A Randomized Controlled Clinical Trial Evaluating the Performance of Bis-GMA Free Resin Composite Posterior Restorations

Sara Ahmed Reda[1], Yasser Fathi Hussein[2], Mona Riad[3]

[1,2]*Operative Dentistry Department, Faculty of Dentistry, Minia University, Minia, Egypt*

[3]*Conservative and Aesthetic Dentistry, Faculty of Dentistry, Cairo University, Egypt*

Abstracts: Objective: This study aims to assess the clinical performance of Bis-GMA free resin composites (RCs) in comparison with Bis-GMA based resin composites as posterior restorations during 1,3,6,9, and 12 months, using a split-mouth, double-blinded randomized design. Methods and Materials: The study included 20 participants who received a pair of class I or II bulk-fill composite restorations. One side of the mouth was filled with Bis-GMA free RC (Admira Fusion x-tra), while the other side received Bis-GMA based RC (X-tra fil). Restoration placement was done by a single operator following the manufacturer's guidelines and was finished and polished immediately following placement. Modified United States Public Health Services (USPHS) criteria have been adopted for restoration assessment at baseline (1 week), 1, 3, 6, 9, and 12 months. The statistical analysis was accomplished utilizing Wilcoxon tests, with a 0.05 significance level. Results: After 12 months, all patients attended the recall visits with a 100% recall rate. The Wilcoxon signed rank tests revealed insignificant differences between both groups ($p \leq 0.05$) for all USPHS parameters. The two studied materials showed a decline from 100% clinically excellent scores, with a few recordings of clinically good scores at 12 months. However, most restorations maintained clinical Alpha and Bravo score throughout the 12-month period. Conclusions: The Bis-GMA-free RCs' clinical performance was comparable to that of Bis-GMA-based RCs in posterior permanent teeth restorations after 12 months. These findings suggest that Bis-GMA-free RCs can be considered a viable alternative to Bis-GMA-based RCs in clinical practice.

Keywords: Bis-GMA Free Composite, Bis-GMA Based Composite, Ryge's Criteria (USPHS), Clinical Resin Composite Evaluation, Randomized Control Trial.

1. INTRODUCTION

During the latest decades, resin composites have emerged as a viable alternative to dental amalgam, showing great potential. Along with being cost-effective and aesthetically pleasing, composite restorations require minimal preparation and help preserve tooth structure. Furthermore, they exhibit favorable clinical outcomes when used to restore posterior teeth [1]. Reviewing relevant literature indicates that the resin composite restoration lifespan in posterior teeth can be reliably anticipated [2].

Dental resins are formulated with a specific monomer composition tailored to their intended use [3]. Typically, this composition consists of one or more monomers, with Bis-GMA being the most commonly used since its development by Bowen in 1956 [4]. Bisphenol A (BPA), one of the unreacted monomers released, is relevant in the present research because it acts as an endocrine disruptor for several metabolic pathways, even at lowered doses [5]. However, using diluent monomers in composites has been shown to increase polymerization shrinkage and water sorption [6]. Additionally, the presence of unreacted monomers in the cured material can make it more toxic to pulp cells that come into contact with it [7]. To address these issues, recent developments in resin composites have been geared towards reducing polymerization shrinkage stress by modifying the polymer matrix [8].

Free methacrylate composite resins have emerged as a result of these undesirable consequences because they don't contain typical methacrylates in their makeup. Bis-GMA substitutional monomer compositions have been created as a remedy to increase durability and biocompatibility. One option is to employ an inorganic-organic co-polymer-based dental composite material called Organic Modified Ceramic (Ormocer) [9]. Due to the lack of monomers, the contraction during polymerization may be kept to about 1%. Additionally, it improves biocompatibility, guarding against potentially harmful effects [10].

While laboratory investigations are important for assessing restorative materials, clinical studies are extremely

crucial to appraise their performances [11], as factors such as humidity fluctuations, temperature changes, mastication forces, and salivary enzymes can affect the material's overall performance [12]. Therefore, the current study aimed to offer additional data in this area by comparing and evaluating the clinical performance of Bis-GMA-free RCs to that of Bis-GMA-based RCs in restoring permanent posterior teeth over a 12-month period. The formulated null hypothesis was that there is no significant difference in the clinical performance of Bis-GMA-free RCs in comparison with Bis-GMA-based RCs in a 12-month period in class I and II restorations.

2. MATERIEL AND METHODS

2. 1. Restorative Materials

A nanohybrid bulk fill RC (Admira fusion x-tra) and packable multi-hybrid bulk fill RC (x-tra fil) with a single bond universal adhesive (Futurabond M$^{+)}$ were utilized in the present study and applied according to the manufacturer's instructions. The two restorative materials and the bonding agent that were examined, along with their brand names, compositions, manufacturers, and specifications, are presented in Table 1.

Table 1 Materials used in the study, their specifications, chemical composition, and manufacturers.

Material	Specification	Composition	Manufacturer	Lot Number
x-tra fil	Packable bulk-fill posterior composite, Universal shade	Matrix: Bis-GMA*, aliphatic di-methacrylate Filler: Inorganic Multi-hybrid filler (not defined by the manufacturer) Filler content %: 86 (w/w)	VOCO, Cuxhaven, Germany service@voco.de	2046140
Admira Fusion x-tra	Nano-hybrid ORMOCER® bulk-fill composite, Universal shade	Matrix: ORMOCER®** Filler: glass ceramics, silica nanoparticles, pigments Filler content %: 84 (w/w)		1942580
Futurabond® M+	Universal adhesive system (All in one)	HEMA***; Bis-GMA; ethanol; Acidic adhesive Monomer; UDMA****; pyrogenic silicic acids		1929088

* Bisphenol A-glycidyl methacrylate. **Organically modified ceramics. ***2-Hydroyethyl methacrylate. ****Urethane di-methacrylate.

2.2. Ethical Approval and Protocol Registration

The study proposal for this research was granted approval by the Institutional Review Boards/Ethical Committee (IRBs/ECs) at the Faculty of Dentistry-Minia University, with a serial number of 419. Additionally, registration in the Clinical Trials Registry was completed for this study on 29/07/2022 under the identifier NCT03692286.

2.3. Patient Selection

The present study recruited 20 adult patients who were receiving dental care at the Operative Department Clinic in the Faculty of Dentistry at Minia University. These patients required a pair of comparable Class I or II restorations and were invited to take part in the study. Prior to participation, the patients were explained the study requirements and purpose and requested to provide their consent by signing a form.

2.4. Study Design

This study's experimental design was consistent with the recommendations of the Consolidated Standards of Reporting Trials statement (CONSORT) [13] Figure 2. A randomized clinical trial was utilized for this study, with a

double-blind approach for both patients and examiners. The experimental protocol included the use of the split-mouth design.

2.5. Sample Size Calculation

The study's sample size determination was accomplished depending upon previous sample size calculations from a study [14] with similar designs that evaluated posterior restorations. Using data from previous investigations, a power analysis was performed, which determined that a 16-per-group sample size is necessitated to achieve an alpha score of 5% and a power of 80%. To account for any potential dropouts, 20 restorations were enrolled in each of the two groups. Previous studies have shown that significant differences between material groups can be detected using similarly designed intraindividual comparison evaluations [14, 15].

