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## Clinical Comparison of Stela Chemically-cured Bulk-fill Composite and Conventional Light-Cured Composite in Posterior Restorations: A 6-Month Clinical Study

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## Abstract:

**Background:** Composite resins are widely used for posterior restorations, but conventional light-cured composites are associated with polymerization shrinkage and postoperative sensitivity. Stela is a newly developed chemically-cured bulk-fill composite designed to simplify placement and reduce shrinkage stress.

Aim: The purpose of this study was to compare the postoperative sensitivity and short-term clinical performance of new chemically-cured bulk-fill composite with a conventional light-cured composite in posterior restorations. Materials and methods: A total of 40 Class I restorations in permanent molars were placed in 20 patients (11 females and 9 males, ranging from 18-40 years of age) each patient requiring at least two posterior restorations participated in this split-mouth clinical study. Each patient received one restoration with chemically-cured bulk-fill composite (Stela Automix, SDI, Australia) after the application of Stela primer and another one with a conventional light-cured composite (Filtek P60, 3M ESPE, USA). All restorations were placed by one operator and directly evaluated by two independent examiners. Postoperative sensitivity was recorded on a 10-point visual analogue scale (VAS) after 48 hours, 1 week, 1 month, and 6 months. Clinical performance was assessed by using modified USPHS criteria, which included marginal adaptation, anatomic form, surface texture, and secondary caries. Data were analyzed statistically using paired t-tests and Chi-square tests, with statistical significance set at p < 0.05.

**Results:** The results at 48 hours and 1 week indicated that Stela Automix restorations showed significantly lower mean VAS scores compared with traditional resin composites restorations (p<0.05). Statistical analysis at 1 and 6 months showed that there was no statistically significant difference between the 2 groups. The results showed that the both groups achieved high clinical ratings for marginal adaptation, anatomic form, and surface texture. Regarding secondary caries, the results showed that the secondary caries were not detected in both groups.

**Conclusion**: The stela chemically-cured bulk-fill composite demonstrated comparable short-term performance to conventional composites, with reduced early postoperative sensitivity. It may offer practical advantages in everyday restorative dentistry, although longer-term clinical studies are recommended.

**Keywords**: Chemical-Cured Resin Composite, Postoperative Sensitivity, Clinical Performance, Permanent Dental Restoration.

## المقارنة السريرية لمركب ستيلا المعالج كيميائيا مع المركب التقليدي المعالج بالضوء في الترميمات الخلفية: دراسة سريرية لمدة 6 أشهر

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#### الملخص

الخلفية: تستخدم الراتنجات المركبة على نطاق واسع في الترميمات الخلفية، ولكن المركبات التقليدية المعالجة بالضوء ترتبط بانكماش البلمرة وحساسية ما بعد الجراحة. ستيلا هو مركب تعبئة سائبة تم تطويره حديثا تم تطويره كيميائيا مصمم لتبسيط وضعه وتقليل إجهاد الانكماش.

الهدف: كان الغُرض من هذه الدراسة هو مقارنة حساسية ما بعد الحشو والأداء السريري على المدى القصير لمركب التعبئة السائبة الجديد المعالج كيميائيا مع مركب تقليدي معالج بالضوء في الترميمات الخلفية.

المواد والطرق: تم وضع مجموعه 40 عملية ترميم من الفئة الأولى في الأضراس الدائمة في 20 مريضا (11 أنثى و 9 ذكور، تتراوح أعمار هم بين 18-40 عاما) كل مريض يحتاج ما لا يقل عن اثنين من الترميمات الخلفية التي شاركت في هذه الدراسة السريرية للفم المنقسم. تلقى كل مريض ترميما واحدا مع مركب تعبئة سائبة معالج كيميائيا, Stela Automix) وآخر مع مركب تقليدي معالج بالضوء

شرة من قبل طبيب اسنان واحد وتم تقييمها مباشرة من (Filtek P60, 3M ESPE, USA). تم وضع جميع عمليات الترميم من قبل طبيب اسنان واحد وتم تقييمها مباشرة من قبل اثنين من الفاحصين المستقلين. تم تسجيل حساسية ما بعد الحشو على مقياس تناظري بصري من 10 نقاط (VAS) بعد 48 ساعة وأسبوع واحد وشهر واحد و  $\delta$  أشهر. تم تقييم الأداء السريري باستخدام معايير USPHS المعدلة والتي شملت: التكيف الهامشي، والشكل التشريحي، والملمس السطحي، والتسوس الثانوي. تم تحليل البيانات إحصائيا باستخدام اختبارات thapper  $\delta$  مع تحديد الأهمية الإحصائية عند.  $\delta$  0.05 مع تحديد الأهمية الإحصائية عند.  $\delta$ 

