**Mansoura University**
**Faculty of Dentistry**
**Operative Dentistry**

# A two-year Clinical Impact of Bulk-fill Low-viscosity Resin Composite Liners in Class II Restorations

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# Protocol:

## Introduction

Patients' increasing desire for aesthetic restorations has led to the use of direct resin composites as the most versatile restoration for both anterior and posterior teeth, with evidence for their success.[1-5] However, polymerization shrinkage and indeed the strains it generates are still one of the main reasons for resin composite restoration failures. This is because it applies tension to the tooth-restoration interface over time, endangering the bonding integrity.[6] Furthermore, these stresses negatively affect cavity margins with leakage and subsequent carious lesion development.[7]

These stresses are widely recognized to be affected by the placement techniques.[8] The standard method for avoiding the clinical effects of polymerization stress is incremental layering.[9-13] The drawbacks of this technique are the possibilities of voids or contaminants inclusion between layers, and difficulties in filling conservative cavities.[14-16] In addition to, a need for restorative procedures that effectively shorten restoration time. In this regard, bulk-fill high-viscosity(regular), and low-viscosity (flowable) methacrylate-based resin composites had been evolved.[17-21]

Different viscosities are due to filler content that has direct relation with material modulus of elasticity.[22] Bulk-fill low-viscosity resin composites (BLRC) are indicated as liners and stress absorbers in class I and class II cavities, requiring an additional layer high-viscosity type.[23] [10, 24-26] While high viscosity (BHRC) types can be inserted up to 5 mm increment, without the need of a veneering layer. [27-30] The increased curing depth were attributed to monomers which act as modulators in the polymerization reaction, resulting in reduced shrinkage.[31-35]

Scientific evidence has shown that bulk-fill resin composites have comparable polymerization shrinkage and stress, depth of cure, physic mechanical properties, and marginal adaptation when compared to conventional composites.[15, 34-41] Other studies have revealed greater values for shrinkage vectors and a higher tendency for debonding.[42] In relation to their clinical performance, data investigating the high-viscosity methacrylate based types had a heterogeneous behaviour and depended mainly in their chemical composition. [43-45] [46, 47] Most of the studies have reported similar results related to marginal degradation when compared to conventional resin composites.[46, 48]

Bulk-fill low-viscosity resin composites (BLRC) as liners demonstrated a stress reduction ability in posterior resin composite restorations, thereby exhibiting a high level of clinical efficacy over three years evaluation.[23, 49-54] Besides, their low elastic modulus may provide a certain stress-absorbing layer, thus relieving the polymerization stress of the veneering regular viscosity composites.[55-58, 14] Moreover, subsequent layer of higher modulus resin composites can be absorbed by an elastic intermediary layer, lowering stress at the tooth-restoration interface. In a RCT one of the restorative systems that used BLRC liner showed the lowest surface staining.[54]

Despite, contradictory evidence had reported decreased adaption and higher polymerization shrinkage stress than the high-viscosity counterpart and other study found no improvement in the clinical performance of a class II restoration .[59, 60] It is unknown, nevertheless, whether low viscosity bulk-fill composites would be susceptible to proximal contact defects comparable to those reported in glass ionomer restoratives.[61, 62]

Resin matrix plays an important role on the shrinkage behaviour of resin composite restorations.[63] The high molecular weight bis-GMA (bisphenol A-glycidyl methacrylate) has been the main monomer used in methacrylate-based resin composites since their development.[64] Due to the high viscosity of this monomer, low molecular weight monomers (diluents) were added to the final blend to get a suitable formulation for clinical use and to allow filler inclusion.[65] These diluent monomers were supposed to increase the polymerization shrinkage of resin composites.[66]

To reduce the clinical problems associated with the conventional methacrylate based resin composites, Ormocers were developed.[67-71] They claimed to lower polymerization stress due to their reduced amount of organic resin.[67, 69, 72-76] On the other hand, their first launched generations did not make any clear progress over the methacrylate-based resin composites.[77] A probable explanation of the attained findings was the inclusion of methacrylate monomers beside ormocer molecule that served as diluents.[78] A pure ormocer resin composite was then introduced to the market and it was placed by incremental layering .[75, 76, 79]

In addition to layering method, the pure material had been implemented for bulk-filling with two viscosities like methacrylates (high viscosity, low viscosity). In comparison with methacrylate resin composites, the pure ormocer material were supposed to lower polymerization shrinkage.[75, 76] Bulk-fill high-viscosity ormocer-based resin composites(BHORC) may be superior alternative to the standard layering method, given similar clinical performance after 24 months, with the advantage of simplified procedures.[80] In addition, a RCT utilized the pure layered ormocer material (Admira-fusion) and found non-significant differences over the compared methacrylate based resin composites after 24 months in class II restorations.[79]

As regard lining ormocer-based resin composites, the data is scarce. Torres et al[81] reported in a one randomized clinical trial to have no influence in their clinical performance. So that the aim of this randomized, split-mouth clinical trial was to evaluate the clinical performance of class II restorations made with the use of BHORC versus BHMRC composites either placed alone or with the effect of BLRC liner of the same type after 2 years follow up.