2.6. Eligibility Criteria

The present study was conducted on 20 patients: 12 females (60%) and eight males (40%). There was no statistically significant difference between teeth as well as class distributions in the two groups. Patients from 18 to 40 had to fulfil specific inclusion criteria to be eligible, such as having two permanent posterior teeth needing restorations, with the antagonist and opposing teeth in contact, a healthy pulp, and no prior experiences of sensitivity or pain in the affected teeth. Additionally, patients needed to have satisfactory oral health status, and the two restorative materials should be used in similarly sized lesions or within the same extension. To be included in the study, teeth had to pass an electric pulp testing and have normal occlusion and complete contact with opposing natural teeth without restorations. Additionally, third molars were not considered for the study. Cases who were at high risk for caries, had extremely poor oral hygiene, were undergoing periodontal surgery or orthodontic treatment, had periodontal disease (chronic periodontitis) or abutments, wear facets on teeth, clenching, and heavy bruxism habits were omitted. Table 2 exhibits the data regarding the characteristics of patients and restored cavities.

Table 2: Frequencies (n), percentages and results of Wilcoxon signed-rank test for comparisons of demographic data in the two groups.

	Admira Fusion x-tra (n = 20)		X-tra Fil (n = 20)		*P*-value
	n	%	n	%	
Tooth					
Mandibular premolars	1	5	1	5	0.750
Mandibular molars	10	50	9	45	
Maxillary premolars	3	15	3	15	
Maxillary molars	6	30	7	35	
Class					
Class I	15	75	14	70	0.655
Class II	5	25	6	30	

**: Significant at P ≤ 0.05*

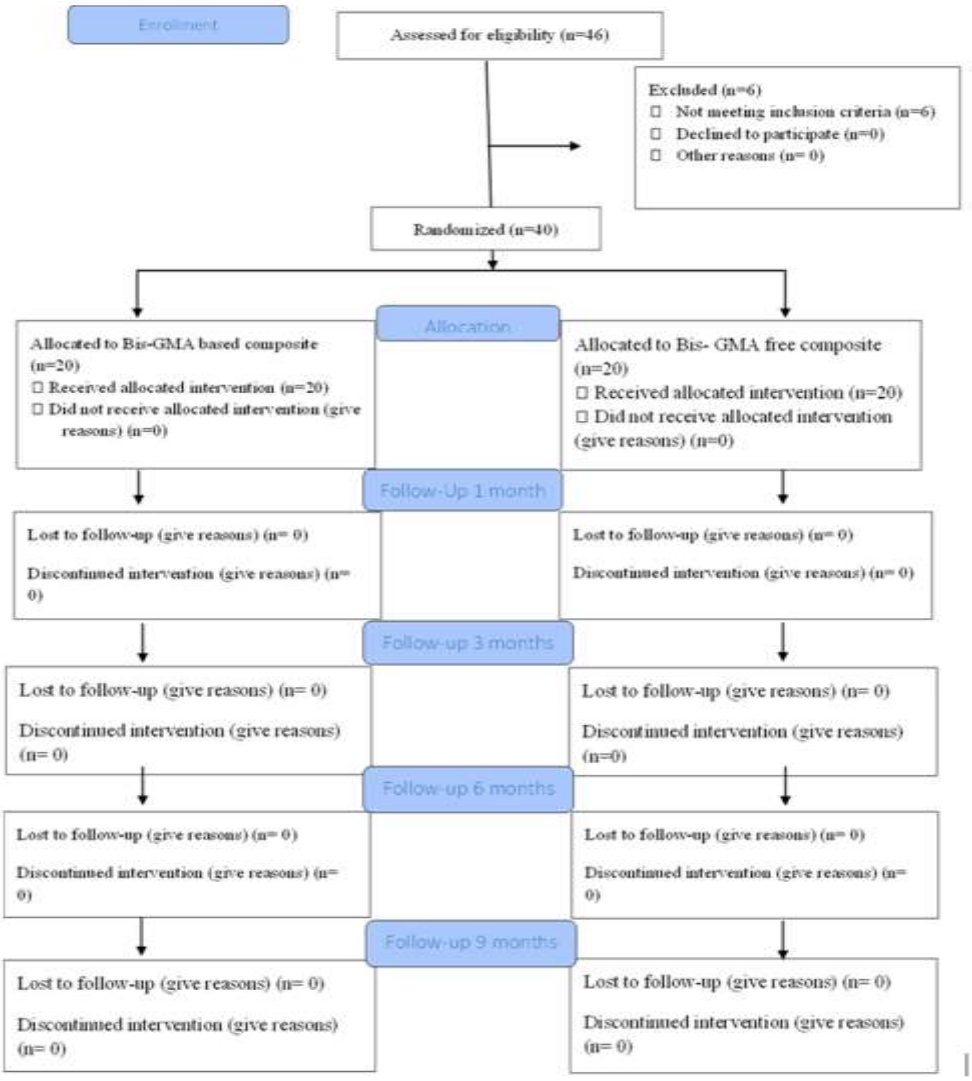

Figure 2. Flowchart of the current investigation (Consolidated Standards of Reporting Trials [CONSORT] 2010).

2.7. Random Sequence Generation and Allocation Concealment

In this study, all patients received a pair of class I or II posterior restorations, one Bis-GMA free RC and one Bis-GMA based RC restoration, each placed on a different side of the mouth. This design is known as a split-mouth design. The placement of the restorations was randomly determined for each pair (20 pairs) utilizing online software (www.randamization.com). A list of participants was created, and a randomization code was established based on the two treatment options (free and containing). In addition, the cavities in each pair were matched in terms of size and location. Nevertheless, the patients remained unaware of their assigned treatment throughout the study. To maintain the patients' blindness to their treatment allocation, an uninvolved staff member prepared the envelopes.

2.9. Clinical Procedures

A single skilled operator accomplished the preparation, restoration, and finishing of 40 class I and II bulk fill RC restorations, utilizing either Bis-GMA free or Bis-GMA-based materials and employing an adhesive cavity design. Prior to the restorative procedures, patients received local anesthesia to minimize discomfort. A rubber dam was applied with strong suction to isolate the operative field. The cavities were prepared using high-speed fissure carbide burs and round diamond stones (Komet, Brasseler GmbH Co. KG, Lemgo, Germany) with water cooling. Any remaining caries were removed using tungsten carbide round burs (Komet, Brasseler GmbH Co. KG) at a low

speed, along with sharp excavators. All preparations received the application of the universal adhesive Futurabond M+ (Voco), according to manufacturer's instructions. adhesive was applied using a disposable brush, and the area was scrubbed for 20 seconds. After that, the adhesive was air-dried for 3-5 seconds, and light-curing was then performed for 10 seconds with a halogen light-curing unit (Astralis 5, Ivoclar Vivadent) according to the manufacturer's recommendation. For class II cavities, a wooden wedge (Unimatrix System, TDV, Pomerode, SC, Brazil) and a separation ring, a metallic sectional matrix (Palodent, Dentsply DeTrey), were used during the restoration procedures in order to re-establish the anatomical shape and proximal contacts of the teeth. A single bulk increment of universal shade was applied. The composite was shaped, and light cured for 20 s. (Radii Plus, SDI, Australia) with an output intensity of 1500 mW/cm^2. To ensure appropriate occlusal morphology and contact, articulating paper (Bausch, Nashua, NH, USA) was utilized, while interproximal radiographs and dental floss were utilized to assess the quality of the cervical adaptation and interproximal contacts. The polishing process was carried out immediately utilizing Soflex discs (3M ESPE) in the suggested sequence (coarse, medium, fine, and superfine) with water as a coolant to acquire a smooth surface.

