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Clinical evaluation of a new chemically-cured bulk-fill composite in posterior restorations: 18-Month multicenter double-blind randomized clinical trial

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ABSTRACT

Objectives: To evaluate the clinical performance of a novel self-cured bulk-fill composite (Stela Automix and Stela Capsule, SDI) with a light-cured bulk-fill composite (Filtek One, Solventum) after 12 and 18 months.
Methods: A total of 165 Class I or Class II posterior restorations were placed in 55 participants. The self-cured composite groups received Stela primer followed by either Automix or Capsule forms. The light-cured group received Scotchbond Universal adhesive and the composite. Restorations were evaluated at baseline, 12, and 18 months using updated FDI criteria. Inter-group differences were analyzed using Friedman repeated measures ANOVA, and intra-group with Chi-square test ($\alpha = 0.05$).
Results: After 12 months, 17 restorations exhibited marginal staining, with no differences between groups ($p = 1.00$), but a significant intra-group change in both the self-cured (Capsules) and light-cured groups compared to baseline ($p = 0.02$). Regarding surface luster and texture, 30 restorations were considered clinically good, with a significant difference favoring the light-cured composite ($p = 0.03$), but no significant intra-group differences ($p > 0.20$). For color match, 32 restorations were rated as good, with a statistically significant result favoring both self-cured composites ($p = 0.03$), and no intra-group changes ($p > 0.20$). At the 18-month recall, the number of restorations rated as good was 22 for surface luster and texture, 27 for marginal staining, and 40 for color match; among these, only marginal staining showed significant intra-group changes ($p < 0.006$).
Conclusion: After 18 months, the self-cured composite (Stela), whether Automix or Capsule, showed comparable functional and biological performance to the light-cured bulk-fill composite.
Clinical significance: The self-cured bulk-fill composite is a reliable alternative for posterior restorations. Despite minor aesthetic differences, clinical outcomes and patient satisfaction were unaffected, supporting its use in daily practice.

1. Introduction

Despite the global decline in caries prevalence worldwide, a substantial number of cavitated dentin carious lesions in posterior teeth remain untreated, particularly in underserved populations across low-income regions [1]. Furthermore, although the placement of dental amalgam has declined over the past 20 years in most countries [2] largely due to the improved durability of direct composite restorations [3] amalgam remains the preferred restorative material for filling direct cavities in posterior teeth in public health systems, especially in low- and

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middle-income countries, due to its clinical reliability and relatively low cost [4].

In this context, dental amalgam is still widely used, and the dental and scientific communities generally recognize it as a safe and durable material [5]. Nonetheless, regarding its potential risks to human health and the environment have emerged, particularly in light of the United Nations Minamata Convention on Mercury [6]. This led to the complete ban on the use of dental amalgam in the European Community, with a total phase-out scheduled for early 2025 [7]. As a result, the search for a viable, cost-effective, and less controversial alternative to amalgam continues to gain momentum.

Although modern restorative materials, particularly resin composites, are reasonable alternatives to amalgam, the placement of resin composites is technique-sensitive, time-consuming, and requires costly equipment such as light-curing devices [8]. These factors increase the overall cost of posterior restorations and can make the procedure stressful for clinicians, especially when working with posterior teeth [9]. Despite numerous efforts have been made to develop an alternative to dental amalgam [10], an ideal substitute has not yet been found [11].

Recently, a self-cured bulk-fill restorative material (Stela, SDI, Victoria, Australia) was introduced to the market as a promising alternative to dental amalgam. Since this material does not contain any photoinitiators in its composition, it does not require light activation and can therefore be used even in the absence of a curing light, as confirmed for a recent study [12]. Moreover, as a self-cured composite, it can be used in a single portion, because it offers an effectively unlimited depth of cure, making it particularly advantageous for deep cavity restorations, even with >5 mm [13]. These three characteristics closely align with those of dental amalgam [14], reinforcing its potential as a viable substitute.

Perhaps the most advantageous feature of self-cured composites is their inherently low shrinkage stress development [15–17]. This advantage is attributed to their low volumetric shrinkage, prolonged pre-gel phase, and gradual polymerization kinetics [9,15]. Typically, in self-cured composites, the polymerization reaction initiates at the center of the restoration, where the temperature is higher due to the greater bulk of material, and then propagates outward toward the periphery [16]. In contrast, for the Stela composite system, the manufacturer recommends the use of a specific primer (Stela Primer, SDI) before composite placement. A recent study [12] demonstrated that, in the presence of Stela Primer, the polymerization begins at the cavity walls and floor. This directional polymerization may help reduce stress development at the adhesive interface, and minimize the formation of gaps and voids when compared to light cured bulk-fill composite [18,19].

These characteristics can be crucial, as the formation of gaps and voids at the adhesive interface may lead to increased postoperative sensitivity. However, only randomized clinical trials can properly evaluate this postoperative sensitivity. In fact, a recent clinical study confirmed this hypothesis; restorations using the chemically-cured composite showed a reduced incidence of postoperative sensitivity compared to those with the light-cured composite, particularly within the first 48 h post-treatment [20].

Also, in the mentioned study, the restorations were evaluated for up to 6 months, showing only borderline differences when compared to the light-cured bulk-fill composite. It is worth mentioning that two different application forms of Stela (Stela Automix and Stela Capsule, SDI) were evaluated in this study. This distinction seems necessary because, according to the manufacturer, the chemical compositions of the two materials are significantly different [21]. However, the authors recognized that the current evidence, mainly from in vitro [12,18,19,22,23] and short-term clinical studies [20], is insufficient, highlighting the need for randomized clinical trials with follow-up periods longer than 6 months to fully assess the performance of this new material in clinical conditions [24,25]. Addressing this gap is the main objective of the present study.

The aim of this multicenter, double-blind, randomized controlled trial was to compare the clinical performance of posterior restorations placed with two forms of self-cured bulk-fill composites (Stela Automix and Stela Capsule, SDI) to those placed with a light-cured bulk-fill composite after 18 months of clinical service. The null hypotheses tested were: (1) the use of chemically cured composites (Stela Automix and Stela Capsule, SDI) does not affect the survival rate (material fracture and/or retention loss) of posterior composite resin restorations; and (2) the use of chemically cured bulk-fill composites does not affect any of the evaluated clinical parameters of posterior resin composite restorations.

