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Original Article

# Evaluation of the Performance of Class IV Restoration Using Organically Modified Ceramic (ORMOCER) in Comparison to a Methacrylate Based Composite Resin Over a Period of 12 Months Follow up: A Randomized Controlled Clinical Trial

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## Abstract

**Aim:** This study aimed to evaluate the clinical performance of ORMOCER in anterior Class IV restorations compared to Methacrylate Based Composite Resin over a one-year follow-up period.

**Subjects and methods:** 26 participants having Class IV cavities were recruited. Participants were randomly assigned equally into two groups, group 1: ORMOCER (Admira Fusion, Voco GmbH, Germany), group2: Methacrylate Based (Ceram.X Spectra ST, Dentsply Sirona, UK). The restorations were assessed immediately (T0), one week (T1), 3 months (T2), and 12 months (T3) using Modified USPHS criteria and Vita Easyshade V spectrophotometer. Criteria assessed were shade match, retention, fracture of restoration, marginal discoloration, wear/anatomic form, recurrent caries, marginal adaptation and surface texture.

**Results:** Showed that there were no significant differences between the two groups regarding shade match using (CIELAB values) within all follow up periods. Intragroup comparison within both groups have shown no statistically significant differences between different follow-up periods. Regarding clinical evaluation of shade match using modified USPHS criteria, no statistically significant differences were found between different follow up periods in intergroup comparison. Intragroup comparison within both groups has shown statistically significant differences between different follow-up periods. Regarding all other clinical criteria, intergroup and intragroup comparisons have shown no statistically significant difference within different follow-up periods..

**Conclusion:** Ormocer showed comparable performance to Methacrylate in aesthetics, functionality, and biological properties. It had slightly better clinical outcomes in surface texture and fracture resistance. Although both materials experienced changes in shade over time, these changes stayed within clinically acceptable limits. There was a significant discrepancy between subjective and objective evaluations of shade matching.

**Keywords:** Admira fusion, CeramX.spectra, anterior restorations, Shade match.

## Introduction

In a society that values aesthetics, a person's smile plays a crucial role in self-esteem, prompting many to seek dental enhancements for both anterior and posterior teeth ***(Porwal et al., 2024)***. Resin composites are favored for their ability to closely mimic natural teeth in color and strength, but challenges remain.

Involvement of the incisal angle in anterior teeth resulted in accompanied reduction in average survival time. In contrast to class I, II, III and V cavity configurations, class IV restorations are stressed at the incisal angle, posing a challenge to the tooth restoration interface, due to their lack of mechanical retention. ***(Korkut & Özcan, 2022)***

In addition, color is one of the most important factors of esthetic restorations, since color change may be due to intrinsic factors as; changes in the filler, matrix and silane coating as well as extrinsic staining; as absorption of stains, chemical reactivity, diet and oral hygiene. ***(Demirci et al., 2018).***

Recent advancements in resin composites aim to improve their mechanical and physical properties through enhanced monomer chemistry **(*Gresnigt et al., 2012)***, though concerns like polymerization shrinkage, microleakage, and discoloration persist. **(*Zhou et al., 2019).***

To overcome these limitations, a new material combining Organically Modified Ceramics and pure silicate technology was developed, improving mechanical properties ***(Çağırır Dindaroğlu & Yılmaz, 2024)***. In 2015, the introduction of Admira Fusion marked the launch of a ceramic-based restorative material free from traditional dimethacrylates, offering improved aesthetics and reduced polymerization shrinkage (~1.25%) ***(Rajeev et al., 2017).***

Ormocer materials undergo polymerization through a matrix of long inorganic silica chains with organic lateral chains, enhancing biocompatibility, reducing monomer leaching, and improving overall performance with nanohybrid fillers ***(Wolter, 2015).*** Unlike conventional resin composites, ormocers form a three-dimensional polymeric network with a large polymer backbone functionalized with polymerizable organic units ***(Kadiyala & Raj, 2016).*** The resin matrix, with its large molecules and numerous double bond linkages, creates a strong polymer network that prevents the leaching of uncured monomers, further enhancing biocompatibility ***(Kalra et al., 2012).***

The use of nanohybrid filler technology, combined with silicone oxide structures, allows for the formation of a silicate framework, enabling a high filler content of 84% by weight ***(Wolter, 2015).***

The current study aims to evaluate and compare the clinical performance of ormocer-based restorative materials versus methacrylate-based composites for Class IV restorations over a 12-month follow-up, using modified United States Public Health Service criteria for assessment. The null hypothesis stated that there would be no difference between both materials regarding their clinical performance.

## Subjects and Methods

Ethical approval was conducted by the Research Ethics Committee (REC), Faculty of Dentistry, Cairo University on 26/07/2022 with identification number: 19722. The study protocol is registered on clinical trials (www.clinicaltrials.gov) with I.D.: NCT05623423.

The materials & Lot number, specifications, chemical composition and manufacturer are shown in **(Table 1)**

- **Sample size calculation:**

Based on a previous study by ***Demirci et al., 2018***. A power analysis was designed to have adequate power to apply statistical test of the research hypothesis to evaluate ormocer composite restorations compared to

polychromatic composite restorations regarding shade matching for restoration of fractured incisal angle after 12 months. According to the results of Demirci et al., in 2018 in which the probability of score alpha for color match of polychromatic composite restorations was (0.923), probability of bravo score was (0.077) with effect size w=0.846 (n=11). If the estimated probability of score alpha for color match of ormocer composite restorations was (0.95), probability of bravo score was (0.05) with effect size w=0.9 (n=10). By adopting an alpha (α) level of 0.05 (5%), power=80%. The predicted sample size was a total of (21). Sample size was increased by (20%) to account for possible dropouts during follow-up intervals to be total of (26) cases i.e. (13) for each group. Sample size calculation was performed using G*Power 3.1.9.2 using chi square test.