2.10. Blinding

This study is double-blind, where the examiners were uninvolved in the clinical procedure and the participants were unaware of the applied treatment. Double-blind studies are essential in reducing bias and increasing the credibility of research findings.

2.11. Clinical Evaluation

Throughout the follow-up period, restorations were appraised for anatomical form, marginal discoloration, marginal adaptation, surface roughness, color match, and secondary caries, utilizing slightly modified USPHS criteria based on van Dijken's 1986 study. Assessments were performed at baseline (after 1 week), as well as 1, 3, 6, 9, and 12 months after the procedure [14]. Assessment score of "Alpha" for the best clinical instance, "Bravo" for clinically acceptable, "Charlie" for clinically unacceptable and requiring repair, or "Delta" for restorations that are missing, mobile, or broken, and need to be immediately replaced.

Additionally, postoperative sensitivity was evaluated for each restoration by directing a compressed air stream towards the restoration for 3 seconds from a 2-3 cm distance and running a probe over the surface of the restored tooth. The occurrence of opacity, softness, or white patches in regions where the explorer becomes caught or is difficult to remove following insertion was considered an indication of secondary caries. Bitewing radiographs (Kodak, Rochester, NY, USA) were obtained at every follow-up appointment. The parameters that required clinical visibility were evaluated using a magnifying dental loupe with a magnification of4.3× and a working distance of 40 cm (EyeMag Pro F, Carl Ziess Meditec Ag, Germany) with a powerful illumination intensity from a light source attached to the loupe (EyeMag Light II, Carl Ziess Meditec Ag) was used to assess the restoration.

Two independent examiners were trained to use the USPHS criteria for assessment. Each examiner evaluated the restorations independently before comparing their scores. If there was a difference in opinion, a third assessment was conducted, and the score was determined by consensus.

Clinical intraoral pictures were obtained at each follow-up appointment, and a standardized case report was utilized to record the USPHS parameters for each patient during the evaluation procedures. Clinical failures were defined as severe marginal weaknesses, retention loss, discoloration requiring replacement or repair, and caries along the edges of the restorations.

2.12. Statistically analysis

In this study, data tabulation, coding, and analysis were accomplished utilizing the Statistical Package for Social Science (SPSS version 26.0, IBM, Armonk, NY, USA). The Friedman test was employed to compare intragroup differences between baseline and other periods, while the Wilcoxon signed-rank test was employed to compare the two groups in each period. All criteria were evaluated using a significance level of 5%. The distribution of data was

inspected to assess the normality of the numerical data, and normality tests, such as the Shapiro-Wilk and Kolmogorov-Smirnov tests, were used.

3. RESULTS

The restorative procedures were executed precisely as intended, without any additional alterations. Table 3 and 4 summarizes the outcomes of this study. All participants attended every follow-up visit at 1-, 3-, 6-, 9-, and 12 months, giving a 100.0% recall rate.

For retention scores, marginal discoloration, and recurrent caries at baseline and after one month, the restorations in both groups received (Alpha) scores. After three, six, nine, and 12 months, few restorations showed bravo scores with a lack of statistically significant differences among both groups.

For the color match criterion, the restorations in both groups received (Alpha) scores at baseline. After one, three, six, nine, and 12 months, slight differences were observed in three restorations in both materials. The observed shade discrepancies were clinically acceptable (Bravo), with no significant differences existing among the studied materials ($P \leq 0.05$). No statistically significant differences were detected among both groups. While in Bis-GMA-containing composite group; there was a statistically significant change in color match scores by time. There was an increase in prevalence of (Bravo) scores after one month and no change was observed from one to three, three to six, six to nine as well as nine to 12 months.

For marginal adaptation, all restorations in both groups received (Alpha) scores at baseline. No statistically significant differences were detected among both groups after one, three, six, nine, and 12 months. Marginal defects were observed in the enamel margin of the restorations, which were small V-shaped defects. These defects were recorded after one month for the bis-GMA-containing restoration and after three months for the two bis-GMA-free restorations.

For postoperative hypersensitivity and contact scores, the restorations in both groups had (Alpha) scores at baseline. The two groups revealed no statistically significant differences after one, three, six, nine, and 12 months.

Table 3: Descriptive statistics and results of Wilcoxon signed-rank test for comparison between retention, contact, color match, marginal discoloration, marginal adaptation, secondary caries, and postoperative hypersensitivity scores in the two groups.