2. Materials and methods

2.1. Ethical approval and protocol registration

The Ethics Committee of the State Univerisity of Ponta Grossa (Ponta Grossa, PR, Brazil) and Universidad de los Andes (Santiago, Chile) reviewed and approved the proposed protocol and authorized the participation of individuals in this study (protocol #5.972758 and #CEC2024049). All participants were informed about the study's objectives and nature and provided written informed consent prior to their inclusion. This clinical trial was registered in the Brazilian Clinical Trials Registry (RBR-255jzz9) and was conducted and reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement [26].

2.2. Trial design, settings, location of data collection and participants recruitment

This was a multicenter, double-blinded (patient and examiner), split-mouth randomized clinical trial conducted at the dental clinics of two universities' Schools of Dentistry. Participants were recruited during screening sessions at these dental clinics and through written notices posted on internal bulletin boards.

2.3. Eligibility criteria

One hundred and fifty participants were examined by two trained dental residents in each center to ensure they met the inclusion criteria, using an explorer, intra-oral mirror, and periodontal probe. Fifty-five participants (aged 27–73) were selected after agreeing to the study terms (Fig. 1). Inclusion required good general health, acceptable oral hygiene (OHI-$S \leq 3$) [27], at least 20 permanent teeth with three needing Class I or II restorations in vital teeth. Exclusion criteria included poor oral hygiene (OHI-$S > 3$) [27], severe periodontitis [28], use of dental prostheses, bruxism, parafunctional habits, ongoing anti-inflammatory or analgesic medication use, allergies to study materials, bleaching treatments, and pregnancy or breastfeeding. All selected participants signed a consent form to participate.

2.4. Characteristics of the teeth cavities to be included

Teeth selected for restoration had to be in occlusion with their natural antagonist and adjacent teeth. Criteria for resin composite restoration included primary caries or deficient existing amalgam or composite (Fig. 2). Only Class I or Class II cavities (involving the occlusal surface) with a depth of 3 mm or larger were considered. Measurements were taken using a bitewing radiograph and a ruler. Teeth requiring endodontic treatment, assessed via radiography and cold pulpal sensitivity tests (Roeko-Endo-Frost, Coltene/Whaledent, Langenau, Germany), were excluded.

2.5. Sample size

The primary outcome for this sample size estimation was the survival rate restorations, defined as the absence of failures requiring

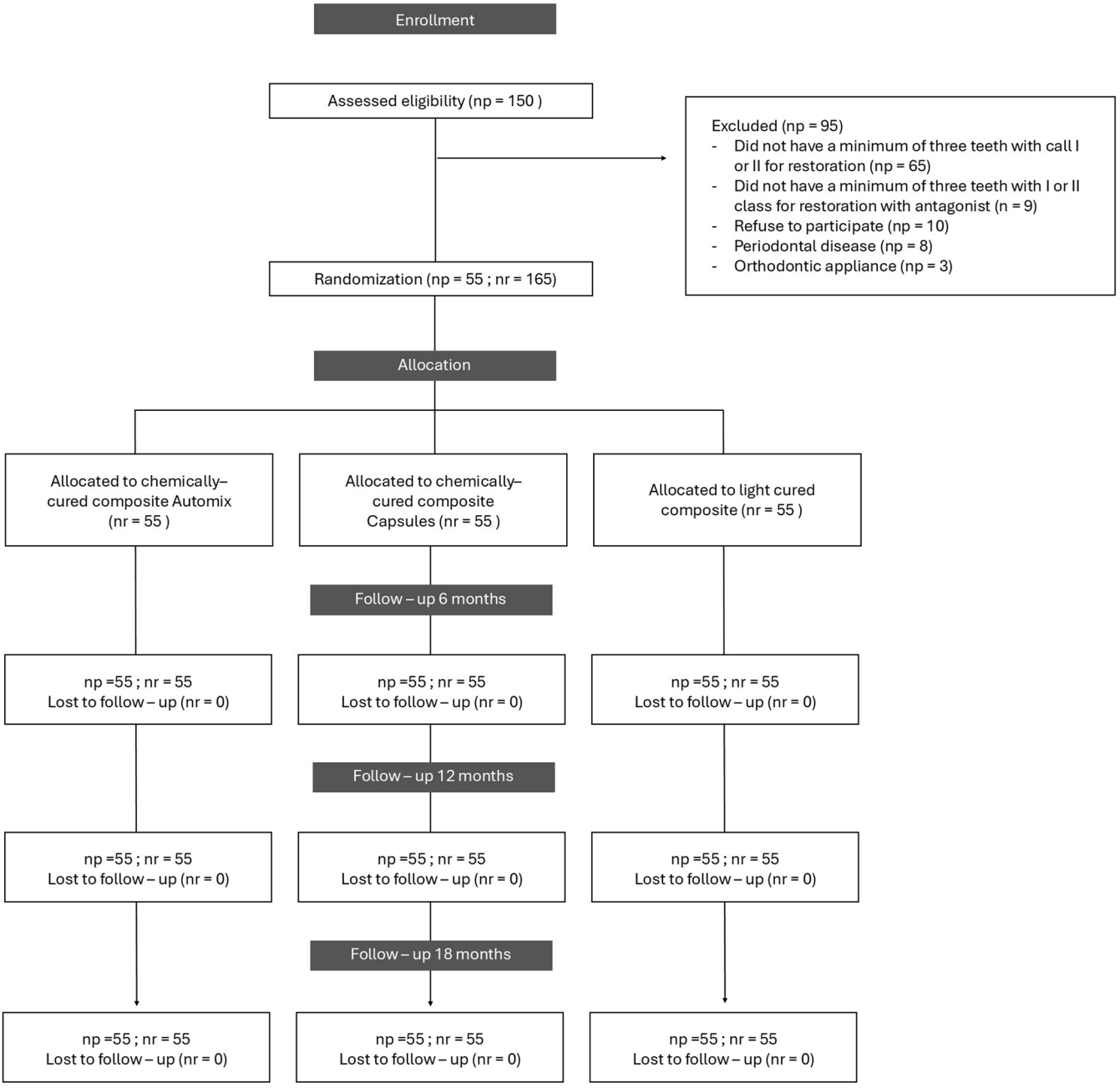

Fig. 1. Flow chart of the experimental design.