- **Study design and participants**

This 12-month randomized controlled trial was conducted at Cairo University's Faculty of Dentistry, with a parallel groups design and a 1:1 allocation ratio. 26 participants were randomly assigned to either the ORMOCER or methacrylate-based composite group (n=13 per group). The randomization list was securely stored for confidentiality. Patients selected sealed envelopes to reveal their group assignments, documented in their charts. The study was double-blinded for participants and assessors, though the operator knew the group assignments due to different application protocols. Restorations were evaluated at immediate application (T0), 1 week (T1), 3 months (T2), and 12 months (T3) using modified USPHS criteria and the Vita Easyshade V Spectrophotometer.

- **Eligibility criteria:**

Participants, aged 18 to 40, were required to have good oral hygiene, no active dental issues, normal occlusion, and able to attend follow-ups. Exclusions included individuals with a high caries index, uncontrolled parafunctional habits, orthodontic appliances, or pregnancy.

- **Recruitment**

Patients from the Conservative Dentistry Department at Cairo University were screened to identify those meeting the inclusion criteria for the study. Eligible patients were contacted, informed about the study details, and those willing to participate underwent further preparation and scheduling. All participants signed an informed consent form, written in Arabic, confirming their understanding and agreement to take part in the study. A CONSORT flow diagram outlined their progression through the randomized clinical trial. **(Figure 1)**

- **Clinical Procedures:**

A diagnostic assessment chart for each patient was recorded.

**A. Field Preparation:**

Prophylactic polishing was done to clean the tooth surfaces and remove any residual dental plaque. To avoid dehydration effects, tooth shade was measured before rubber dam isolation using the VITA Easyshade V spectrophotometer (VITA Zahnfabrik, Bad Säckingen, Germany). The device was calibrated, and the Base shade determination mode was selected. Three measurements were taken, and the average was recorded using the CIE LAB color system. Shade data was wirelessly transferred and securely stored with a copy added to the patient's outcome assessment chart. Combinations of composite resin buttons to identify the ideal shade for each tooth was done under optimal moisture and lighting conditions ***(Nahsan et al., 2012).***

An impression of the upper anterior teeth was taken to create a silicone palatal index for forming a palatal shell using the Bertholdo/Ricci/Barrote (BRB) Matrix technique. The process involved constructing the palatal wall in the patient's mouth with condensation silicone (Zetaplus. Zhermack, Badia Polesine, Rovigo, Italy), outlining the lost tooth structure's margins with a pen, and trimming the silicone with a carbide bur to ensure the correct palatal shape without

exceeding the cavo-surface margin ***(Durán, 2020; Freitas et al., 2021).*** Lastly, multiple isolation using rubber dam (Nic Tone, Expertech Solutions, Bucharest, Romania) was performed.

**B. Cavity Preparation Steps:**

Cavity margins were extended to the proximal area, incisal edge, and facial surface based on the missing tooth structure, with sharp angles rounded ***(Romero et al., 2016).*** Labial enamel margins were beveled at a 45° angle with a width of 0.5-2.0 mm using a tapered red-coded fine diamond stone (MANI, INC., Japan) to ensure a smooth shade transition from composite to tooth. A tapered yellow-coded fine diamond stone (MANI, INC., Japan) was then used to finish the outer margin with an infinite bevel.

**C. Restorative procedure Steps:**

Before acid etching, Teflon was placed over adjacent unprepared teeth. The prepared tooth surfaces were selectively etched with 37% phosphoric acid gel (Meta Etchant, Meta Biomed, Korea) for 15 seconds, rinsed, and slightly dried. A single coat of light-cured universal adhesive (Futurabond M+, Voco GmbH, Germany) was then applied to the cavity, agitated for 20 seconds, air-thinned for 5 seconds, and cured for 10 seconds using an LED light-curing unit (Woodpecker iLED II, Guilin Woodpecker Medical Instrument Co., Ltd.) with an intensity of 1200 mW/cm², as per the manufacturer's instructions.

For both intervention and comparator materials, a thin layer of the selected enamel shade was applied against the silicone palatal index to create a palatal shell and cured for 20 seconds. The Unica anterior matrix system (Unica Anterior, Polydentia, Switzerland) was used to restore interproximal walls and contacts with the enamel shade. Layers of the selected dentin/body shade were applied to shape the tooth, with each layer cured for 20 seconds. Internal dental anatomy, including mamelons, was shaped, leaving a 0.5 mm space for labial enamel, which was created using a Misura hand instrument (Misura, LM Arte, Finland). Finally, an additional layer of the previously chosen enamel shade was applied and modelled using the Tokuyama No.24 composite modelling brush (Tokuyama Dental Corporation, Taitō-Ku, Tokyo, Japan)

To enhance the restorations' surface topography and replicate adjacent teeth, a pencil was used for aesthetic accuracy. Primary anatomy was shaped with yellow-coded diamond stones and aluminum oxide discs (Sof-Lex, 3M; St. Paul, MN), progressing from coarse to fine. Line angles were refined and verified with a mirror. Secondary anatomy was detailed with a low-speed perio bur (Komet, Brasseler, Germany). Surfaces were blended with KENDA dental polishers (Coltene, Altstätten, Switzerland), followed by polishing with EVE Diacomp twist wheels (EVE Emst Vetter GmbH, Germany). A Jiffy Brush with Ultradent™ Diamond Polish paste (Ultradent Products, Inc., South Jordan, UT, USA) and a felt wheel provided the final aesthetic finish. Occlusion was checked and adjusted.

- **Outcome assessment:**

Patients were evaluated immediately after restoration, baseline (1 week), 3 months and one year. Clinical performance was assessed using a sharp dental probe and diagnostic mirror in daylight ***(Gençer et al., 2023),*** following established protocols **(Table 2, Figure 2).** Assessors filled out assessment charts for each restoration and reached consensus in cases of differing scores. Shade matching was evaluated using the VITA Easyshade V spectrophotometer.