Recall time (months)		**0**	**1**	**3**	**6**	**9**	**12**	**0**	**1**	**3**	**6**	**9**	**12**	**0**	**1**	**3**	**6**	**9**	**12**
Restorative system		**Alpha**						**Bravo**						**Charlie**					
Retention scores																			
BIS-GMA-free composite (n=20)	n	20	20	19	19	19	19	0	0	1	0	0	0	0	0	0	1	1	1
	%	100	100	95	95	95	95	0	0	5	0	0	0	0	0	0	5	5	5
BIS-GMA-containing composite (n=20)	n	20	20	19	19	19	19	0	0	1	1	1	1	0	0	0	0	0	0
	%	100	100	95	95	95	95	0	0	5	5	5	5	0	0	0	0	0	0
P-value		1	1	1	0.655	0.655	0.655	1	1	1	0.655	0.655	0.655	1	1	1	0.655	0.655	0.655
Color match scores																			
BIS-GMA-free composite (n=20)	n	19	18	18	17	17	17	1	2	2	3	3	3	0	0	0	0	0	0
	%	95	90	90	85	85	85	5	10	10	15	15	15	0	0	0	0	0	0
BIS-GMA-containing composite (n=20)	n	20	17	17	17	17	17	0	3	3	3	3	3	0	0	0	0	0	0
	%	100	85	85	85	85	85	0	15	15	15	15	15	0	0	0	0	0	0
P-value		0.317	1	0.564	1	1	1	0.317	1	0.564	1	1	1	0.317	1	0.564	1	1	1
Marginal discoloration scores																			
BIS-GMA-free composite (n=20)	n	20	20	20	20	19	19	0	0	0	0	1	1	0	0	0	0	0	0
	%	100	100	100	100	95	95	0	0	0	0	5	5	0	0	0	0	0	0
BIS-GMA-containing composite (n=20)	n	20	20	19	19	19	19	0	0	1	1	1	1	0	0	0	0	0	0
	%	100	100	95	95	95	95	0	0	5	5	5	5	0	0	0	0	0	0
P-value		1	1	0.317	0.317	1	1	1	1	0.317	0.317	1	1	1	1	0.317	0.317	1	1
Marginal adaptation scores																			
BIS-GMA-free composite (n=20)	n	20	20	18	18	18	18	0	0	2	2	2	2	0	0	0	0	0	0
	%	100	100	90	90	90	90	0	0	10	10	10	10	0	0	0	0	0	0
BIS-GMA-containing composite (n=20)	n	20	19	19	19	19	19	0	1	1	1	1	1	0	0	0	0	0	0
	%	100	95	95	95	95	95	0	5	5	5	5	5	0	0	0	0	0	0
P-value		1	0.317	0.564	0.564	0.564	0.564	1	0.317	0.564	0.564	0.564	0.564	1	0.317	0.564	0.564	0.564	0.564
Secondary caries scores																			
BIS-GMA-free composite (n=20)	n	20	20	19	19	19	19	0	0	0	0	0	0	0	0	1	1	1	1
	%	100	100	95	95	95	95	0	0	0	0	0	0	0	0	5	5	5	5
BIS-GMA-containing composite (n=20)	n	20	20	20	20	20	20	0	0	0	0	0	0	0	0	0	0	0	0
	%	100	100	100	100	100	100	0	0	0	0	0	0	0	0	0	0	0	0
P-value		1	1	0.317	0.317	0.317	0.317	1	1	0.317	0.317	0.317	0.317	1	1	0.317	0.317	0.317	0.317
Post-operative sensitivity scores																			
BIS-GMA-free composite (n=20)	n	20	20	18	19	19	19	0	0	1	1	1	1	0	0	1	0	0	0
	%	100	100	90	95	95	95	0	0	5	5	5	5	0	0	5	0	0	0
BIS-GMA-containing composite (n=20)	n	20	19	19	20	20	20	0	1	1	0	0	0	0	0	0	0	0	0
	%	100	95	95	100	100	100	0	5	5	0	0	0	0	0	0	0	0	0
P-value		1	0.317	0.414	0.317	0.317	0.317	1	0.317	0.414	0.317	0.317	0.317	1	0.317	0.414	0.317	0.317	0.317
Contact scores																			
BIS-GMA-free composite (n=20)	n	20	19	19	19	19	19	0	1	1	1	1	1	0	0	0	0	0	0
	%	100	95	95	95	95	95	0	5	5	5	5	5	0	0	0	0	0	0
BIS-GMA-containing composite (n=20)	n	20	19	18	19	19	19	0	1	1	1	1	1	0	0	1	0	0	0
	%	100	95	90	95	95	95	0	5	5	5	5	5	0	0	5	0	0	0
P-value		1	1	0.414	1	1	1	1	1	0.414	1	1	1	1	1	0.414	1	1	1

Table 4: Descriptive statistics and results of Friedman's test for comparison between retention, contact, color match, marginal discoloration, marginal adaptation, secondary caries, and postoperative hypersensitivity scores at different follow up periods within each group.

Recall time (months)		0	1	3	6	9	12	0	1	3	6	9	12	0	1	3	6	9	12	*P*-value
Restorative system		**Alpha**						**Bravo**						**Charlie**						
Retention scores																				
BIS-GMA-free composite (n=20)	n	20	20	19	19	19	19	0	0	0	0	0	0	0	0	1	1	1	1	0.416
	%	100	100	95	95	95	95	0	0	0	0	0	0	0	0	5	5	5	5	
BIS-GMA-containing composite (n=20)	n	20	20	19	19	19	19	0	0	0	1	1	1	0	0	1	0	0	0	
	%	100	100	95	95	95	95	0	0	0	5	5	5	0	0	5	0	0	0	
Color match scores																				
BIS-GMA-free composite (n=20)	n	19	18	18	17	17	17	1	2	2	3	3	3	0	0	0	0	0	0	0.283
	%	95	90	90	85	85	85	5	10	10	15	15	15	0	0	0	0	0	0	
BIS-GMA-containing composite (n=20)	n	20	17	17	3	3	3	0	3	3	3	3	3	0	0	0	0	0	0	0.032*
	%	100	85	85	15	15	15	0	15	15	15	15	15	0	0	0	0	0	0	
Marginal discoloration scores																				
BIS-GMA-free composite (n=20)	n	20	20	20	20	19	19	0	0	0	0	1	1	0	0	0	0	0	0	0.416
	%	100	100	100	100	95	95	0	0	0	0	5	5	0	0	0	0	0	0	
BIS-GMA-containing composite (n=20)	n	20	20	19	19	19	19	0	0	1	1	1	1	0	0	0	0	0	0	
	%	100	100	95	95	95	95	0	0	5	5	5	5	0	0	0	0	0	0	
Marginal adaptation scores																				
BIS-GMA-free composite (n=20)	n	20	20	18	18	18	18	0	0	2	2	2	2	0	0	0	0	0	0	0.075
	%	100	100	90	90	90	90	0	0	10	10	10	10	0	0	0	0	0	0	
BIS-GMA-containing composite (n=20)	n	20	19	19	19	19	19	0	1	1	1	1	1	0	0	0	0	0	0	0.416
	%	100	95	95	95	95	95	0	5	5	5	5	5	0	0	0	0	0	0	
Secondary caries scores																				
BIS-GMA-free composite (n=20)	n	20	20	19	19	19	19	0	0	0	0	0	0	0	0	1	1	1	1	0.416
	%	100	100	95	95	95	95	0	0	0	0	0	0	0	0	5	5	5	5	
BIS-GMA-containing composite (n=20)	n	20	20	20	20	20	20	0	0	0	0	0	0	0	0	0	0	0	0	---
	%	100	100	100	100	100	100	0	0	0	0	0	0	0	0	0	0	0	0	
Post-operative sensitivity scores																				
BIS-GMA-free composite (n=20)	n	20	20	18	19	19	19	0	0	1	1	1	1	0	0	1	0	0	0	0.257
	%	100	100	90	95	95	95	0	0	5	5	5	5	0	0	5	0	0	0	
BIS-GMA-containing composite (n=20)	n	20	19	19	20	20	20	0	1	1	0	0	0	0	0	0	0	0	0	0.416
	%	100	95	95	100	100	100	0	5	5	0	0	0	0	0	0	0	0	0	
Contact scores																				
BIS-GMA-free composite (n=20)	n	20	19	19	19	19	19	0	1	1	1	1	1	0	0	0	0	0	0	0.416
	%	100	95	95	95	95	95	0	5	5	5	5	5	0	0	0	0	0	0	
BIS-GMA-containing composite (n=20)	n	20	19	18	19	19	19	0	1	1	1	1	1	0	0	1	0	0	0	0.352
	%	100	95	90	95	95	95	0	5	5	5	5	5	0	0	5	0	0	0	

4. DISCUSSION

Restorative materials underwent constantly changing conditions of the oral cavity to evaluate the restorative materials accurately. The clinical assessment necessitates consistent, applicable, and objective criteria [16–18]. So, our study used the split-mouth design to evaluate their performance.

The quality of the composite restoration is appraised utilizing the USPHS (or Ryge) Criteria, a set of clinical parameters established by Gunnar Ryge [19]. These criteria were modified from the USPHS criteria [20]. Nevertheless, this assessment procedure was established to distinguish between acceptable (yes/no) outcomes rather than measuring the success degree.