replacement (i.e., material fracture or loss of retention). Based on an estimated 5-year failure rate of approximately 5 % for posterior composite restorations [29,30], a non-inferiority margin of 15 % was selected. This margin reflects clinical relevance, as the procedural advantages of the novel chemically-cured composite, such as simplified placement and elimination of the need for light-curing unit, justify its consideration as a viable clinical alternative even its survival rate were up to 15 percentage points lower than the standard technique. Assuming no significant difference between the standard treatment (Filtek One Bulk Fill, Solventum, St. Paul, MN, USA) and the new treatments (Stela Automix or Stela Capsule, SDI), a total of 165 restorations (55 per group) is required to achieve over 80 % statistical power with a one-sided alpha of 0.05

2.6. Randomization sequence, allocation, and blinding

Randomization was conducted using software from http://www.sealedenvelope.com by an independent staff member. Each participant received three restorations, one from each group, in an intra-individual design. Group assignments were placed in opaque, sequentially numbered sealed envelopes, opened on the day of the procedure to ensure allocation concealment and prevent selection bias. Only the clinician performing the restoration was aware of the group assignment, as procedural knowledge was necessary. Participants and outcome examiners remained blinded, maintaining the double-blind, randomized clinical trial design.

2.7. Baseline characteristics of the selected teeth

Before placing restorations, the characteristics of posterior

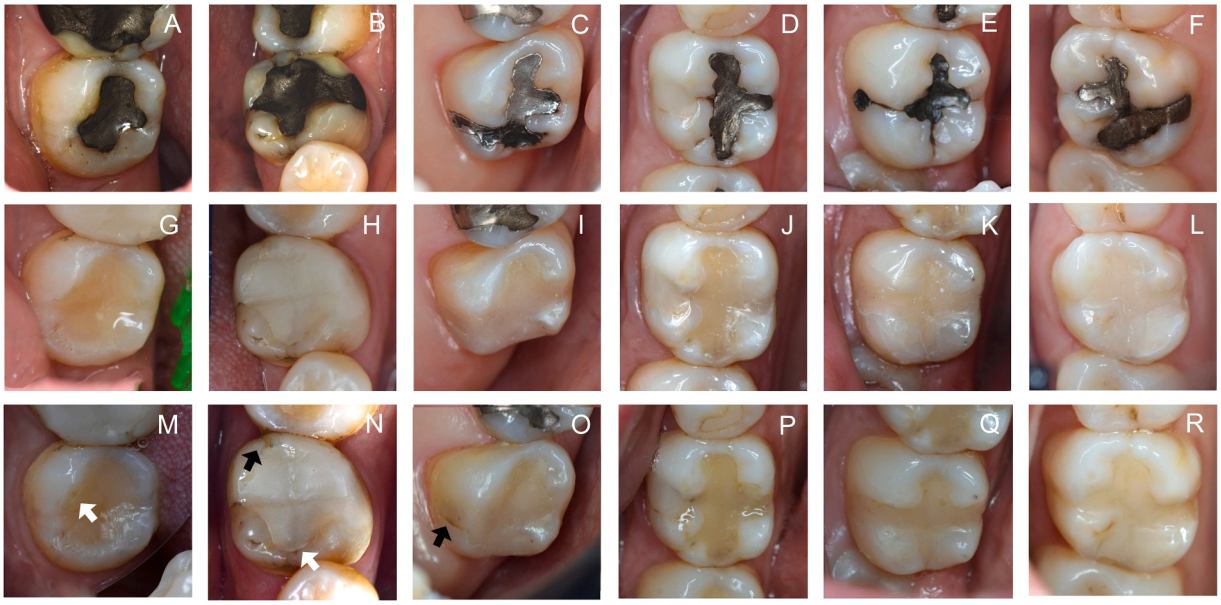

Fig. 2. Examples of posterior restorations performed in the present study. The upper row (A–F) illustrates amalgam restorations, which were replaced either due to defects or for esthetic reasons (based on patient complaints). The middle row (G–L) shows the appearance of the restorations at baseline, while the lower row (M–R) presents the same restorations after 18 months of follow-up. Bulk-fill light-cured composite restorations were rated as 'good' for color match both at baseline (G and J) and after 18 months (M and P). Chemically-cured composites applied in Capsule form showed a more polished and glossy surface at 18 months (N and Q) compared to their baseline appearance (H and K); however, they were rated as 'good' for surface texture and luster only at the baseline. Similarly, chemically-cured composites applied in Automix form also presented a more polished and glossy surface at 18 months (O and R) when compared to baseline (I and L). In this case, only the restoration in (I) was rated as 'good' for surface texture and luster. Additionally, slight loss of marginal adaptation (M and N; white arrows) and mild marginal staining (N and O; black arrows) were observed, though all of these were still rated as 'good' across all restorative materials.

restorations were evaluated, including the presence of antagonists and attrition facets (Table 1). Patient assessments involved caries risk and parafunctional habits (e.g., bruxism), based on clinical and sociodemographic data, and considered factors like incipient caries, caries history, and parafunctional habits (Table 1). Preoperative sensitivity, both spontaneous and in response to various stimuli (air, cold, heat, palpation, and vertical and horizontal percussion), was assessed before examination and were previously described [20].

2.8. Calibration procedure

Since the study involved two centers, clinicians from each center visited the other to calibrate restoration placement. The study director initially performed one restoration per group to outline the protocol in a laboratory setting. Then, clinicians inserted 3–4 restorations of each material, identifying any procedural difficulties. Following this, clinicians performed an additional four restorations per group in a clinical setting under the study director's supervision. Any discrepancies were addressed and resolved before starting the study, ensuring the clinicians were fully trained and qualified to perform the procedures.