- **Primary Outcome:**

**Table (1):** Modified USPHS criteria, scores, description and measuring method for shade match assessment of dental restorations.

- **Secondary Outcome:**

a) Restorations were evaluated using Modified USPHS criteria: retention, fracture of restoration, marginal discoloration and wear/anatomic form, recurrent caries, marginal

adaptation and surface texture ***Demirci et al., (2018) and Karaman et al., (2017)*** (**Table 2).**

b) Shade match measured by Vita Easyshade Spectrophotometer using CIELAB values to calculate total color difference by the formula:

**$\Delta E^*ab = [(\Delta L2) + (\Delta a2) + (\Delta b2)]1/2$**
**(Blum et al., 2018)**

- **$\Delta E < 1$:** no changes observed by the clinician.
- **$\Delta E > 3.3$:** changes easily observed clinically.

- **Statistical Analysis**

Data analysis was performed using Medcalc software (version 19). Categorical data were analyzed with the Chi-Squared test ($P \leq 0.05$), and intragroup comparisons used Cochran's Q and Friedman's tests ($P \leq 0.0083$). Continuous data were analyzed with the independent t-test ($P \leq 0.05$) and repeated measures ANOVA ($P \leq 0.0083$). Clinical significance was assessed with relative risk, and survival rates were analyzed using the Kaplan-Meier method and Log-rank test, all with 95% confidence and 80% power

## Results

### 1. Demographic data:

There were no significant differences between the groups in terms of gender ($P = 0.6256$), age (mean age 27±6.2 years, $P = 0.542$), or tooth distribution (all restorations were on maxillary central incisors, $P = 1.0000$).

### 2. Shade matching (CIELAB):

Intergroup comparisons between the groups showed no statistically significant differences at different follow-up periods (immediate, 1 week, 3 months, and 12 months) (P-values > 0.05). Intragroup comparisons within each group also revealed no significant differences between follow-up periods ($P > 0.0083$), as shown in **Table 3**

### 3. Clinical evaluation:

#### A. Esthetic properties:

Intergroup comparisons showed no statistically significant differences between the groups for shade matching, surface texture, or marginal discoloration at any follow-up period (P-values for all >0.05). Intragroup comparisons, however, revealed significant differences in shade matching over time ($P<0.001$), while no significant changes were observed for surface texture or marginal discoloration within each group ($P>0.0083$ and $P=0.392$, respectively). After 12 months, the risk of shade matching issues was similar for both ormocer and methacrylate composites in Class IV restorations (RR=1.0000, 95% CI: 1 to 1; P=1.0000). In terms of surface texture, ormocer showed a 33% lower risk for issues (scores B and C) compared to methacrylate composites, although this difference was not statistically significant (RR=0.6666, 95% CI: 0.1325 to 3.3541; P=0.6228). For marginal discoloration, both materials showed similar risk levels after 12 months (RR=1.0000, 95% CI: 0.06973 to 14.3409; P=1.0000) **(Table 4).**

#### B. Biological properties:

Both marginal adaptation and recurrent **caries** demonstrated no statistically significant differences between groups at any follow-up period (P=1.0000). Intragroup comparisons also revealed no significant differences (P=1.0000). After 12 months, there was no increased risk for marginal adaptation (scores B and C) or recurrent caries (score C) for ormocer compared to methacrylate (RR=1.0000, 95% CI: 0.02129 to 46.9632, P=1.0000) **(Table 5).** These findings suggest similar performance in terms of marginal adaptation and recurrent caries between the two materials over time.

#### C. Functional properties:

No statistically significant differences were found between groups for retention, fracture of the restoration, or wear/anatomic form at any follow-up period ($P = 1.0000$ for retention and wear, $P > 0.05$ for fracture). Intragroup

comparisons also showed no significant differences (P = 1.0000 for retention and wear, P > 0.0083 for fracture). After 12 months, ormocer demonstrated no risk for retention or wear (scores B and C) compared to methacrylate composites (RR = 1.0000, 95% CI: 0.02129 to 46.9632, P = 1.0000). While ormocer exhibited a 66% lower risk for restoration fracture (scores B and C), the difference was not statistically significant (RR = 0.3333, 95% CI: 0.03967 to 2.8011, P = 0.3117). (**Table 6)**

**D. Survival analysis:**

Overall survival of ormocer and methacrylate composites for class IV restorations was assessed after 12 months, one restoration failed in each group (scoring C in shade matching). Kaplan-meier analysis was used to obtain survival curves, comparison of survival curves was performed using Logrank test, there was no statistically significant difference between groups (P = 1.0000). Both materials had a 92.3% success rate for class IV restorations. There were no significant changes in overall success between follow-up periods (P < 0.0083). **(Figure 3).**

**Table (1):** The materials & Lot number, specifications, chemical composition and manufacturer.

| Material Name & Lot Number | Specification | Chemical Composition | Manufacturer |
|---|---|---|---|
| **Admira Fusion® #2209596** | Universal nano-hybrid ORMOCER based composite | **Matrix:** Resin Ormocer **Filler:** (84% by weight) Ba-Al-glass (glass cermaics), $SiO_2$[1] (1 µm) **Photoinitiator:** CQ[2] | VOCO GmbH, Cuxhaven, Germany https://www.voco.dental/ |
| **Ceram.x Spectra™ ST #2203001065** | Resin-based composite (Nanohybrid ceramic spherical fillers) | **Matrix:** Methacrylic modifed polysiloxane nanoparticles, dimethacrylate resin **Filler:** (78–80% by weight) Spherical, pre-polymerized SphereTEC fillers (particle size < 0.1µm) Barium- aluminium-borosilica glass (1.1-1.5µm), ytterbium fluoride **Photo-initiator:** CQ[2], | Dentsply Sirona, Konstanz, Germany https://www.dentsplysirona.com/ |
| **Ceram.x Spectra™ ST Effects #0843 #0313** | | | |
| **Meta Etchant MET2112101** | 37% Phosphoric acid etch | Phosphoric acid, $H_2O$, xanthan gum | Meta Biomed, Chungcheongbuk-do, Republic of Korea https://www.meta-biomed.com/ |
| **Futurabond M+ #2147450** | universal adhesive | BIS-GMA[3], Acidic monomer (10-MDP[4]), UDMA[5],HEMA[6], Ethanol,catalyst,BHT[7], Pyrogenic silicic acid. | VOCO GmbH, Cuxhaven, Germany https://www.voco.dental/ |