The null hypotheses in the study were as follows: (1) Different types of matrix structures (ormocer vs. methacrylate) have no effect on the clinical performance of restorations; (2) A layer of bulk-fill resin composite liner of the same category would not affect clinical parameters evaluated.

**Aim of the study**

The current study was intended to evaluate the effect of flowable lining resin composites on 2-year clinical performance of bulk-fill ormocer versus methacrylate-based restorative systems in class II cavities according to FDI criteria.

**Null hypothesis**

The null hypothesis that will be tested in this project is that there would be no significant difference among the four tested restorative strategies at different clinical evaluation periods.

## Materials and Methods

### Materials

Bulk-fill high viscosity methacrylate-based resin composite (BHMRC) (XTra-fill Voco, Germany), Bulk-fill high-viscosity ormocer-based resin composite (BHORC) (Admira-Fusion-Xtra Voco, Germany), Bulk-fill low-viscosity methacrylate-based resin composite (XTra-Base Voco, Germany) (BLMRC) and bulk-fill low-viscosity ormocer-based resin composite (BLORC) (Admira-Fusion-Base Voco, Germany). All restorations were performed using the universal adhesive (Futura U bond Voco, Germany).

### Methods

### Clinical trial design

This clinical trial will be conducted according to CONSORT guidelines for Randomized Clinical Trials (RCTs).[45] It will be carried out after gaining approval from Medical Ethics Committee of Mansoura University.

### Recruitment

Patients enrolled in this study were from the Outpatient Clinic at Mansoura University, Faculty of Dentistry. Patients were informed on the background of the study and who accepted the study condition signed a consent form. The consent form was approved by the ethical committee at faculty of dentistry, Mansoura University.

### Eligibility criteria

Participants were examined to form a group with 30 patients that justify the inclusion and exclusion criteria. Patients were required to have good general health, be older than 18 years old. Patients with extremely poor oral hygiene, severe or chronic periodontitis, or heavy bruxism habits will be excluded from the study.

Patients had to present at least four teeth with class II cavities to be restored (molars or premolar). Also, unsatisfactory class II restorations that are moderately deep with an adjacent tooth was involved.

**Randomization**

Randomization was applied by noting each tooth to be restored (FDI 2- digit code) on one paper and type of restorative strategy on a second. First, a tooth number was drawn blindly. Subsequently a restorative protocol was allocated to this tooth by blind drawing. This procedure was repeated if more than three restorations must be placed.

**Interventions: Restorative procedures**

A split-mouth design was used in this study. For ormocer- based resin composite restorative system, it will be placed without resin flowable liner in one side, while it will be lined in the other side. The same protocol will be applied for methacrylate-based resin composite restorative system. Hence, each patient will receive four restorations with different strategies. All restorative procedures will be carried out by a single operator.

After administration of local anesthetic, rubber dam will be placed. The cavity preparation was then carried out with an outline limited to caries progression. The cavities depth in mm will be measured by a periodontal probe to give an idea about the thickness of the flowable composite liner (when used) and preserve 2 mm depth for the overlying resin. Restorative systems were then be applied according to the instructions recommended by their manufactures. Sectional pre-contoured matrix with ring, and wave like contour plastic wedges was used to restore the shape of the proximal walls. Adhesive and resin composites was cured using a LED (light

emitting diode) curing unit in the standard application mode and an output of 650 $mW/cm^2$.

**Clinical evaluation**

All restorations were clinically evaluated using FDI criteria.[46] This evaluation was done at the baseline, then after 12-month and finally at 24-months.

**Statistical analysis:**

The Chi-Square test was used for comparison between the four groups within every follow up period, while marginal homogeneity test was used to compare the changes within each group per time.

## Results:

Table: Scores of all tested criteria and results of Chi-Square and Marginal homogeneity tests

| category | score | Baseline (n=30) | | | | # | 6 Months (n=30) | | | | # | 12 Months (n=30) | | | | # | 18 Months (n=30) | | | | # | 24 Months (n=30) | | | | # | XF $^{s}$ | XB $^{s}$ | AFX $^{s}$ | AFB $^{s}$ |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | XF | XB | AFX | AFB | | XF | XB | AFX | AFB | | XF | XB | AFX | AFB | | XF | XB | AFX | AFB | | XF | XB | AFX | AFB | | | | | |
| 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=1.0 | 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=0.317 | p1=0.157 | p1=0.083 | p1=1.0 |
| | 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 | | | | | |
| 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** | | **30** | **30** | **30** | **30** | | **30** | **30** | **30** | **30** | | **30** | **30** | **30** | **30** | | **30** | **30** | **30** | **30** | | **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 | **p=1.0** | 0 | 0 | 0 | 0 | **p=1.0** | 0 | 0 | 0 | 0 | **p=1.0** | 0 | 0 | 0 | 0 | **p=1.0** | 0 | 0 | 0 | 0 | **p=1.0** | 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 | | | | | |

#USED test: Chi-Square test for comparing between groups (EXF, SDR and TNFBF) $^{\$}$USED test: Marginal Homogeneity test for comparing between different follow up times as compared to baseline value

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