2.9. Interventions: restorative procedure

Before the restorative procedures, clinicians cleaned the teeth with pumice and water, applied local anesthesia (3 % mepivacaine, Mepisv 3 %, DFL, Rio de Janeiro, RJ, Brazil), and isolated the teeth with a rubber dam, without additional retention or beveling. After isolation, cavity preparation was done using stainless steel burs (#329, 330, and/or 245, KG Sorensen, Barueri, SP, Brazil) in a high-speed handpiece with air-water irrigation, removing only caries-infected dentin and defective restorations. For Class II cavities, a Palodent sectional matrix system (Dentsply-Sirona, Charlotte, NC, USA) was used with proximal wedges for contouring. No liner or base was applied. Cavity dimensions (height, width, and depth) were measured with a periodontal probe (#6 Satin Steel Handled). After cavity preparation, the envelopes were opened, and clinicians were informed about the restorative materials to be used. These procedural details were previously described in our earlier study [20]. All participants received each of the three restorations as part of the following combination:

1. Automix group: Stela primer (SDI) was applied, followed by Stela Automix (SDI) using a syringe, according to the manufacturer's instructions (Table 2).
2. Capsule group: Stela primer (SDI) was applied, then Stela Capsules (SDI) were used following the manufacturer's guidelines (Table 2).
3. Control group (Filtek One Bulk Fill; Solventum): Scotchbond Universal (Solventum) was applied in self-etch mode only, to ensure a direct and methodologically consistent comparison with the self-etching Stela primer, followed by Filtek One Bulk Fill resin (shade A2B; Solventum) using a syringe, per the manufacturer's instructions. Light-curing was performed using the Radii Xpert (SDI) in the monowave mode for 10 s (adhesive) and 30 s (composite) at an irradiance of 1000 mW/cm^2. The light-curing tip was protected with a disposable plastic barrier specifically designed for this purpose. For composite polymerization, the tip was positioned in direct contact with the occlusal surface of the restoration. The irradiance was verified prior to each restoration using a radiometer (Bluephase Meter, Ivoclar Vivadent, Schaan, Liechtenstein; Table 2).

After removal of the metal matrix, proximal regions of Class II restorations were additionally polymerized buccally and lingually/palatally faces for 10 s. After completing the restorations, occlusal adjustment and final polishing were done [20]. Final results are shown in Figure 3. Proximal contacts were checked with dental floss and adjusted with finishing strips (Solventum). If necessary, a new radiograph was taken for confirmation.

2.10. Clinical evaluation

To ensure consistency in the evaluation process across both centers

Table 1
Characteristics of the Research Subjects, Dental Arches and Cavities per Group.

Characteristics of Research Subjects	No. of Subjects		
Gender Distribution			
Male	20		
Female	35		
Age distribution, years			
20–29	10		
30–39	15		
40–49	09		
>49	21		
Characteristics of Dental Arches and Cavities	Number of restorations		
	Chemically cured composite		Light-cured composite
	Automix	Capsule	
Presence of antagonist			
Yes	55	55	55
No	0	0	0
Attrition facet			
Yes	23	20	21
No	32	35	34
Tooth distribution			
Premolar	14	15	10
Molar	41	40	45
Arc distribution			
Maxillary	26	27	24
Mandibular	29	28	31
Cavity Depth			
3 mm	20	23	22
4 mm	20	15	22
> 4 mm	15	17	11
Black Classification			
I	37	36	41
II	18	19	14
Number of Restored Surfaces			
1	27	34	31
2	22	18	21
3	5	3	3
4	1	0	0
Reasons for Restoration			
Marginal fracture	11	10	7
Esthetic reasons (substitution of amalgam restorations)	39	40	43
Marginal discoloration	1	0	0
Bulk Fracture	0	1	0
Primary/Secondary caries lesion	4	4	5

involved in this study, representatives from each site visited the other for calibration purposes. A total of four fully trained and experienced evaluators, two at each center, independently assessed the restorations. These examiners were blinded to the treatment groups and had not participated in the restorative procedures. Calibration of the FDI evaluation criteria [31] was achieved through the review of 10 reference photographs illustrating the full range of scoring. Each examiner assessed 10 to 15 teeth on two separate occasions. Prior to beginning the clinical evaluations, a minimum intra- and inter-examiner agreement of 85 % was required to confirm calibration. Before assessments, dental prophylaxis with pumice and water was performed on all teeth. Evaluations were conducted using a dental explorer and intraoral mirror. For Class II restorations, proximal marginal adaptation was additionally assessed using dental floss and, when deemed necessary by the examiner, bitewing radiographs.

The standardized examination procedure included intraoral digital photographs of each restoration and a paper case report completed at each recall visit, ensuring that evaluators remained blinded to previous assessments throughout the follow-up period. Restorations were evaluated for spontaneous postoperative sensitivity (POS) at baseline (within 24 h), at 48 h, 7 days, and 6 months, as previously described [20]. The

Table 2
Material composition, adhesive, and restorative procedures.

Material [Batch Number]	Composition(*)	Adhesive and restorative procedures
Stela Primer (SDI, Victoria, Australia) [1210,131]	Methyl ethy ketone (10–30 %), 4-methacryloxyethyl trimellitic anhydride (10–30 %), acrylic monomer (10–30 %), 10-methacryloyloxydecyl dihydrogen phosphate (10-MDP; 10–30 %) and diurethane dimethacrylate (DUDMA; 10–30 %)(**)	1. Dispense 1–2 drops of Stela Primer into a plastic mixing well; 2. Apply the Stela Primer to all surfaces and margins for 10 s with vigorous agitation using a disposable applicator brush (Points, SDI). 3. Leave for 5 s; 4. Gently blow with air for 2–3 s.
Stela Automix (Chemically cured composite; SDI, Victoria, Australia) [1210,270]	Organic matrix(***): DUDMA (10–25 %), glycerol dimethacrylate (GDMA; 5–10 %), ytterbium fluoride (3–7 %) and 10-MDP (1–5 %). Filler content(****): Fluoro-alumino-silicate glass: mean particle size 4.0 μm (distribution range approx. 2 to 8 μm) and Barium-alumino-borosilicate glass: mean particle size 2.8 μm (distribution range approx. 2 to 5 μm). Filler loading: 61.2 wt % (36.4 vol %).	1. Remove cap of Stela Automix; 2. Attach the Stela Automix tip; 3. Dispense and discard the first 2–3 mm of paste to ensure even mixing; 4. After bending the metal tip to your preferred angle, extrude in a single step, slightly overfilling the cavity and its margins; 5. Delicately sculpt. Do not remove material from margins before it is fully set; 6. Stella will polymerise 4 min after mixing; 7. After four minutes, remove the inhibition layer using a gauze; 8. Finish and polish the restoration.
Stela Capsules (Chemically cured composite; SDI, Victoria, Australia) [1210,270]	Organic matrix(***): DUDMA (10–25 %), GDMA (5–10 %), silica amorphous, fumed (1–10 %), ytterbium fluoride (3–7 %) and 10-MDP (1–5 %). Filler content(****): Fluoro-alumino-silicate glass: median particle size 4.0 μm (distribution range approx. 2 to 8 μm). Filler loading: 76.8 wt % (55.4 vol %).	1. Activate the Stela capsule by pressing down on the plunger; 2. Mix Stela capsule for 10 s (Ultramat 2, SDI); 3. Place Stela capsule into the SDI applicator; 4. Click the trigger of the capsule applicator until paste is seen through the clear nozzle; 5. Extrude in a single step, slightly overfilling the cavity and its margins; 6. Delicately sculpt. Do not remove material from margins before it is fully set;