النتائج: أشارت النتائج في 48 ساعة وأسبوع واحد إلى أن ترميمات ستيلاً أوتوميكس أظهرت متوسط درجات VAS أقل بكثير مقارنة بترميمات المركبات التقليدية. (p<0.05) أظهر التحليل الإحصائي في شهر و6 أشهر أنه لا يوجد فرق كبير إحصائيا بين المجموعتين. أظهرت النتائج أن كلتا المجموعتين حققتا تقييمات سريرية عالية للتكيف الهامشي والشكل التشريحي والملمس السطحي. اما فيما يتعلق بالتسوس الثانوي، أظهرت النتائج أنه لم يتم اكتشاف التسوس الثانوي في كلتا المجموعتين.

الخلاصة: أظهر مركب التعبئة السائبة المعالجة كيميائيا أداء مماثلا على المدى القصير للمركبات التقليدية، مع انخفاض الحساسية المبكرة بعد الحشو. قد يقدم مزايا عملية في طب الأسنان التصالحي اليومي، على الرغم من التوصية بإجراء در اسات سريرية طويلة الأحل.

الكلمات المفتاحية: مركب الراتنج المعالج كيميائيا، حساسية ما بعد الحشو، الأداء السريري، ترميم الأسنان الدائم.

## Introduction

Dental composite resins have become the preferred material for posterior restorations due to their superior aesthetics, direct bonding ability, and ongoing improvements in mechanical properties [1]. Despite their advantages, conventional light-cured composites have significant clinical limitations. The incremental placement technique, which is necessary to ensure an adequate depth of cure and reduce polymerisation shrinkage, is time-consuming and technique-dependent [2] [3]. Furthermore, polymerisation shrinkage stress can impair marginal integrity, resulting in postoperative sensitivity, marginal discolouration, secondary caries, and even restoration failure [4] [5]. These issues continue to pose a challenge in daily dental practice, particularly in deep Class I and Class II cavities. To address these limitations, bulk-fill composites were introduced, which allow for up to 4-5 mm increment thickness and promise to reduce shrinkage stress while improving clinical efficiency [6]. The majority of bulk-fill materials are light-cured, and many studies have yielded favorable results [7] [8]. However, their curing efficiency in deep cavities is still affected by light intensity, shade, cavity configuration, and operator technique, raising concerns about incomplete polymerisation and compromised mechanical and biological performance [9].

A new category of chemically-cured composites was recently developed, with the goal of overcoming the depth of cure limitations of light-activated materials [10] [11]. One example is Stela (SDI, Australia), which relies on a self-cure mechanism and is supplied in automix or capsule form. This material is designed to simplify placement, eliminate the need for light activation, and reduce polymerisation stress by curing uniformly throughout the restoration, regardless of cavity depth or access. Many in vitro studies have evaluated this Stela composite, showing good results [12] [13]. This new dental composite includes various fillers like strontium fluoro-alumino-silicate glass, calcium aluminate, silica, and ytterbium trifluoride agglomerates. While some might question whether this dental filling material qualifies as a compomer, the manufacturer of STELA classifies it as a new-generation, resin-based bulk-fill restorative material with distinct chemico-physical properties [14]. According to the manufacturer, Stela has lower technique sensitivity and may reduce the incidence of postoperative sensitivity (SDI, 2022) [15]. Chemically cured composites were widely used in previous generations of resin materials, but their popularity waned due to poor aesthetics and handling properties [16]. A modern self-cure bulk-fill material is a novel development, but independent evidence of its clinical performance remains limited. Laboratory studies have investigated the depth of cure, shrinkage stress and mechanical properties [17] [18]. Only a few clinical

trials, primarily in high-income countries, have evaluated postoperative sensitivity and short-term outcomes [19] [20].

In Libya, where access to new restorative technologies is limited, clinicians are looking for materials that improve efficiency and patient comfort. As a result, the purpose of this clinical study was to compare the postoperative sensitivity and short-term clinical performance of a chemically cured bulk-fill composite (Stela Automix, SDI, Australia) to a conventional light-cured composite (Filtek P60, 3M ESPE, USA) in posterior restorations. The findings are intended to provide preliminary clinical evidence to inform local practitioners about the potential benefits and limitations of this new material in our community.