**[1]: $SiO_2$: Silicone dioxide**
**[2]: CQ: Camphorquinone**
**[3]: BIS-GMA: Bisphenol A Diglycidyl Ether Dimethacrylate**
**[4]: 10-MDP: 10-Methacryloyloxydecyl Dihydrogen Phosphate**
**[5]: UDMA: Urethane Dimethacrylate**
**[6]: HEMA: 2-Hydroxyethyle Methacrylate**
**[7]: BHT: Butylated Hydroxytoluene**

CONSORT
TRANSPARENT REPORTING of TRIALS

**CONSORT 2010 Flow Diagram**

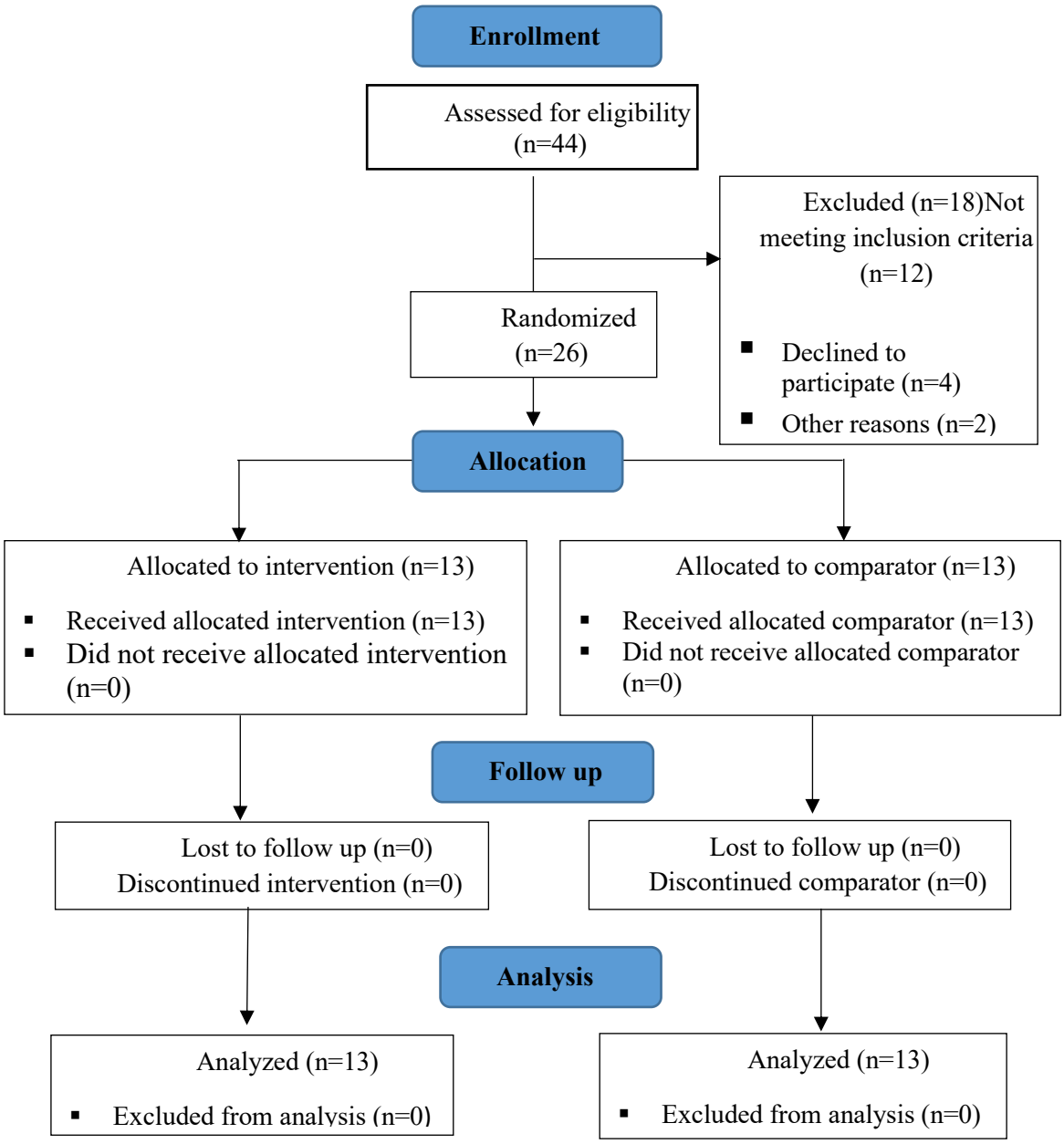


**Figure (1):** CONSORT flow diagram.

**Table (2):** Modified USPHS criteria, scores and description and measuring method for assessment of dental restorations