Conventional monomers, such as Bis-GMA, TEGDMA, and UDMA, may negatively affect pulpal cells [21–24]. Studies have shown that Ormocer-based resin is much-decreased cytotoxicity compared to di-methacrylate composites. The presence of numerous polymerizable units within the Ormocer molecule reduces the amount of leachable and uncured monomers. This is due to the numerous crosslinkers formed by Ormocer molecules, which contribute to their improved biocompatibility [25, 26]. Using low-stress and low-shrinkage Ormocer composite may offer an effective marginal sealing. Research indicates that higher shrinkage stress can lead to wider and more numerous marginal gaps, which may result in poor marginal sealing. In vitro, studies have shown that Ormocer has reduced volumetric polymerization shrinkage, considerably reducing cuspal deflection in mesio-occlusal-distal cavities within upper premolar teeth [27, 28].

To achieve adequate light penetration and reduce shrinkage stress, incremental placement techniques have been traditionally used by general practitioners. This process involves placing 2 mm increments of composite material, which are then cured separately with light [29]. However, this process can consume additional time, increase the contamination risk, and result in voids within the restoration. Whereas inferior adaptation may lead to secondary caries, debonding, microleakage, and postoperative sensitivity, adhesive dental medicine aims to achieve a tight interfacial adaptation. To ensure optimal adaptation, bulk-fill resin composites were utilized in our study and were applied using the technique recommended by the manufacturers and laboratory studies [30, 31]. This involved placing a single increment of bulk-fill composite material with a regular thickness [32].

Due to their stress-relieving monomers and lowered polymerization shrinkage, bulk-fill resin composites are applicable in thick increments (up to 4 mm). Our study found no significant differences between both bulk-fill composite types for any of the parameters studied across various periods, and therefore, we accept the null hypothesis. Nevertheless, the increased success rate documented in this study may be attributed to the fact that the restorations were accomplished via an experienced clinician in ideal clinical conditions and the careful selection of teeth based on specific inclusion and exclusion criteria.

Most scores for both restorative materials utilized in the current study were within the Alpha to Bravo range, which is considered acceptable. Based on the acceptance criteria of the American Dental Association (ADA) [33], the restorations failure rate should be less than 5% at two years in order to be considered clinically acceptable. Based on this criterion, both ormocer and micro-hybrid restorations utilized in this study were considered acceptable. These findings contrasted with Oberländer et al. [34], who reported the failure of ormocer to meet the ADA acceptance standards for restorative materials.

Rosin et al. [35] found that ormocer restorations exhibited excellent marginal integrity after six months of clinical use. Similarly, Bottenberg et al. [36] indicated that the performance of ormocer-based composite materials resembled that of conventional bisphenol A diglycidyl ether dimethacrylate-based composites in occlusal stress-bearing cavities, which accords with our findings.

After a 12-month follow-up, no substantial differences occurred regarding the overall effect of marginal adaptation between conventional restorations and composites containing a modified monomer. Marginal adaptation may be influenced by various aspects linked to restorative procedures, composite characteristics, and operator skills. Some authors have suggested that the resin composite kind and viscosity can affect the gap between the restoration and the tooth [37, 38]. Marginal adaptation can also be influenced by the insertion technique along with the finishing and polishing procedures [39, 40].

Efes et al. [41] clinically evaluated Ormocer-based composite restorations, with and without lining with flowable composite. They reported that the two restorative materials demonstrated ideal clinical outcomes and did not result in postoperative sensitivity or secondary caries. In the current investigation, only a single instance of secondary caries was detected at the 6-month recall in the Bis-GMA-free (Ormocer-based) group. Evaluation at the 12-month follow-up revealed that irrespective of the restorative material used, most restorations exhibited no secondary caries. In the case where secondary caries were present, no considerable differences were detected between the Bis-GMA-free and Bis-GMA-based composites, and no significant differences existed among the two groups.

Similarly, Ernst et al. [42] reported no cases of secondary caries in their two-year study. However, it should be noted that a one-year evaluation is insufficient to detect the development of secondary caries, which typically occurs after 4-6 years of intra-oral aging, as revealed in previous longer-term follow-up studies [43].

In contrast to an earlier study that utilized cotton rolls and suction devices for operative field isolation, the present study and the study by Ernst et al. [42] employed rubber dam isolation after applying the matrix system. The latter two studies indicated no considerable differences in the annual failure rate among restorative materials, which approves the earlier study's findings of insignificant clinical differences [44].

The secondary caries development around dental restorations is a major cause of resin composite restoration failure, and the method for controlling or preventing caries in these areas is still under discussion [45]. Although the choice of restorative material may influence secondary caries development, individual factors may also be involved. Additionally, the type and location of the cavity can affect secondary caries development, making this condition multifactorial [29].

At the one-year evaluation, both restorative materials showed good color stability, with only three cases in each group receiving Bravo scores, which were not significantly different. However, it may be desirable to have a slight color mismatch in tooth-colored restorations in posterior teeth to avoid damage to the adjacent enamel during finishing.

Regarding marginal discoloration, most scores were Alpha, with only Bis-GMA-free and methacrylate-based restorative materials receiving Bravo scores at the one-year examination. The discoloration observed in all cases was found at the enamel margin and was considered clinically acceptable. The patient's food choices and smoking habits may have influenced this discoloration [46].

Various factors can contribute to marginal discoloration, including the adhesive system used, smoking, and consuming heavily pigmented beverages [47–49]. Poor marginal adaptation and excessive placement of restorative material can also promote marginal discoloration [50]. Although all restorations in the studies included underwent finishing and polishing procedures, patient habits concerning food and drink consumption and smoking was not reported, making assessment difficult. However, marginal discoloration did not have a significant relationship with caries, and it could often be resolved with re-polishing [51, 52].

The degree of polymerization shrinkage exhibited by resin composites has a direct relation to restoration retention, which is a critical aspect in the success of dental restorations [53]. The resin composite's shrinkage occurs

as it bonds to the dental cavity walls, resulting in the development of stresses that can cause loss of marginal adaptation and failure of restoration retention [48]. Furthermore, polymerization shrinkage stress can also cause postoperative sensitivity of resin composites [54, 55]. However, sensitivity is frequently associated with bacterial infiltration and other irritants across restoration edges that reach the pulp [55]. Most of the studies did not report instances of postoperative sensitivity during the 12-month follow-up assessments. Of the studies that did not report cases of postoperative sensitivity, Bottenberg et al. [36] showed the worst results. Bottenberg et al.'s study involved using glass ionomer cement to line deep cavities, and the polymerization time adhered to the manufacturer's recommendations of 40 to 60 seconds. Other studies that assessed postoperative sensitivity at 12 months also documented that each increment was light activated for 40 seconds, but no sensitivity instances were reported [48, 53–55].

In a study conducted by Ferracane and Hilton in 2016 [49], the impact of stress and polymerization shrinkage on the restorations' clinical performance was examined. The researcher observed the absence of clear indication signifying that polymerization shrinkage alone can reduce the durability of restorations, where its impacts are not always distinguishable from inadequate adhesion. Furthermore, reducing polymerization shrinkage by itself may not be linked to a reduction in stresses at the resin-tooth interface [56], and this approach does not appear to carry any significant clinical implications [41]. Therefore, it cannot be claimed that modified monomers composites, which offer lowered polymerization shrinkage, will have better clinical behavior than conventional composites. Although materials' mechanical and physical characteristics are essential, they are not the only factors determining the restorations' clinical performance. Factors such as the operator's experience, position, treatment circumstances, teeth morphological features, contact points, occlusal loading, parafunctional habits, occlusion, and salivary composition can all contribute to the final result [47].