#### Methods

## Study Design and Ethical Approval

This study was designed as a prospective, randomised, split-mouth clinical trial that took place at a private clinic in Sirte, Libya from December 2024 to May 2025. The protocol was approved by the Human Ethics Committee of the Faculty of Dentistry at Sirte University in Libya (Ref. No. 2: SU-DEN/2024/10). Prior to enrolment, all participants provided written informed consent.

## Sample Selection

This split-mouth clinical study included 20 patients (11 females and 9 males, ages 18 to 40). Each patient had two Class I posterior restorations of different restorative materials in permanent molars, for a total of 40 restorations: 20 with Stela Automix (SDI, Australia) and 20 with a conventional light-cured composite (Filtek P60, 3M ESPE, USA).

#### **Inclusion criteria:**

- Vital teeth with occlusal carious lesions limited to dentin without cusp involvement.
- No spontaneous pain or periapical pathology.
- Good oral hygiene and absence of parafunctional habits.

#### **Exclusion criteria:**

- Non-vital, cracked, or heavily restored teeth.
- Patients with bruxism, systemic diseases, or poor compliance.

#### Randomization and Blinding

The two molars in each patient were randomly assigned to treatment groups using a computer-generated random sequence (Excel Random Number Generator). Allocation concealment was maintained by opening opaque sealed envelopes during the restoration process. All postoperative evaluations were performed by two independent, calibrated examiners who were not aware of the material type. Examiner calibration was achieved through the joint scoring of ten pilot restorations. 10 pilot restorations.

## **Operative Procedure**

The same operator under standardized clinical conditions (dental unit illumination  $\approx 8000$  lux, room temperature  $\approx 24$  °C) placed all restorations.

## 1. Anesthesia and Isolation

Local anaesthesia was achieved using 2% lidocaine and 1:80,000 epinephrine (Xylocaine, Dentsply Sirona, Germany). Rubber-dam isolation was used in all cases, supplemented with cotton rolls and a saliva ejector as needed.

#### 2. Cavity Preparation

Caries removal and cavity preparation were performed using a high-speed air-turbine handpiece (NSK Pana-Air, Japan) with continuous water coolant and new #245 tungsten-carbide burs (SS White, USA) for each pair of restorations. The cavity design followed a conservative Class I configuration with rounded internal angles and flat pulpal floors. Cavity depth was standardized between 3.0–4.0 mm measured with a periodontal probe.

## 3. Restorative Procedures:

## Group 1 – Chemically-Cured Bulk-Fill Composite (Stela Automix, SDI, Australia).

Once the cavity has been prepared, cleaned, and isolated, add one or two drops of Stela Primer to a plastic mixing dish. Use a bendable dental bond brush (Points, SDI Limited) to apply Stela Primer to all surfaces and margins, and then wait five seconds. Without the need for light curing or acid etching, gently blow with air for two to three seconds. Using an automixtip, a single 4-mm increment of composite paste was injected directly into the cavity using a Stela Automix syringe. No light curing was done; the material self-activated during mixing. At 37 °C, the

final polymerisation took place in 5 minutes after a working time of 90 seconds. Following setting, occlusion was examined and small adjustments were made with fine-grit finishing burs.

#### Group 2 – Conventional Light-Cured Composite (Filtek P60, 3M ESPE, USA).

Phosphoric acid gel 37% (Scotchbond Etchant, 3M ESPE, USA) was used to acid-etch the cavity for 15 seconds on the enamel and 10 seconds on the dentin. To keep dentin moist, thoroughly rinse for ten seconds and gently air dry. Using a microbrush, Adper Single Bond 2 (3M ESPE, USA) was applied to the dental substrates. It was then air-thinned for five seconds and light-cured for ten seconds using an LED-curing unit (XL3000; 3M ESPE) with a curing intensity of 600 mW/cm. Before every use, a radiometer was used to confirm the light intensity. A flat-faced condenser was used to insert the composite in 2-mm increments, and each one was light-cured for 20 seconds at a distance of 1 mm using the same LED-curing unit. Occlusal anatomy was re-established and confirmed using articulating paper (40 µm) following build-up.