(*continued on next page*)

Table 2 (*continued*)

Material [Batch Number]	Composition(*)	Adhesive and restorative procedures
		7. Stella will polymerise 4 min after mixing; 8. Finish and polish the restoration.
Scotchbond Universal Adhesive (Solventum, St Paul, MN, USA) [691,954]	10-MDP, phosphate monomer, dimethacrylate resins, hydroxyethyl methacrylate, methacrylate-modified polyalkenoic acid copolymer, filler, ethanol, water, silane and camphorquinone	1. Dispense 1–2 drops of adhesive into a plastic mixing well; 2. Apply the adhesive for 20 s with vigorous agitation using a disposable applicator brush (Points, SDI). 3. Gently air for 5s 4. Light cure for 10 s (1000 mW/cm^2)
Filtek Bulk Fill Posterior Restorative (Light-cured composite; Solventum, St. Paul, MN, USA) Shade A3 [N68566]	Organic Matrix: aromatic urethane dimethacrylate (AUDMA), UDMA, 1,12-dodecane-DMA and camphorquinone. Filler content: non-agglomerated/non-aggregated 20 nm silica filler, a non-agglomerated/non-aggregated 4 to 11 nm zirconia filler, aggregated zirconia/silica cluster filler (comprised of 20 nm silica to 4 to 11 nm zirconia particles), and ytterbium trifluoride filler of 100 nm particles. Filler loading: 76.5 wt 58.4 vol %.	1. Single increments of 4–5 mm were placed and light-cured (1000 mW/cm^2) for 40 s in each restoration

(*) 10-MDP: 10-methacryloyloxydecyl dihydrogen phosphate; DUDMA: diurethane dimethacrylate; GDMA: glycerol dimethacrylat; AUDMA: aromatic urethane dimethacrylate; UDMA: diurethane dimethacrylate; DMA: dimethacrylate.
(**) Stela Primer (2023). Available in: https://www.sdi.com.au/pdfs/sds/au/stela%20primer_sdi_sds_au.pdf.
(***) Stela Product brochure (2023). Available in: https://www.sdi.com.au/pdfs/brochures/en-us/stela_sdi_brochures_en-us.pdf.
(****) Stela Automix, Stela Capsule. MSDS (2022). Available in: https://www.sdi.com.au/pdfs/sds/au/stela%20automix_sdi_sds_au.pdf.. More details regarding Stela Primer, Stela Automix and Stela capsules can be found in [38].

same procedure was repeated at the 12- and 18-month recalls. Final POS outcomes were categorized into two parameters: (1) the percentage of patients reporting POS at least once during the evaluation period (absolute risk), and (2) the overall intensity of POS across the 12- and 18-month timepoints.

All other clinical parameters outlined in the updated version of the FDI criteria (Supplementary Table S1) were assessed at baseline and after 6 months [20], as well as at 12 and 18 months of clinical service. The functional, biological, and aesthetic parameters are described in Supplementary Table S1. Each evaluated property was rated according to the FDI criteria using the following clinical ratings: excellent/very good (VG), clinically good (CG), clinically satisfactory (SS), clinically unsatisfactory (CU), and clinically poor (PO) [31] (Supplementary Table S1). In the present study, postoperative hypersensitivity and pulpal status (B3) were included among the evaluated parameters and assessed according to the FDI criteria.

Also, two criteria categorized as miscellaneous were evaluated: patient's view (M1) as previously reported [20]. For M1, the patient satisfaction was accessed after 12 and 18 months. Participants selected the option that best reflected their level of satisfaction with the procedure. In cases of dissatisfaction, details were recorded on issues such as pain, hypersensitivity, chewing comfort, occlusion, proximal contacts, cleanability, contours, and aesthetics. For M2, radiographic examination was performed only if the patient reported symptoms or if contact point/food impaction (F3) was rated as unsatisfactory or poor [31]. All restorations were evaluated individually by the examiners, and any disagreements were resolved by consensus before the participant was dismissed.

2.11. Statistical analysis

The statistician was blinded to group allocation. Statistical analysis followed the intention-to-treat principle, as recommended by CONSORT [26]. Descriptive statistics were used to summarize the distribution of evaluated criteria. For all outcomes, differences between the three groups at 12 and 18 months were analyzed using the Friedman repeated measures ANOVA by rank. Additionally, changes in the ratings within each group from baseline to 12 and 18 months were evaluated using the Chi-square test ($\alpha = 0.05$). Inter-examiner agreement was assessed using Cohen's kappa statistic (Statistica for Windows 7.0, StatSoft Inc., Tulsa, OK, USA).

3. Results

A total of 150 participants were screened for eligibility, and 95 were excluded for not meeting the inclusion criteria (Fig. 1). Consequently, 165 restorations were placed in 55 participants (20 males and 35 females) as shown in Table 1. Each participant received three restorations—one from each experimental group—($n = 55$). The restorative procedures were carried out exactly as planned, with no deviations from the protocol. Baseline cavity characteristics were recorded for all restorations (Table 1). At each follow-up, restorations were clinically evaluated and photographed (Fig. 2). Inter- and intra-examiner agreement levels exceeded 0.85 across all evaluation periods. All participants attended the one-week, 6-, 12-, and 18-month recall visits. The clinical outcomes at the 6-month follow-up were previously reported in detail [20]. Table 4 presents the data from all follow-up periods, while Fig. 2 shows representative images of the restorations at baseline and at the 18-month recall

3.1. Functional properties

At the 12-month follow-up, no restorations exhibited material fractures or loss of retention (F1), loss of contact point/food impaction (F3), deviations in form and contour (F4), or issues related to occlusion and wear (F5; Table 3). Minor deviations in marginal adaptation (F2), rated as clinically good, were observed in only seven restorations. These findings are consistent with previous results [20], with no statistically significant differences observed either among the groups or within each group when comparing baseline and 18-month evaluations ($p > 0.11$; Table 3).