While laboratory investigations have shown that modified monomer composites may decrease the consequences of polymerization shrinkage, practical considerations, including cost-effectiveness and the experience of clinicians, must be considered when implementing such materials in clinical practice. It cannot be concluded that modified monomer composites exhibit better clinical performance than conventional composites, as the long-term success of restorations is affected by various aspects, comprising the operator's experience, the location and circumstances of the procedure, and the morphological features of the teeth [57].

Using newer composites is often associated with higher costs than conventional methacrylate-based composites. Additionally, certain brands of newer composites require a higher dexterity level to achieve optimal sculpting. While the most recent and modified monomer composites, including bulk-fill composites, offer the benefit of faster placement and shorter time of light activation, their clinical advantages remain unclear. Clinicians should exercise caution when using bulk-fill composites, especially those applied to a single increment until further studies confirm their clinical benefits [58]. According to a recent meta-analysis, more long-term clinical investigations are necessitated to evaluate the effectiveness of newer composites [59].

While restorative composites with modified monomers have consistent clinical performance, they are generally more expensive than conventional methacrylate-based composites and do not necessarily exhibit better clinical endurance or efficacy. Certain brands may also require greater practical skills to achieve optimal sculpting, and the advantages of the latest modified monomer composites, particularly bulk-fill composites, seem to be limited to the faster placement and shorter light activation times.

In a study by Efes et al.2013 [56], the clinical efficacy of packable ormocer, nanofilled, and hybrid composites were compared in minimally invasive occlusal cavities. Both materials exhibited satisfactory clinical outcomes, even with the increased configuration factor of the cavity. An investigation compared the clinical effectiveness of micro-hybrid composites with Class I resin composites made of ormocer, nanofilled, and nanohybrid materials over two years. The results showed that all restorative materials exhibited acceptable clinical performance [18].

Various factors influence the oral environment, including temperature fluctuations, bacterial flora, pH

imbalances, and occlusal stresses. Due to the individual differences between patients, it is challenging to replicate oral physiology accurately. Therefore, the split-mouth design was used in this study. While in vitro studies can provide valuable insights into restorative materials' mechanical and physical characteristics, they cannot accurately predict their clinical handling characteristics or performance. Hence, the clinical oral environment represents the most appropriate way to evaluate restorative materials and techniques [59]. To assess the clinical performance of restorative materials accurately, consistent, applicable, and objective criteria must be established for the clinical evaluation process [18].

Randomized controlled clinical trials are considered the gold standard for assessing treatment outcomes. They provide a rigorous and systematic approach to comparing different treatment modalities and assessing their effectiveness. By randomly assigning participants to different treatment groups and controlling for confounding variables, randomized controlled trials can provide a more accurate estimate of the treatment effect than observational studies [60].

CONCLUSIONS

The findings of this randomized controlled clinical trial provide scientific evidence that supports the use of Bis-GMA free resin composite; Ormocer based on organically modified ceramic technology as a viable alternative to conventional methacrylate-based resin composites, as their clinical performance was similar. However, additional investigations are necessitated to fully estimate the long-term success of restorations using resin composites with modified monomers and to determine if any real advantages exist.

Authors' Contributions

S.R.: Conceptualization, methodology, investigation, resources, writing the original draft. HMT: Methodology, visualization, formal analysis, writing—review, and editing. RK: Methodology, visualization, formal analysis, writing—review, and editing. All authors reviewed the manuscript and gave final approval.

Regulatory Statement

The current study was accomplished in compliance with the guidelines and policies of the ethical committee of Minia University regarding human subjects. The study was granted approval with code number 419.

Disclosure of Conflicts of Interest

The authors declare that they have no financial interest in any of the companies or materials mentioned in this article.

Disclosure of Potential Conflicts of Interest

The authors affirm that they have no personal, financial, or proprietary interests that could have influenced the presentation of any product, service, or company discussed in this article.

REFERENCES

[1] Á. Ástvaldsdóttir *et al.*, "Longevity of posterior resin composite restorations in adults–A systematic review," J Dent, vol. 43, no. 8, pp. 934–954, 2015.

[2] N. J. M. Opdam *et al.*, "Longevity of posterior composite restorations: a systematic review and meta-analysis," J Dent Res, vol. 93, no. 10, pp. 943–949, 2014, doi: 10.1177/0022034514544217.

[3] J. Tiu, R. Belli, and U. Lohbauer, "Characterization of Heat-Polymerized Monomer Formulations for Dental Infiltrated Ceramic Networks," Appl Sci, vol. 11, no. 16, p. 7370, 2021, doi: 10.3390/app11167370.

[4] R. L. Bowen, "Use of Epoxy Resins in Restorative Materials," J Dent Res, vol. 35, no. 3, pp. 360–369, 1956, doi: 10.1177/00220345560350030501.

[5] L. Li, Q. Wang, Y. Zhang, Y. Niu, X. Yao, and H. Liu, "The molecular mechanism of bisphenol A (BPA) as an endocrine disruptor by

interacting with nuclear receptors: insights from molecular dynamics (MD) simulations," PLoS One, vol. 10, no. 3, pp. e0120330–e0120330, 2015, doi: 10.1371/journal.pone.0120330.

[6] A. Peutzfeldt, "Resin composites in dentistry: the monomer systems," Eur J Oral Sci, vol. 105, no. 2, pp. 97–116, 1997, doi: 10.1111/j.1600-0722.1997.tb00188.x.

[7] W. Geurtsen, F. Lehmann, W. Spahl, and G. Leyhausen, "Cytotoxicity of 35 dental resin composite monomers/additives in permanent 3T3 and three human primary fibroblast cultures," J Biomed Mater Res, vol. 41, no. 3, pp. 474–480, 1998, doi: 10.1002/(sici)1097-4636(19980905)41:3<474::aid-jbm18>3.0.co;2-i.

[8] J. L. Ferracane, "Resin composite—State of the art," Dent Mater, vol. 27, no. 1, pp. 29–38, 2011, doi: 10.1016/j.dental.2010.10.020.

[9] S. Kalra, A. Singh, M. Gupta, and V. Chadha, "Ormocer: An aesthetic direct restorative material; An in vitro study comparing the marginal sealing ability of organically modified ceramics and a hybrid composite using an ormocer-based bonding agent and a conventional fifth-generation bonding agent," Contemp Clin Dent, vol. 3, no. 1, pp. 48–53, 2012, doi: 10.4103/0976-237X.94546.

[10] A. Bacchi, V. P. Feitosa, A. S. Q. da Silva Fonseca, L. M. A. Cavalcante, N. Silikas, and L. F. J. Schneider, "Shrinkage, stress, and modulus of dimethacrylate, ormocer, and silorane composites," J Conserv Dent, vol. 18, no. 5, pp. 384–388, 2015, doi: 10.4103/0972-0707.164051.