## 4. Polishing and Finishing

After using water-cooled fine-grit diamond burs for finishing, Sof-LexTM discs (3M ESPE) were used in a descending abrasive sequence (coarse  $\rightarrow$  medium  $\rightarrow$  fine  $\rightarrow$  superfine) for 30 seconds at a time. Silicone points (Enhance, Dentsply Sirona) were used for the final polishing in dry conditions.

#### **Clinical Assessment**

#### 1. Postoperative Sensitivity (POS)

At 48 hours, one week, one month, and six months following restoration, patients were instructed to report sensitivity using a 10-point Visual Analogue Scale (VAS) (0 = no pain; 10 = severe pain). Two blinded examiners used standardised cold-air stimulation to conduct the evaluations.

#### 2. Clinical Performance

The Modified United States Public Health Service (USPHS) criteria for marginal adaptation, anatomic form, surface texture, and secondary caries were used to evaluate restorations after six months. Each criterion received a Charlie (unacceptable), Bravo (acceptable), or Alpha (excellent) grade. Consensus was used to settle disagreements.

#### **Statistical Analysis**

SPSS v25.0 (IBM, USA) was used to analyse the data. The Chi-square test was used to compare categorical USPHS ratings, and the paired t-test was used to analyse VAS scores (continuous data). A significance level of p < 0.05 was established.

## Results

#### Features of the patient

Twenty patients (11 females and 9 males, ranging from 18-40 years of age) were enrolled in the clinical trial. Each patient received two posterior restorations, resulting in a total of 40 restorations: 20 with Stela Automix and 20 with a conventional light-cured composite. The number of participants attending recalls is relevant to obtaining reliable data regarding the performanse of the filling in clinical trials. In this study, all participants completed the 48 hours, 1 week and 1-month follow-ups, but two participants were absent to follow up at 6 months, leaving 18 restorations per group available for final evaluation.

## **Testing hypotheses**

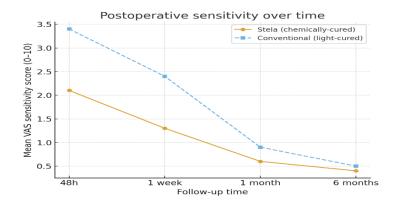
In terms of postoperative sensitivity and short-term clinical performance, the null hypothesis predicted no difference between Stela Automix and traditional light-cured composite. Nevertheless, this hypothesis was partially refuted by the study's findings. Stela Automix restorations were linked to significantly lower postoperative sensitivity at 48 hours and 1 week, even though both groups displayed similar clinical outcomes at 1 and 6 months

## Postoperative sensitivity

The mean VAS scores for postoperative sensitivity are compiled in (Table 1). Stela Automix restorations had a mean sensitivity score of  $2.1 \pm 1.0$  at 48 hours, while conventional composite restorations had a mean score of  $3.4 \pm 1.2$ . A similar pattern was seen at one week, but the Stela group's sensitivity was much lower  $(1.3 \pm 0.8 \text{ vs. } 2.4 \pm 1.1)$  (P is 0.02). Stela Automix restorations had a mean sensitivity score of  $0.6 \pm 0.5$  at one month, while conventional composite restorations had a mean score of  $0.9 \pm 0.6$ . At six months, Stela Automix restorations had a mean sensitivity score of  $0.4 \pm 0.5$ , while conventional composite restorations had a score of  $0.5 \pm 0.5$ . Postoperative sensitivity had declined in both groups by the 1-month and 6-month follow-up periods, and no statistically significant differences were found. (Figure 1)

**Table 1.** Mean VAS scores for postoperative sensitivity (0–10 scale).

Time point	Stela (mean ± SD)	Conventional composite (mean ± SD)	P-value
48 hours	$2.1 \pm 1.0$	$3.4 \pm 1.2$	0.03
1 week	$1.3 \pm 0.8$	$2.4 \pm 1.1$	0.02
1 month	$0.6 \pm 0.5$	$0.9 \pm 0.6$	0.20
6 months	$0.4 \pm 0.5$	$0.5 \pm 0.5$	0.60



**Figure 1.** Mean postoperative sensitivity (VAS scores) at different follow-up intervals for restorations placed with Stela Automix (chemically cured) and conventional light-cured composites. Stela Automix showed lower sensitivity at 48 hours and 1 week, while both materials demonstrated similar outcomes by 1 and 6 months.