After 18 months, one Class II restoration in the self-cured composite applied via Capsule presented a small proximal box fracture (rated as clinically good for both F1 and F3). The number of restorations with minor deviations in marginal adaptation (rated as clinically good for F2) increased to nineteen; however, this difference was not statistically significant among the groups ($p = 1.0$; Table 3). In contrast, a significant difference was observed when comparing baseline and 18-month data within each group ($p < 0.02$; Table 3). Both the self-cured composite in Capsule form and the light-cured composite exhibited slight deviations in marginal adaptation at the 18-month follow-up.

Twelve restorations exhibited minor deviations in form and contour (F4), all rated as clinically good, with no statistically significant differences observed either among the groups or within each group when comparing baseline to 18-month evaluations ($p > 0.06$; Table 3). No issues related to occlusion and wear (F5) were identified at the 18-month follow-up.

Table 3
Number of evaluated restorations for each experimental group(*) classified according to the World Dental Federation (FDI) criteria for functional, biological and aesthetic properties [31].

Functional properties	Time (*;**)	Baseline AU	CA	CO	6-month AU	CA	CO	12-month AU	CA	CO	18-month AU	CA	CO
F1. Fracture of material and retention	VG	55	55	55	55	55	55	55	55	55	55	54	55
	GO	–	–	–	–	–	–	–	–	–	–	01	–
	SS	–	–	–	–	–	–	–	–	–	–	–	–
	CU/PO	–	–	–	–	–	–	–	–	–	–	–	–
F2. Marginal adaptation	VG	55	55	55	53	54	51	53	54	51	49	48	49
	GO	–	–	–	02	01	04	02	01	04	06	07	06
	SS	–	–	–	–	–	–	–	–	–	–	–	–
	CU/PO	–	–	–	–	–	–	–	–	–	–	–	–
F3. Contact point/food impact (***)	VG	18	19	14	18	19	14	18	19	14	18	18	14
	GO	–	–	–	–	–	–	–	–	–	–	01	–
	SS	–	–	–	–	–	–	–	–	–	–	–	–
	CU/PO	–	–	–	–	–	–	–	–	–	–	–	–
F4. Form and contour	VG	55	55	55	55	55	55	55	55	55	51	50	52
	GO	–	–	–	–	–	–	–	–	–	04	05	03
	SS	–	–	–	–	–	–	–	–	–	–	–	–
	CU/PO	–	–	–	–	–	–	–	–	–	–	–	–
F5. Occlusion and wear	VG	55	55	55	55	55	55	55	55	55	55	55	55
	GO	–	–	–	–	–	–	–	–	–	–	–	–
	SS	–	–	–	–	–	–	–	–	–	–	–	–
	CU/PO	–	–	–	–	–	–	–	–	–	–	–	–

Biological and aesthetic properties	Time	Baseline AU	CA	CO	6-monht AU	CA	CO	12-month AU	CA	CO	18-month AU	CA	CO
B1. Recurrence of caries	VG	55	55	55	55	55	55	55	55	55	55	55	55
	GO	–	–	–	–	–	–	–	–	–	–	–	–
	SS	–	–	–	–	–	–	–	–	–	–	–	–
	CU/PO	–	–	–	–	–	–	–	–	–	–	–	–
B2. Dental hard tissue defects at the restoration margin	VG	55	55	55	55	55	55	55	55	55	55	55	55
	GO	–	–	–	–	–	–	–	–	–	–	–	–
	SS	–	–	–	–	–	–	–	–	–	–	–	–
	CU/PO	–	–	–	–	–	–	–	–	–	–	–	–
B2. Postoperative hypersensitivity and pulpal status	VG	55	55	55	55	55	55	55	55	55	55	55	55
	GO	–	–	–	–	–	–	–	–	–	–	–	–
	SS	–	–	–	–	–	–	–	–	–	–	–	–
	CU/PO	–	–	–	–	–	–	–	–	–	–	–	–
A1. Surface luster and surface texture	VG	45	41	49	45	41	49	45	41	49	47	45	51
	GO	10	14	06	10	14	06	10	14	06	08	10	04
	SS	–	–	–	–	–	–	–	–	–	–	–	–
	CU/PO	–	–	–	–	–	–	–	–	–	–	–	–
A2. Marginal staining	VG	55	55	55	55	55	55	50	49	49	47	44	47
	GO	–	–	–	–	–	–	05	06	06	08	11	08
	SS	–	–	–	–	–	–	–	–	–	–	–	–
	CU/PO	–	–	–	–	–	–	–	–	–	–	–	–
A3. Color match	VG	47	48	38	47	48	38	47	48	38	44	43	38
	GO	08	07	17	08	07	17	08	07	17	11	12	17
	SS	–	–	–	–	–	–	–	–	–	–	–	–
	CU/PO	–	–	–	–	–	–	–	–	–	–	–	–

(*)AU (Automix chemically-cured composite), CA (Capsule chemically-cured composite), LC (light-cured composite).
(**)VG for clinically excellent/very good; GO for clinically good; SS for clinically satisfactory; CU for clinically unsatisfactory and; PO for clinically poor.
(***)Only for Class II restorations.

3.2. Biological properties

No restorations were scored for recurrence of caries (B1), defects in dental hard tissues at the restoration margin (B2), or postoperative 'hypersensitivity' and pulpal issues (B3; Table 3). Although significant differences in 'spontaneous' postoperative sensitivity were observed within the first 48 h,favoring the self-cured bulk-fill composites [20], no significant differences were found after 7 days and 6 months [20], or after 12 and 18 months of clinical evaluation ($p = 1.00$; Table 3). Additionally, no patients reported 'spontaneous' postoperative sensitivity at the 12- or 18-month follow-ups.

3.3. Aesthetic properties

After 12 months, seventeen restorations exhibited marginal staining, rated as clinically good (A2; Table 3), with no statistically significant differences observed among the groups ($p = 1.00$; Table 3). However, a significant difference was observed within the groups receiving the self-cured composite in Capsules and the light-cured composite when comparing baseline to 12-month data ($p = 0.02$; Table 3).

For surface luster and texture (A1) and color match (A3), the number of restorations rated as clinically good at the 12-month evaluation remained consistent with the previous assessment (Table 4; [20]). Specifically, thirty restorations were rated as clinically good for A1, with a significant difference favoring the light-cured composite over the self-cured composite in Capsules (Fig. 2; $p = 0.03$; Table 3). However, no statistically significant differences were observed within each group when comparing baseline to 12-month data ($p = 1.0$; Table 3). For color match (A3), thirty-two restorations were rated as clinically good, with a significant difference favoring both self-cured composites over the light-cured composite (Fig. 2; $p = 0.03$; Table 3). Again, no significant differences were observed within each group when comparing baseline to 12-month evaluations ($p = 1.0$; Table 3).