[11] S. H. Mahmoud, A. E. El-Embaby, and A. M. AbdAllah, "Clinical Performance of Ormocer, Nanofilled, and Nanoceramic Resin Composites in Class I and Class II Restorations: A Three-year Evaluation," Oper Dent, vol. 39, no. 1, pp. 32–42, 2014, doi: 10.2341/12-313-c.

[12] C.-P. Ernst, M. Martin, S. Stuff, and B. Willershausen, "Clinical performance of a packable resin composite for posterior teeth after 3 years," Clin Oral Investig, vol. 5, no. 3, pp. 148–155, 2001, doi: 10.1007/s007840100117.

[13] K. F. Schulz, D. G. Altman, D. Moher, and C. Group, "CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials," BMJ, vol. 340, pp. c332–c332, 2010, doi: 10.1136/bmj.c332.

[14] J. W. V van Dijken and U. Pallesen, "A randomized controlled three year evaluation of 'bulk-filled' posterior resin restorations based on stress decreasing resin technology," Dent Mater, vol. 30, no. 9, pp. e245–e251, 2014, doi: 10.1016/j.dental.2014.05.028.

[15] J. W. V van Dijken and U. Pallesen, "Randomized 3-year Clinical Evaluation of Class I and II Resin restorations Placed with a Bulk-fill Resin Composite and a One-step Self-etching Adhesive," J Adhes Dent, vol. 17, no. 1, pp. 81–88, 2015.

[16] M. de A. Durão *et al.*, "Thirty-six-month clinical evaluation of posterior high-viscosity bulk-fill resin composite restorations in a high caries incidence population: interim results of a randomized clinical trial," Clin Oral Investig, vol. 25, no. 11, pp. 6219–6237, 2021, doi: 10.1007/s00784-021-03921-9.

[17] R. Hickel *et al.*, "FDI World Dental Federation: clinical criteria for the evaluation of direct and indirect restorations—update and clinical examples," Clin Oral Investig, vol. 14, no. 4, pp. 349–366, 2010, doi: 10.1007/s00784-010-0432-8.

[18] S. H. Mahmoud, A. E. El-Embaby, A. M. AbdAllah, and H. H. Hamama, "Two-year clinical evaluation of ormocer, nanohybrid and nanofill composite restorative systems in posterior teeth," J Adhes Dent, vol. 10, no. 4, pp. 315–322, 2008.

[19] G. Ryge and M. Snyder, "Evaluating the Clinical Quality of Restorations," J Am Dent Assoc, vol. 87, no. 2, pp. 369–377, 1973, doi: 10.14219/jada.archive.1973.0421.

[20] J. W. V Dijken, "A clinical evaluation of anterior conventional, microfiller and hybrid composite resin fillings," Acta Odontol Scand, vol. 44, pp. 357–367, 1985.

[21] M.-C. Chang *et al.*, "The role of reactive oxygen species and hemeoxygenase-1 expression in the cytotoxicity, cell cycle alteration and apoptosis of dental pulp cells induced by BisGMA," Biomaterials, vol. 31, no. 32, pp. 8164–8171, 2010, doi: 10.1016/j.biomaterials.2010.07.049.

[22] C. T. Hanks, S. E. Strawn, J. C. Watahai, and R. G. Craig, "Cytotoxic Effects of Resin Components on Cultured Mammalian Fibroblasts," J Dent Res, vol. 70, no. 11, pp. 1450–1455, 1991, doi: 10.1177/00220345910700111201.

[23] G. Batarseh, L. J. Windsor, N. Y. Labban, Y. Liu, and K. Gregson, "Triethylene Glycol Dimethacrylate Induction of Apoptotic Proteins in Pulp Fibroblasts," Oper Dent, vol. 39, no. 1, pp. E1–E8, 2014, doi: 10.2341/12-417-l.

[24] H.-H. Chang *et al.*, "The mechanisms of cytotoxicity of urethane dimethacrylate to Chinese hamster ovary cells," Biomaterials, vol. 31, no. 27, pp. 6917–6925, 2010, doi: 10.1016/j.biomaterials.2010.05.059.

[25] A. Schubert, C. Ziegler, A. Bernhard, R. Bürgers, and N. Miosge, "Cytotoxic effects to mouse and human gingival fibroblasts of a nanohybrid ormocer versus dimethacrylate-based composites," Clin Oral Investig, vol. 23, no. 1, pp. 133–139, 2018, doi: 10.1007/s00784-018-2419-9.

[26] C. R. G. Torres, M. G. Augusto, I. F. Mathias-Santamaria, R. Di Nicoló, and A. B. Borges, "Pure Ormocer vs Methacrylate Composites on Posterior Teeth: A Double-blinded Randomized Clinical Trial," Oper Dent, vol. 45, no. 4, pp. 359–367, 2019, doi: 10.2341/19-079-c.

[27] G. J. P. Fleming, D. P. Hall, A. C. C. Shortall, and F. J. T. Burke, "Cuspal movement and microleakage in premolar teeth restored with posterior filling materials of varying reported volumetric shrinkage values," J Dent, vol. 33, no. 2, pp. 139–146, 2005, doi: 10.1016/j.jdent.2004.09.007.

[28] E. Yarmohamadi, P. R. Jahromi, and M. Akbarzadeh, "Comparison of Cuspal Deflection and Microleakage of Premolar Teeth restored with Three Restorative Materials," J Contemp Dent Pract, vol. 19, no. 6, pp. 684–689, 2018, doi: 10.5005/jp-journals-10024-2320.

[29] A. J. Feilzer, A. J. De Gee, and C. L. Davidson, "Setting Stress in Composite Resin in Relation to Configuration of the Restoration," J Dent Res, vol. 66, no. 11, pp. 1636–1639, 1987, doi: 10.1177/00220345870660110601.

[30] R. Hirata, W. Kabbach, O. S. de Andrade, E. A. Bonfante, M. Giannini, and P. G. Coelho, "Bulk Fill Composites: An Anatomic Sculpting Technique," J Esthet Restor Dent, vol. 27, no. 6, pp. 335–343, 2015, doi: 10.1111/jerd.12159.

[31] N. Ilie and R. Hickel, "Investigations on a methacrylate-based flowable composite based on the SDR™ technology," Dent Mater, vol. 27, no.

4, pp. 348–355, 2011, doi: 10.1016/j.dental.2010.11.014.

[32] Y. Bayraktar, E. Ercan, M. M. Hamidi, and H. Çolak, “One-year clinical evaluation of different types of bulk-fill composites,” J Investig Clin Dent, vol. 8, no. 2, 2016, doi: 10.1111/jicd.12210.

[33] ADA Council on Scientific Affairs, “American Dental Association Acceptance Program Guidelines—Restorative Materials,” Chicago: American Dental Association, 1996, pp. 1–10.

[34] H. Oberländer, K.-A. Hiller, B. Thonemann, and G. Schmalz, “Clinical evaluation of packable composite resins in Class-II restorations,” Clin Oral Investig, vol. 5, no. 2, pp. 102–107, 2001, doi: 10.1007/s007840100111.

[35] M. Rosin *et al.*, “One-year evaluation of an Ormocer restorative—a multipractice clinical trial,” Clin Oral Investig, vol. 7, no. 1, pp. 20–26, 2003, doi: 10.1007/s00784-002-0189-9.