| | | Scores and Description | Measuring method |
|---|---|---|---|
| **Esthetic properties** | **Shade matching (Primary outcome)** | **(A)*:** No mismatch in color, shade or translucency between the restoration and the adjacent tooth structure | **Visual inspection by diagnostic mirror and probe** |
| | | **(B)*:** Mismatch in color, shade, or translucency between the restoration and adjacent tooth structure, but within a normal range. | |
| | | **(C)*:** Mismatch in color, shade, or translucency between the restoration and adjacent tooth structure, outside the normal range. | |
| | **Surface texture** | **(A):** Restoration is smooth. | |
| | | **(B):** Restoration is slightly rough, can be refinished. | |
| | | **(C):** Surface deeply pitted, irregular grooves (not related to anatomy), cannot be refinished. | |
| | | **(D)***: Surface is fractured or flaking. | |
| | **Marginal discoloration** | **(A):** No marginal discoloration, with the restoration color matching the adjacent tooth structure. | |
| | | **(B):** Marginal discoloration at the restoration-tooth interface, without penetration towards the pulp. | |
| | | **(C):** Marginal discoloration between the restoration and tooth structure, extending towards the pulp. | |
| **Biological properties** | **Recurrent caries** | **(A):** No evidence of caries at margin of the restoration. | |
| | | **(C):** Evidence of caries at margin of the restoration. | |
| | **Marginal adaptation** | **(A):** No visible crack along the margin that the explorer can enter. | |
| | | **(B):** Visible crack along the margin into which the explorer will enter. Enamel is not exposed | |
| | | **(C):** Visible evidence of a crack along the margin into which the explorer will enter. The enamel is exposed | |
| | | **(D):** The restoration is fractured or missing in part. | |
| **Functional properties** | **Retention** | **(A):** Restoration present | |
| | | **(C):** Restoration absent | |
| | **Fracture of restoration** | **(A):** No fracture | |
| | | **(B):** Minor crack lines or tiny chipping (<1/4 of restoration) | |
| | | **(C):** Partial fracture of restoration (<1/4 of restoration) | |
| | | **(D):** Debonding of restoration | |
| | **Wear/Anatomic form** | **(A):** Continuity of restoration with apparent anatomic form | |
| | | **(B):** Restoration discontinuity with anatomic form, but no dentin or body exposure. | |
| | | **(C):** Loss of sufficient material to show dentin or body. | |

**(A) Alpha:** Ideal clinical conditions
**(B) Bravo:** Acceptable clinically
**(C) Charlie:** Unacceptable; restoration necessitates replacement
**(D) Delta:** Fractured/cracked, missing, or mobile restoration that requires immediate replacement.


**Figure (2):** Preoperative and Postoperative photos showcasing the restorations of the upper centrals using Ceram.x Spectra ST and Admira Fusion:

**a):** Preoperative photo showcasing the upper centrals to be restored with Ceram.x Spectra ST
**b):** Immediate (Ceram.x Spectra ST) **c):** 1 week (Ceram.x Spectra ST)
**d):** 3 months (Ceram.x Spectra ST) **e):** 12 months (Ceram.x Spectra ST)

**f)** Preoperative photo showcasing the upper centrals to be restored with Admira Fusion
**g):** Immediate (Admira Fusion) **h):** 1 week (Admira Fusion)
**d):** 3 months (Admira Fusion) **e):** 12 months (Admira Fusion)

**Table (3):** Mean and SD for ΔE for the intergroup comparison within each follow-up and intragroup comparison within each group.

| Follow-up | Ormocer | | Methacrylate | | P value |
|---|---|---|---|---|---|
| | **Mean** | **SD** | **Mean** | **SD** | |
| **Immediate** | 5.41 | 2.64 | 7.77 | 2.65 | P = 0.1460 |
| **1 week** | 5.43 | 3.07 | 6.96 | 2.80 | P = 0.3872 |
| **3 months** | 5.54 | 2.64 | 4.30 | 2.92 | P = 0.4219 |
| **12 months** | 3.93 | 2.72 | 5.23 | 2.79 | P = 0.4383 |
| **P value** | **P = 0.793** | | **P = 0.113** | | |

**Table (4):** Frequency and percentage for Esthetic properties scores for the intergroup comparison within each follow-up and intragroup comparison within each group between different follow-up periods.

| Criteria | Composite | Ormocer | | | Methacrylate | | | |
|---|---|---|---|---|---|---|---|---|
| | **Follow-up** | **A** | **B** | **C** | **A** | **B** | **C** | **P value** |
| **Shade Matching** | **Immediate** | 13(100%) | 0(0%) | 0(0%) | 13(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | **1 week** | 13(100%) | 0(0%) | 0(0%) | 13(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | **3 months** | 1(7.7%) | 11(84.6%) | 1(7.7%) | 1(7.7%) | 11(84.6%) | 1(7.7%) | P = 1.0000 |
| | **12 months** | 0(0%) | 12(92.3%) | 1(7.7%) | 0(0%) | 12(92.3%) | 1(7.7%) | P = 1.0000 |
| | **P value** | | **P <0.001** | | | **P <0.001** | | |
| **Surface Texture** | **Immediate** | 13(100%) | 0(0%) | 0(0%) | 13(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | **1 week** | 13(100%) | 0(0%) | 0(0%) | 13(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | **3 months** | 12(92.3%) | 1(7.7%) | 0(0%) | 10(76.9%) | 3(23.1%) | 0(0%) | P = 0.2864 |
| | **12 months** | 11(84.6%) | 2(15.4%) | 0(0%) | 10(76.9%) | 3(23.1%) | 0(0%) | P = 0.6256 |
| | **P value** | | **P = 0.194** | | | **P = 0.029** | | |
| **Marginal Discoloration** | **Immediate** | 13(100%) | 0(0%) | 0(0%) | 13(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | **1 week** | 13(100%) | 0(0%) | 0(0%) | 13(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | **3 months** | 13(100%) | 0(0%) | 0(0%) | 13(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | **12 months** | 13(100%) | 0(0%) | 0(0%) | 13(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | **P value** | | **P = 1.0000** | | | **P = 1.0000** | | |

**Table (5):** Frequency and percentage for Biological properties scores for the intergroup comparison within each follow-up and intragroup comparison within each group between different follow-up periods.