After 18 months, 22 restorations were rated as clinically good for

surface luster and texture (A1), 27 for marginal staining (A2), and 40 for color match (A3), with no statistically significant differences among the groups (Fig. 2; $p > 0.15$; Table 3). However, a significant difference was observed within all groups when comparing baseline to 18-month data for marginal staining (A2) ($p < 0.006$; Table 3). No statistically significant differences were observed within each group when comparing baseline to 18-month evaluations for surface luster and texture (A1) or for color match (A3); $p = 1.0$; Table 3).

3.4. Miscellaneous criteria

From the patient's perspective (M1), all participants reported being very satisfied with their restorations at both the 12- and 18-month follow-ups, even the individual who experienced a small fracture in a Class II restoration (F3), as previously reported. In this specific case, an additional radiograph was taken (M2), but no further issues were detected (Table 3).

4. Discussion

This randomized clinical trial assessed the clinical performance of a novel chemically-cured resin composite applied in two delivery forms, Automix and Capsule, and compared it to light-cured bulk-fill resin composite restorations. The findings demonstrated that, regardless of the application form, the chemically-cured composite exhibited a comparable survival rate in terms of material fracture and retention when used in posterior restorations, relative to light-cured bulk-fill composites. These results support the acceptance of the first null hypothesis. To the best of our knowledge, this is the first clinical investigation to compare both delivery modes of this new chemically-cured resin composite with a light-cured bulk-fill composite over an 18-month evaluation period. Despite the relatively short 18-month follow-up period, this randomized clinical trial was justified by the need to generate early clinical data for a new chemically-cured resin composite developed for direct posterior restorations. As this material is newly introduced, it is important to discuss its characteristics in detail to help explain the outcomes (primary and secondary) observed in the present study.

The very good clinical performance of the chemically-cured composites, particularly regarding material fracture and retention, can be directly explained by key material properties such as the type and amount of filler particles, a higher degree of resin matrix conversion, and strong filler-resin interaction. According to the manufacturer, although both commercial presentations of the chemically-cured composite share the same name (Stela), their compositions differ depending on the delivery form. Stela Automix contains 61.2 wt % filler, while the Stela Capsule formulation has a higher filler content of 76.8 wt %. This high filler loading in the Capsule version, which is comparable to that of the light-cured bulk-fill control (76.5 %) [32,33], contributes to its superior mechanical properties compared to the Automix form [12,18,19,22,23]. Nevertheless, both chemically-cured materials demonstrated flexural strengths above 80 MPa, which is considered adequate for load-bearing posterior restorations [34].

Notably, both chemically-cured versions exhibited mechanical properties values comparable to or even exceeding those of other materials commonly used for posterior restorations [12,13,18,19,22,23]. This performance may be explained by their material's unique fracture behaviour and their superior internal structure [12,13,18,19,22,23]. While conventional composites often exhibit a brittle fractures, recent in vitro study confirms that Stela tends to fracture into multiple smaller fragments, a behavior described as a "globally ductile fracture". This pattern, which suggests an ability to dissipate energy and resist catastrophic failure, is attributed to the material's microstructure [13]. Studies have shown that Stela's formulation results in low internal porosity and a strong filler-matrix interface, leading to superior adaptation and an absence of gaps [18,19,22].

The degree of conversion is another critical factor influencing the mechanical properties of resin-based materials, as higher conversion rates lead to enhanced performance [35,36]. However, the degree of conversion can be influenced by the mode of polymerization. Light-cured composites rely on a light-curing unit for polymerization, and manufacturers typically recommend curing bulk-fill composites in increments no thicker than 5 mm [37]. Consequently, the degree of conversion is directly dependent on the performance of the light-curing unit, as well as the thickness of the composite layer being cured.

In contrast, self-cured composites, such as Stela, do not contain photoinitiators and therefore can polymerize without the need for a curing light [38]. As a result, they offer an effectively unlimited depth of cure and may achieve a higher degree of conversion compared to light-cured composites [12,39,40]. In fact, a recent in vitro study reported a degree of conversion of approximately 72 % for the chemically-cured composite [12], whereas the bulk-fill light-cured composite reached comparable values only in the superficial areas closest to the light source [39,40]. Taking together, these characteristics help to explain the comparable functional performance between the chemically-cured and light-cured bulk-fill composites in our study. It should also be noted that the success rate regarding material fracture and retention loss in the current study was around 95 %, similar to Loguercio et al. [41] and Bayraktar et al. [42], when restorations of light-cured composites were performed.

However, when compared to baseline values, some signs of degradation on the margin of the restorations were observed for all restorative materials, as observed for the number of restorations with defects in the margin, as well as with marginal staining after 18 months of clinical evaluation. A significant drawback of all methacrylate-based composites is that their polymerization process is inherently accompanied by considerable shrinkage, which occurs concurrently with bonding to the tooth structure [15–17,43]. This polymerization shrinkage creates internal contraction forces that result in stress development both within the material and at the adhesive interface. Clinically, the composite's ability to relieve strain is limited by its confinement within the bonded cavity, causing shrinkage to translate directly into stress. This stress can compromise the integrity of the adhesive interface and is considered one of the primary contributors to the formation of internal or marginal gaps [15–17].

Therefore, taking in consideration that chemically-cured composites showed a higher degree of conversion when compared to bulk-fill light-cured composite, it is possible to think that the former will be achieve a higher stress in the adhesive interface. In fact, while light-cured composites tend to generate faster and higher polymerization shrinkage stresses immediately after light activation, chemically-cured composites undergo a slower and more gradual polymerization process. This extended reaction results in a longer viscous phase, allowing the material to flow for a longer period compared to light-cured composites [16,43]. As a result, the prolonged flowability of chemically-cured composites helps minimize polymerization shrinkage and the associated stress. In contrast, light-cured composites quickly lose their capacity to flow, become more rigid, and develop a higher elastic modulus—ultimately resulting in greater residual shrinkage stresses within the restoration [17].