[36] P. Bottenberg, M. Alaerts, and F. Keulemans, “A prospective randomised clinical trial of one bis-GMA-based and two ormocer-based composite restorative systems in class II cavities: Three-year results,” J Dent, vol. 35, no. 2, pp. 163–171, 2007, doi: 10.1016/j.jdent.2006.07.002.

[37] S. D. Heintze, D. Monreal, and A. Peschke, “Marginal quality of class II composite restorations placed in bulk compared to an incremental technique: Evaluation with sem and stereomicroscope,” J Adhes Dent, vol. 17, no. 2, pp. 147–154, 2015, doi: 10.3290/j.jad.a33973.

[38] A. Peutzfeldt and E. Asmussen, “Determinants of in vitro gap formation of resin composites,” J Dent, vol. 32, no. 2, pp. 109–115, 2004, doi: 10.1016/j.jdent.2003.08.008.

[39] L. St-Pierre *et al.*, “Effect of Polishing Direction on the Marginal Adaptation of Composite Resin Restorations,” J Esthet Restor Dent, vol. 25, no. 2, pp. 125–138, 2013, doi: 10.1111/jerd.12020.

[40] E. A. Campos, S. Ardu, D. Lefever, F. F. Jassé, T. Bortolotto, and I. Krejci, “Marginal adaptation of class II cavities restored with bulk-fill composites,” J Dent, vol. 42, no. 5, pp. 575–581, 2014, doi: 10.1016/j.jdent.2014.02.007.

[41] B. G. Efes, C. Dörter, Y. Gömec, and F. Koray, “Two-year clinical evaluation of ormocer and nanofill composite with and without a flowable liner.,” J Adhes Dent, vol. 8, no. 2, 2006.

[42] C.-P. Ernst, M. Brandenbusch, G. Meyer, K. Canbek, F. Gottschalk, and B. Willershausen, “Two-year clinical performance of a nanofiller vs a fine-particle hybrid resin composite,” Clin Oral Investig, vol. 10, no. 2, pp. 119–125, 2006, doi: 10.1007/s00784-006-0041-8.

[43] J. W. V van Dijken and K. Sunnegårdh-Grönberg, “Fiber-reinforced packable resin composites in Class II cavities,” J Dent, vol. 34, no. 10, pp. 763–769, 2006, doi: 10.1016/j.jdent.2006.02.003.

[44] J. W. V Van Dijken and P. Hörstedt, “Effect of the use of rubber dam versus cotton rolls on marginal adaptation of composite resin fillings to acid-etched enamel,” Acta Odontol Scand, vol. 45, no. 5, pp. 303–308, 1987, doi: 10.3109/00016358709096351.

[45] M. Rosin, A. D. Urban, C. Gärtner, O. Bernhardt, C. Splieth, and G. Meyer, “Polymerization shrinkage-strain and microleakage in dentin-bordered cavities of chemically and light-cured restorative materials,” Dent Mater, vol. 18, no. 7, pp. 521–528, 2002, doi: 10.1016/s0109-5641(01)00078-1.

[46] F. S. Goncalves, C. D. Leal, A. C. Bueno, A. B. Freitas, A. N. Moreira, and C. S. Magalhaes, “A double-blind randomized clinical trial of a silorane-based resin composite in class 2 restorations: 18-month follow-up,” Am J Dent, vol. 26, no. 2, pp. 93–98, 2013.

[47] B. Baracco, J. Perdigão, E. Cabrera, I. Giráldez, and L. Ceballos, “Clinical Evaluation of a Low-shrinkage Composite in Posterior Restorations: One-Year Results,” Oper Dent, vol. 37, no. 2, pp. 117–129, 2012, doi: 10.2341/11-179-c.

[48] N. Akimoto, M. Takamizu, and Y. Momoi, “10-year Clinical Evaluation of a Self-etching Adhesive System,” Oper Dent, vol. 32, no. 1, pp. 3–10, 2007, doi: 10.2341/06-46.

[49] J. L. Ferracane and T. J. Hilton, “Polymerization stress – Is it clinically meaningful?,” Dent Mater, vol. 32, no. 1, pp. 1–10, 2016, doi: 10.1016/j.dental.2015.06.020.

[50] R. Walter *et al.*, “Three-Year Clinical Evaluation of a Silorane Composite Resin,” J Esthet Restor Dent, vol. 26, no. 3, pp. 179–190, 2013, doi: 10.1111/jerd.12077.

[51] D. Kaisarly and M. El Gezawi, “Polymerization shrinkage assessment of dental resin composites: a literature review,” Odontology, vol. 104, no. 3, pp. 257–270, 2016, doi: 10.1007/s10266-016-0264-3.

[52] D. S. M. Casselli and L. R. M. Martins, “Postoperative sensitivity in Class I composite resin restorations in vivo.,” J Adhes Dent, vol. 8, no. 1, 2006.

[53] E. JD, “Polymerization shrinkage of posterior composite resins and its possible influence on postoperative sensitivity,” Quintessence int, vol. 17, pp. 103–111, 1986.

[54] C. Gasparello, C. Nassar, P. Busato, M. Mendonça, L. Bertacchini, and V. Camilotti, “Clinical Evaluation of Class I Restorations Made with Composite with Low Degree of Polymerization Shrinkage,” Br J Med Med Res, vol. 16, no. 9, pp. 1–7, 2016, doi: 10.9734/bjmmr/2016/26225.

[55] A. R. Yazici, I. Ustunkol, G. Ozgunaltay, and B. Dayangac, “Three-year Clinical Evaluation of Different Restorative Resins in Class I Restorations,” Oper Dent, vol. 39, no. 3, pp. 248–255, 2014, doi: 10.2341/13-221-c.

[56] B. G. Efes, C. A. N. Batu Yaman, Ö. Gurbuz, and B. Gumuştas, “Randomized controlled trial of the 2-year clinical performance of a silorane-based resin composite in class 1 posterior restorations,” Am J Dent, vol. 26, no. 1, pp. 33–38, 2013.

[57] B. Windsor, I. Popovich, V. Jordan, M. Showell, B. Shea, and C. Farquhar, “Methodological quality of systematic reviews in subfertility: a comparison of Cochrane and non-Cochrane systematic reviews in assisted reproductive technologies,” Hum Reprod, vol. 27, no. 12, pp. 3460–3466, 2012, doi: 10.1093/humrep/des342.

[58] K. F. Schulz, D. G. Altman, D. Moher, and C. Group, "CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials," PLoS Med, vol. 7, no. 3, pp. e1000251–e1000251, 2010, doi: 10.1371/journal.pmed.1000251.

[59] R. Hickel *et al.*, "Recommendations for conducting controlled clinical studies of dental restorative materials," Clin Oral Investig, vol. 11, no. 1, pp. 5–33, 2007, doi: 10.1007/s00784-006-0095-7.

[60] S. C. Bayne and G. Schmalz, "Reprinting the classic article on USPHS evaluation methods for measuring the clinical research performance of restorative materials," Clin Oral Investig, vol. 9, no. 4, pp. 209–214, 2005, doi: 10.1007/s00784-005-0017-0.

DOI: https://doi.org/10.15379/ijmst.v10i5.2561