| Criteria | Composite | Ormocer | | | Methacrylate | | | |
|---|---|---|---|---|---|---|---|---|
| | Follow Up | A | B | C | A | B | C | P value |
| marginal adaptation | **Immediate** | 13(100%) | 0(0%) | 0(0%) | 13(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | **1 week** | 13(100%) | 0(0%) | 0(0%) | 13(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | **3 months** | 13(100%) | 0(0%) | 0(0%) | 13(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | **12 months** | 13(100%) | 0(0%) | 0(0%) | 13(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | **P value** | **P = 1.0000** | | | **P = 1.0000** | | | |
| Recurrent Caries | **Immediate** | 13 (100%) | | 0 (0%) | 13 (100%) | | 0 (0%) | P = 1.0000 |
| | **1 week** | 13 (100%) | | 0 (0%) | 13 (100%) | | 0 (0%) | P = 1.0000 |
| | **3 months** | 13 (100%) | | 0 (0%) | 13 (100%) | | 0 (0%) | P = 1.0000 |
| | **12 months** | 13 (100%) | | 0 (0%) | 13 (100%) | | 0 (0%) | P = 1.0000 |
| | **P value** | **P = 1.0000** | | | **P = 1.0000** | | | |

**Table (6):** Frequency and percentage for Functional properties scores for the intergroup comparison within each follow-up and intragroup comparison within each group between different follow-up periods.

| | Composite | Ormocer | | | Methacrylate | | | P value |
|---|---|---|---|---|---|---|---|---|
| | Follow-Up | A | B | C | A | B | C | |
| Fracture of the Restoration | **Immediate** | 13(100%) | 0(0%) | 0(0%) | 13(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | **1 week** | 13(100%) | 0(0%) | 0(0%) | 13(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | **3 months** | 13(100%) | 0(0%) | 0(0%) | 13(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | **12 months** | 12(92.3%) | 1(7.7%) | 0(0%) | 10(76.9%) | 3(23.1%) | 0(0%) | P = 0.2864 |
| | **P value** | **P = 0.392** | | | **P = 0.029** | | | |
| Wear | **Immediate** | 13(100%) | 0(0%) | 0(0%) | 13(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | **1 week** | 13(100%) | 0(0%) | 0(0%) | 13(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | **3 months** | 13(100%) | 0(0%) | 0(0%) | 13(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | **12 months** | 13(100%) | 0(0%) | 0(0%) | 13(100%) | 0(0%) | 0(0%) | P = 1.0000 |
| | **P value** | **P = 1.0000** | | | **P = 1.0000** | | | |
| Retention | **Immediate** | 13 (100%) | | 0 (0%) | 13 (100%) | | 0 (0%) | P = 1.0000 |
| | **1 week** | 13 (100%) | | 0 (0%) | 13 (100%) | | 0 (0%) | P = 1.0000 |
| | **3 months** | 13 (100%) | | 0 (0%) | 13 (100%) | | 0 (0%) | P = 1.0000 |
| | **12 months** | 13 (100%) | | 0 (0%) | 13 (100%) | | 0 (0%) | P = 1.0000 |
| | **P value** | **P = 1.0000** | | | **P = 1.0000** | | | |

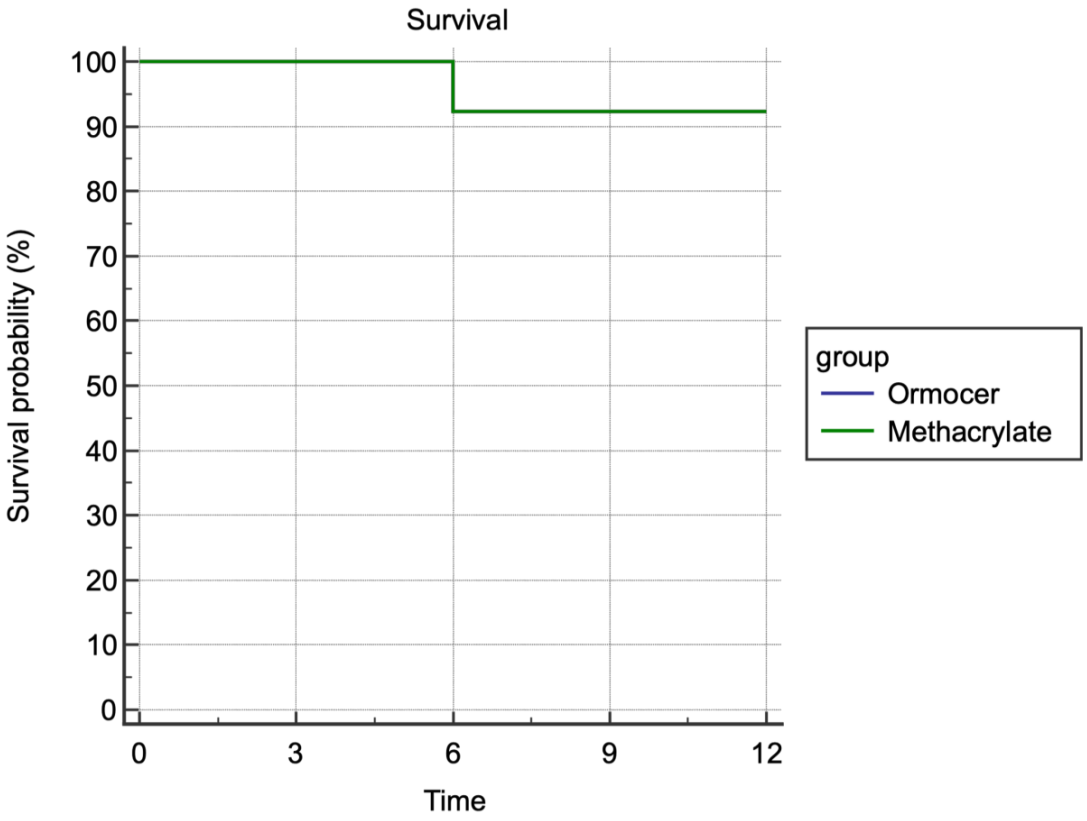


**Figure (3):** Survival analysis of ormocer and methacrylate for class IV restorations after 12 months

## Discussion

The growing demand for aesthetic and durable dental restorations has driven the development of new resin composites. Recent advancements in filler technology and resin matrices aim to enhance both mechanical strength and aesthetics ***(Torres et al., 2020).***