## Clinical performance (secondary outcomes)

At the 6-month evaluation, most restorations in both groups were rated Alpha (excellent) according to modified USPHS criteria for marginal adaptation, anatomic form, and surface texture (Table 2). Only a small number of Bravo scores were recorded, and no Charlie (failure) ratings were observed. Importantly, no secondary caries were detected in either group.

**Table 2.** Clinical performance according to modified USPHS criteria at 6 months.

Criterion	Rating	Stela Automix (n=18)	Conventional composite (n=18)
Marginal adaptation	Alpha	17 (94%)	16 (89%)
	Bravo	1 (6%)	2 (11%)
Anatomic form	Alpha	18 (100%)	17 (94%)
	Bravo	0	1 (6%)
Surface texture	Alpha	17 (94%)	16 (89%)
	Bravo	1 (6%)	2 (11%)
Secondary caries	_	0	0

#### Discussion

The number of participants who attend recalls is important for getting accurate information on the performance of filling in clinical trials. In this study, all participants completed the 48-hour, one-week, and one-month follow-ups, but two patients were abcent to follow-up at six months, leaving 18 restorations per group for final evaluation. The longevity of restorations is determined by a variety of factors, such as the techniques and materials used, patient oral hygiene compliance, and caries susceptibility [16] [21]. The majority of patients assessed had good hygiene and no periodontal diseases or primary caries formation, resulting in a low rate of filling failure. This study compared a newly developed chemically-cured bulk-fill composite (Stela Automix, SDI) to a traditional light-cured composite in posterior restorations. The main finding was that Stela Automix had lower postoperative sensitivity during the early follow-up period (48 hours and 1 week), but no significant differences were found at one or six months.

Post-operative pain following posterior composite filling is common challenge of dental professionals for long time. Factors contributing to this including the curing mechanism of resin composites; the hardening process involves inherent contraction, creating internal stress that can compromise the bonding interface and lead to gaps, enamel cracks or deformation of the surrounding tooth structure, all these factors can lead to potential post-operative pain [22]. The magnitude of polymerization shrinkage stress varies according to the mode of curing, with light-cured composites generally producing faster and more polymerization shrinkage stresses than chemically-cured composite [23].

The reduction in early postoperative sensitivity with Stela Automix could be attributed to its self-cure polymerisation mechanism, which allows for uniform curing throughout the restoration and slower and delayed polymerization process, allowing the composites to flow due to their extended viscous phase compared to light-cured composites [5]. These findings are consistent with those of Loguercio et al [19], who found that Stela Automix and Capsule restorations were associated with significantly lower sensitivity at 24-48 hours but not at later follow-up points. The similarity between studies suggests that Stela's self-cure mechanism may be especially useful in reducing early postoperative discomfort. By minimizing both polymerization shrinkage and the associated stress, the integrity of the adhesive bond is maintained [22]. The lower initial post-operative sensitivity observed with the self-cured Stela Automix material aligns with in vitro findings, such as those by Pires et al. [14]. Their research noted superior adaptation and an absence of interfacial gaps when using Stela in simulated Class I restoration, a stark contrast to conventional light-cured composites which consistently showed gaps and voids, this suggest that the prolonged and gradual curing process inherent in chemically-cured composites accounts for the reduced incidence of immediated and short-term (up to 48 hours) post-operative pain compared to their; light-cured counterparts.

Our results of the present study came in full agreement with Loguercio et al. [19], who found that Stela Automix maintaining comparable retention, marginal adaptation, and surface properties after six months. Furthermore, an eighteen-month multicenter clinical trial found that Stela performed similarly to traditional bulk-fill composites in biological and functional criteria [20]. These studies support the idea that Stela can be used as a reliable alternative to traditional composites in clinical practice. Results of the present study revealed that the newly developed chemically-cured bulk-fill composite (Stela Automix, SDI) and a conventional light-cured composite performed similarly in terms of marginal adaptation, anatomic form, and surface texture, indicating comparable short-term clinical outcomes. These findings are consistent with the 18-month multicenter trial by Loguercio et al. [20], which found that Stela Automix and Capsule maintained high functional and biological performance, with survival rates comparable to light-cured bulk-fill composites. The absence of secondary caries and high retention rates in our study add to Stela's clinical reliability in the short term.

