the AFX system may be attributed to lower water sorption, facilitated by higher filler loading and ormocer molecules with a high degree of conversion, thereby reducing pigment absorption and adsorption.[29]

Nonsignificant differences were observed in parameters related to functional properties. However, minor fractures were noted at the 24-month follow-up, with no negative impact on all restoration systems. It is crucial to acknowledge that patients did not exhibit uniform and consistent occlusion, and there is a possibility of dental movement in some cases. Moreover, a 24-month duration may be insufficient for the development of significant variations among tested categories, posing a potential limitation in this study. It is anticipated that in subsequent follow-ups, the fracture rate of the restorations will tend to remain low, indicating excellent performance.

In the assessment of contact points and food impact, no significant differences were observed among all restorations. A separate study evaluating proximal contacts in class II restorations using AFX and XF found that all teeth scored α for this criterion after 2 years. Additionally, Van Ende et al[6] suggested that bulk-fill packable resin composite might contribute to achieving a good contact point.

Unfortunately, at the 2-year follow-up period, eight restorations (one restoration in XF, two restorations in XB, three restorations in AFX, and two restorations in AFB) exhibited slightly excessive contact points, but this did not result in a significant difference across the various restoration systems. Clinical literature evaluating the intensity of proximal contacts related to BFFL usage according to FDI criteria is limited. Algamaiah et al[30] reported that volumetric changes in BFFL may compromise the precision of proximal contacts, potentially leaving space between adjacent teeth for food impaction.

In terms of marginal discrepancies, no significant difference was observed when comparing the addition of BFFL versus complete bulk-fill techniques (AFX, XF) after 24 months of clinical evaluation. This, in turn, could improve the sealing properties and reduce debonding of resin composite materials in proximal posterior boxes.[31] However, the results of this study do not align with the study published by Yazici et al. The authors showed lower marginal discrepancies when adopting a complete bulk-filling technique.

All the restorations exhibited similar biological properties. No caries recurrence was observed, indicating that both XF and AFX had excellent polishability and low biofilm retention. However, it should be noted that recurrent decay might occur later and may be detected in longer-term follow-up periods. Therefore, a more extended follow-up time may be necessary to confirm the observed results.Top of Form

Nonsignificant differences were observed in terms of postoperative sensitivity. This aligns with the results of a separate clinical investigation, where it was noted that the risk of sensitivity remained unaffected by both the adhesive type and the restorative material employed.[32] Moreover, all restorations in the current RCT were completed using a universal adhesive (Futura U bond) containing the 10-MDP acidic monomer. This monomer exhibited chemical bonding, creating a hybrid layer and tags to tooth structure, promoting bonding durability.[33] Furthermore, to prevent shrinkage stresses from affecting the developing dentin bond, it is crucial to ensure sufficient and immediate copolymerization between the adhesive layer and resin composite.

Limitation of the Study

RCTs frequently employ stringent inclusion and exclusion criteria to manage confounding variables. Consequently, the study population might not completely reflect the diversity of the larger patient demographic, thereby restricting the applicability of the results to real-world scenarios. Additionally, certain outcomes, especially those related to long-term or delayed effects, may not be thoroughly captured within the specified timeframe. This constraint can impact the capacity to evaluate the intervention's influence over an extended duration. Future studies should be conducted to observe the clinical performance of bulk fill composite materials over a longer time period.

Conclusions

After a 2-year evaluation, it was observed that the use of BFFL or the complete bulk-fill technique demonstrated similar clinical performance, irrespective of the material composition.

Clinical Relevance

The incorporation of BFFL in class II restorations did not influence the clinical performance of bulk-fill ormocer or methacrylate-based resin composites over a 2-year period.

Conflict of Interest
None declared.

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