Color matching is crucial for the success of resin composite esthetic restorations, with technological advancements improving optical qualities. However, discoloration remains a challenge due to both intrinsic and extrinsic factors, especially in challenging scenarios like in extensive Class IV cases ***(Ceci et al., 2017; Sherif et al., 2020)***. Repairing these cavities can be particularly challenging, notably in achieving precise color matching with the surrounding tooth structure, carrying a risk of patient dissatisfaction and lack of trust in the effectiveness of the treatment ***(Hashem et al., 2023; Ismail, 2021)***. Efforts to improve clinical performance have focused on enhancing properties like elasticity and degree of conversion, but these have also increased polymerization shrinkage and water sorption ***(Fugolin and Pfeifer, 2017)***; recent developments, such as ORMOCER, aim to address these issues by offering a low-shrinkage composite (***Abd El-Maksoud et al., 2023).***

The scarcity of clinical data on ORMOCER resin composites and the lack of long-term evidence reveal a significant knowledge gap in this area ***(Ebaya et al., 2022)***. To address this, a novel study was proposed to evaluate the clinical effectiveness of ORMOCER composites compared to traditional resin-based composites. Although some in-vivo trials suggest potential benefits of ORMOCER composites, clinical trials are limited. This randomized controlled trial aimed to compare the clinical performance of Admira Fusion, an ORMOCER-based composite, with Ceram.X Spectra ST, a methacrylate-based composite, to provide valuable insights for clinicians in

selecting restorative materials for anterior restorations.

The study assessed dental restorations at three follow-up intervals: baseline (1 week), 3 months, and 12 months. While these periods may not fully reflect the long-term performance of the materials, the one-year evaluation provides valuable insights into their short-term effectiveness ***(Celik et al., 2010; El-Bialy et al., 2020)***. ***Hickel et al. 2023,*** suggested that one-week baseline assessment, conducted after the restoration insertion, allows time for the resin composite to mature and for any post-procedural discomfort to subside. In the current study 26 participants with Class IV cavities were enrolled, divided evenly into intervention and comparator groups. All participants completed the 12-month follow-up, achieving a 100% retention rate.

Clinical performance was categorized into four groups: A) Esthetic properties (including shade match, surface texture, and marginal discoloration), B) Biological properties (marginal adaptation, reccurent caries), C) Functional properties (retention, fracture of restoration, wear/anatomic form), and D) Survival analysis. No significant differences were found among the modified USPHS criteria, except for shade match, which showed a significant difference in intra-group comparisons for both materials over different follow-up periods.

In the study, shade match for esthetic properties was evaluated using modified USPHS criteria. No significant differences were found between groups at different follow-up periods. This aligns with studies by ***Mahmoud et al., 2014 and Torres et al., 2020***. Filler size and distribution, with nanoparticles are crucial for surface properties ***(Angerame and De Biasi, 2018).*** However, ***Llena et al., 2017,*** found that methacrylate-based composites showed better shade match than ormocer composites which they attributed to the insufficient integration of micro-filled particles and siloxane in the ormocer composite, potentially leading to greater water absorption and discoloration ***(Gregor et al., 2016).*** Within each group, significant differences were observed across follow-up periods. After 12 months, ormocer and methacrylate composites showed similar risks for shade matching. According to ***Karaman et al. 2017 and Demirci et al. 2018,*** a Bravo score was not considered a clinical failure, with only one restoration scoring Charlie, not indicating material failure. Shade changes are influenced by various intrinsic and extrinsic factors, including polymerization degree, water sorption, dietary habits, oral hygiene, and surface smoothness ***(Barutcigil & Yıldız, 2012; Ebaya et al., 2022)***. Additionally, exposure to factors in the oral cavity can negatively impact the esthetic quality of restorations and tooth surfaces, leading to shade mismatch ***(Shetty et al., 2021).***

Based on the current study, the shade match was evaluated using a spectrophotometer and the CIE Lab system, showing no significant differences between groups or within each group at different follow-up periods. ***Ceci et al., 2017,*** found similar shade-matching capacities for various composite resins over 28 days, with Admira Fusion and Ceram-X showing the lowest color variation and less staining. This was supported by ***Ebaya et al., 2022***, who noted no significant differences in shade matching for both materials. The unique pure silicate technology in ormocer resin composites enhances their ability to blend with surrounding tooth structures. Nano-filled methacrylate-based resin composites use specialized fillers that reflect natural tooth colors, aiding shade matching ***(Bakti et al., 2018).*** However, ***Gregor et al., 2016, Llena et al., 2017, and Sherif et al., 2020*** found that ormocer composites showed higher discoloration compared to methacrylate-based composites, indicating lower color stability. The clinical evaluation showed that the shade match scores were Alpha and Bravo, indicating acceptable matches. However, ΔE values (>3.3) showed noticeable changes since the restoration's immediate placement, conflicting with clinical results ***(Blum et al., 2018).*** Mean ΔE values dropped after 12 months, suggesting good material response. No

significant difference was found between materials, though ormocer-based composites had better ΔE values at the end of the study.