The anatomic form is preserved by the dental composites' ability to withstand wear result from food and liquids consumed during the mastication [24]. The amount, and type of filler, chemical composition can all affect the wear on filling [24]. The chemical composition of the dental composite can also affect their viscosity and handling properties. The composite resins viscosity is determined by a number of factors, including the shape and size of the inorganic filler, the filler components, the ratio and type of resin matrix contents, and, most importantly, interfacial interactions between resin matrix and the filler particles, and the interlocking of filler particles [24] [25]. Even with the viscosity difference and handling between Stela Automix and Filtek P60, the variation were not statistically significant, and both materials performed similarly in terms of marginal adaptation, anatomic form, and surface texture, implying comparable short-term clinical results. Absence of long-term clinical evaluation could explain the study's relatively similar results after a 6-month assessment of two restorative materials.

Despite minor differences in post-operative pain between the materials, these demonstrated acceptable clinical outcomes and were excluded from the failure category, necessitating only restoration assessment [26]. It should be noted that when important aspects such as biological and functional properties were evaluated, all restorations were rated clinically excellent/very good, with no significant differences found between composites. A new in vitro study [12] [27] found that both materials (Automix and Capsule) of the new chemically-cured composite performed well in many aspect such as of solubility, hardness, water sorption, and flexural strength, exceeding ISO standards [28] and exhibiting mechanical properties comparable with those of light-cured composites used for posterior dental filling [29]. From a clinical standpoint, Stela Automix's simplified handling, which eliminates the need for incremental layering and light activation, can save valuable chairside time. This is especially important in resource-constrained environments like Libya, where high-powered curing lights are not always available. Clinicians in these settings seek restorative options that are both efficient and predictable. The use of such materials may improve patient care by shortening treatment times while maintaining outcomes.

The study has limitations. The sample size was small, and the follow-up period was limited to six months. Furthermore, only one private clinic was involved, limiting the generalisability of the findings. Longer-term clinical trials with larger populations are required to assess restoration survival, resistance to secondary caries, and patient-reported outcomes across multiple years. In conclusion, this study supports Stela Automix, a chemically cured bulk-fill composite, as a promising restorative material. It provides clinical performance similar

to conventional light-cured composites, in addition the benefit of reducing early post-operative sensitivity. These findings, combined with recent international trials, support Stela as a viable restorative option in daily practice. However, they emphasis the importance of long-term follow-up studies in a variety of clinical settings.

#### **Limitations and Future Directions**

When interpreting the findings, must be qualified by the study's limitations. First, the sample size was small (20 patients, 40 restorations), limiting the statistical power and generalisability of the findings. Second, the six-month follow-up period was insufficient to evaluate long-term restoration survival, secondary caries, and wear resistance. Third, the study was conducted in a single private clinic, with all restorations performed by the same operator. While this reduced variability, it also introduced operator bias and does not accurately reflect the range of clinical conditions seen in practice. Furthermore, the outcome assessment was primarily based on clinical examination using USPHS criteria; radiographic follow-up and quantitative measures such as wear or micro-leakage would have enhanced the evaluation. Finally, true blinding was not an option for the operator, which may have influenced the placement process.

Future research should concentrate on larger, multicenter trials involving both private and public dental clinics to improve external validity. Long-term studies lasting at least two to five years are required to assess restoration survival, resistance to secondary caries, and mechanical integrity under functional load. Comparative trials with other commercially available bulk-fill composites would help determine Stela's relative performance in a variety of clinical situations. Endpoints like treatment time, handling characteristics, shade stability, and patient-reported outcomes (comfort, aesthetics, and satisfaction) should also be considered. In resource-constrained environments such as Libya, cost-effectiveness analyses and educational integration could help to clarify Stela's practical restorative potential.

#### Conclusion

This study, which was limited in scope, discovered that the chemically-cured bulk-fill composite (StelaAutomix) performed similarly to a conventional light-cured composite in posterior restorations. Patients treated with Stela Automix had lower postoperative sensitivity during the early follow-up period, but these differences were not statistically significant after one month. After six months, both materials showed excellent retention, marginal adaptation, anatomic form, and surface texture, with no secondary caries detected. These findings indicate that Stela Automix could be an effective alternative restorative material in routine clinical practice, particularly in communities where simplified procedures and reduced technique sensitivity are desirable. However, more studies with larger samples and longer follow-up periods are required to confirm these preliminary findings and establish long-term outcomes.

#### Disclaimer

The article has not been previously presented or published, and is not part of a thesis project.

## **Conflict of Interest**

The authors declare no conflicts of interest related to this study.

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