Objective (spectrophotometer) and subjective evaluations (visual) highlight that lightness is most strongly correlated with shade match accuracy ***(Browning et al., 2009).*** Spectrophotometers can detect subtle variations in lightness, hue, and chroma that human eyes cannot ***(Gómez-Polo et al., 2014).*** Visual assessments are less reproducible (65%) compared to spectrophotometers (80%), with accuracy affected by factors such as tooth surface convexity and probe placement ***(Paul et al., 2002).*** Visual assessment is often seen as more important than objective methods because patient acceptance is based on visual judgment ***(Paravina et al., 2019).***

Regarding surface texture, both materials were clinically acceptable within 12 months. Class IV restorations with Admira fusion had a 33% lower risk of surface texture issues compared to Ceram X Spectra ST ***(Cavalcante et al., 2011; Wolter, 2015)***. Similar findings were reported by ***Mahmoud et al., 2014, and Jansen van Rensburg et al., 2023***, attributing the polishability to nano-sized fillers. A review by ***Kaizer et al., 2014*** highlighted the superior smoothness and gloss retention of nano-filled composites. Both composites demonstrated excellent polishability, reducing biofilm retention and maintaining surface shine ***(Sherif et al., 2020, & Torres et al., 2020).*** The polymer network's composition and structure are essential for adapting to oral environmental changes.

Regarding marginal discoloration, the study found no significant differences between both groups at all follow-ups. After 12 months, both materials showed similar risks of marginal discoloration, aligning with ***Mahmoud et al. 2014, Demirci et al. 2018, and Torres et al., 2020.*** Marginal discoloration could indicate a bond breakdown, potentially resulting in leakage. Selective enamel etching effectively prevents this issue ***(Peumans et al., 2010; Perdigão et al., 2014).***. The slight discoloration observed may be due to pigments from food, beverages, and tobacco ***(Dukic et al., 2010)***. ***Garapati et al. 2014***, confirmed no significant differences between ormocer-based and methacrylate-based composites regarding marginal leakage and discoloration. However, ***Kalra et al. 2012***, ***McHugh et al., 2017, and Sudhapalli et al., 2018*** found that ormocer composites showed significantly less marginal discoloration. Polymerization shrinkage is a primary cause of marginal discoloration. It depends on filler load, filler surface treatment, and monomer molecular weight ***(Palaniappan et al., 2012; Sudhapalli et al., 2018)***. ***Tauböck et al., 2019,*** noted that ormocer's resin matrix system leads to less shrinkage and stress compared to other materials. ***Hussien et al., 2020***, explained that ormocer contains ceramic polysiloxane, which undergoes less shrinkage due to its longer molecule length compared to Bis-GMA.

In the current study, biological properties focusing on marginal adaptation and recurrent caries for both materials exhibited clinically acceptable scores Statistical comparisons over 12 months showed no significant differences in outcomes between the materials or within the material groups. These results are consistent with studies by ***Mahmoud et al., 2014 and Torres et al., 2020***, which also found no significant clinical differences in these aspects.

In Class IV cavities, bevel preparation plays a crucial role in enhancing marginal control and improves marginal adaptation. Beveling increases surface area for better adhesion and aesthetic transition, which is especially important for achieving optimal marginal integrity ***(Ramírez-Barrantes, 2021).***

Secondary or recurrent caries, a common cause of clinical failure, often occurs at the interface between the restoration and tooth surface. Factors such as marginal adaptation, microleakage, material type, and biofilm presence can contribute to this issue**.** Polymerization shrinkage, for example, can create gaps between the restoration and tooth, leading to recurrent caries and eventual failure

*(Zhou et al, 2019)*. However, secondary caries typically develops after several years of intraoral aging (usually 4-6 years), suggesting that longer observation periods are needed to confirm findings related to recurrent caries ***(Beck et al., 2019)***

In this study, both Ceram.x Spectra ST and Admira Fusion showed clinically acceptable functional properties over 12 months, with no significant differences. No catastrophic failures were noted, though Ceram.x Spectra ST had slightly lower strength within the acceptable range. This is consistent with ***Mahmoud et al., 2014 and Torres et al., 2020.*** Bevels in Class IV cavities improve retention by increasing adhesive surface area and wettability ***(Ramírez-Barrantes, 2021).*** The study used a selective enamel etching mode with a universal adhesive containing 10-MDP for enhanced bond durability ***(Carrilho et al., 2019).*** In the study Minor fractures, classified as score B, were likely due to biting hard objects. Ormocer restorations had fewer fractures. Nano-sized fillers in both materials contributed to their mechanical properties ***(Kaizer et al., 2014).*** Ormocer's cross-linked structure and ring-opening systems reduce polymerization shrinkage and improve mechanical properties ***(Jansen van Rensburg et al., 2023).*** Filler content influenced the wear/anatomic form of restorations, consistent with ***Schubert et al., 2019, Torres et al., 2020, and Şenol et al., 2023.***

After one year, the null hypothesis was accepted, indicating both restorations performed adequately with no failures. Significant differences were only observed in shade match during intra-group comparisons. Clinically, both materials received satisfactory scores on modified USPHS criteria, with Admira Fusion showing slightly better esthetic performance than Ceram.X Spectra ST. However, the study has limitations due to subjective assessment and follow-up duration. A longer follow-up is recommended for more reliable results.

**Conclusions:**

1- Ormocer-resin composite exhibited comparable performance to Methacrylate composite regarding their properties.

2- Observed Shade match changes were within clinically acceptable limits for both materials through visual evaluation. Which indicated that a variance was evident between subjective visual and objective evaluation methods.

**Recommendations:**

1. Longer clinical trials with follow-up periods beyond 12 months are necessary to assess the long-term effectiveness of Ormocer-resin composites.

2. Visual assessment under standardized conditions should be prioritized, as it better correlates with patient satisfaction than objective numerical measurements.

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The authors declare no conflict of interest.

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**Ethics:**
This study protocol was approved by the ethical committee of the faculty of dentistry- Cairo university on: 26/07/2022, approval number: 19722.

**Data Availability:**
Data will be available upon request.

**Clinical trial registration:**
The protocol for this study was registered on clinicaltrials.gov, under ID: NCT05623423.

**Credit statement:**

LAS, MAH, NKH, and ZOT conceptualized the study and designed the methods. LAS conducted the clinical trial. LAS and ZOT conducted the data analysis and interpretation and drafted the manuscript. MAH and ZOT reviewed and edited the manuscript. All authors read and approved the final manuscript.

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