Interestingly, a recent in vitro study demonstrated that Stela Automix exhibits a relatively fast polymerization rate [12], which differs from other dual- or self-cured materials that typically have slower reaction kinetics [44,45]. Moreover, this polymerization rate appears to be further enhanced when the chemically-cured composite is used in conjunction with the Stela Primer [12]. Notably, the direction of the polymerization front also shifts when Stela Primer, a specific touch-curing primer, is applied.

While conventional chemically-cured composites generally begin polymerizing from the center of the restoration, where the temperature is highest due to the greater bulk, the use of Stela Primer initiates the polymerization reaction at the cavity walls and floor. This shift in polymerization direction, beginning at the adhesive interface rather

than in the central mass, may contribute to improved bonding to the tooth structure and reduced gap formation at the interface, as recently shown in vitro studies [18,19]. Unfortunately, the specific formulation and initiator components of Stela Primer and Stela composite are proprietary and protected under patent rights [38]. As a result, the underlying mechanisms are not fully disclosed or understood. However, since all restorative materials showed similar scores for marginal adaptation, differences in polymerization appear to have had a greater impact on the lower postoperative sensitivity observed with chemically cured composites compared to bulk-fill light-cured composites, as previously reported in the immediate follow-up results [20].

Another factor that helps explain these marginal discrepancies is the adhesive system used in the restorative procedure. Note that Scotchbond Universal was used with the light-cured composite, whereas Stela Primer was associated with the chemically cured composites. Both materials are considered ultra-mild adhesives due to their relatively high pH (~3.2), including Stela Primer (2–3; internal data). This pH may account for the significant deterioration in marginal adaptation and increased marginal staining observed from baseline to 18 months, particularly when the self-etch strategy is employed, as in the present study and in agreement with the previous ones [41,42,46,47]. The less aggressive etching pattern of self-etch adhesives, when compared to protocols involving prior phosphoric acid etching, may help explain these outcomes [48,49]. However, despite these marginal discrepancies, both materials contain MDP in their composition, a functional monomer known for its ability to chemically bond to hydroxyapatite, thereby enhancing the durability and stability of the adhesive interface [50], and both materials were applied with active agitation using a micro brush, a technique known to enhance bonding effectiveness to enamel, when adhesives are applied in the self-etch mode [48]. It is also important to highlight that the marginal discrepancies were primarily observed at the enamel margins and they are in agreement with previous studies [41,42,46]. This finding was not considered a clinical failure, as it can typically be resolved with simple repolishing of the restoration [31].

Although this randomized clinical trial assessed only the short-term (18-month) clinical performance of the materials, notable differences were observed among the groups, particularly in surface luster, surface texture, and color match, even within this limited evaluation period. The chemically cured composite applied in capsule form exhibited lower surface luster and a rougher texture compared to the light-cured composite. This difficulty in achieving a smooth, glossy finish may be attributed to challenges in polishing these restorations [51]. Notably, the capsule-based chemically cured composite contains irregular fillers, with mean particle sizes of 4 μm (range: 2–8 μm), whereas the light-cured composite features spherical nanofillers ranging from 4 to 100 nm. Larger and irregular fillers are more prone to dislodgement during polishing, leading to pits or surface defects. In contrast, nanofill composites such as the light-cured material used in this study, are known for their excellent polishability and ability to maintain surface gloss after finishing and polishing [52,53]. Although no significant differences were observed between the two chemically cured composites, some compositional variations help explain the present findings. The Automix material contains smaller average filler particles and a lower filler loading (61.2 wt %) compared to 76.8 wt % in the Capsule formulation. These differences likely contribute to the superior polishability observed with the Automix chemically cured composite [52,53].

However, it seems that these material characteristics were more relevant in the initial recall periods, as the number of restorations showing deviations in surface luster and texture decreased after 18 months, even among the light-cured composite group. This may be explained by the natural smoothing of the restoration surfaces due to functional wear over time, as well as the potential effects of regular oral hygiene and polishing during follow-up visits, which can enhance surface uniformity regardless of the initial material properties [31].

In terms of color match, the light-cured composite exhibited a greater degree of mismatch (31 %) compared to the chemically-cured composites (14 %). Part of the clinical success of bulk-fill composites is attributed to their ability to achieve deep polymerization. To facilitate this, bulk-fill materials are designed to be more translucent than incrementally placed composites, which allows for greater light penetration into deeper layers and reduces light scattering [54,55]. Several studies have confirmed the higher translucency of bulk-fill composites, a property commonly associated with the incorporation of larger filler particles and a lower concentration of color pigments [54,55].

However, this increased translucency can negatively impact the esthetic outcome of restorations, particularly in cases where bulk-fill composites are used to replace amalgam restorations—, as was the case in 74 % of the restorations in the present study. Dentin with dark discoloration beneath amalgam fillings is typically associated with the presence of corrosion by-products [56], which are difficult to mask using bulk-fill composites alone. Restorations rated as color match B often exhibited a slight grayish hue [20].

Conflicting results have been reported regarding the rate of color mismatch in posterior restorations using bulk-fill composites. While some authors [41,57] found mismatch values similar to those observed in the present study, others reported that 100 % of the restorations achieved an ideal match with the adjacent tooth structure in terms of color and translucency [46]. Two key factors may help explain these discrepancies. First, studies reporting higher rates of color mismatch often clearly stated the reasons for replacing the restorations. Second, these studies employed the FDI evaluation criteria, also used in the present study [41,57], as opposed to others that relied on the USPHS [42,46,47]. It is well established that the FDI criteria are more sensitive to subtle esthetic discrepancies compared to the USPHS system. However, it is worth mentioning two points: (1) despite some initial color mismatch, there was no significant increase over the 18-month follow-up period, indicating that all materials used demonstrated acceptable color stability over time; and (2) this initial color mismatch may be of minor concern in posterior teeth, but it becomes more critical in premolars, where esthetics play a more prominent role [58].

Although some differences were observed among the materials in terms of aesthetic properties, these minor discrepancies were not considered failures and were classified as clinically acceptable, requiring only periodic monitoring of the restorations [31]. Nevertheless, it is important to note that aesthetic properties are generally less critical in posterior restorations compared to functional and biological performance. In this regard, all restorations were rated as clinically excellent or very good, with no significant differences observed among the composites when key functional and biological criteria were assessed.

Several limitations of this study should be acknowledged. First, the 18-month follow-up represents a short-term evaluation, which may not be sufficient to fully determine the long-term clinical performance of the newly developed chemically-cured composites. Extended follow-up periods are therefore essential. Second, >60 % of the restorations in this study were Class I, which typically present a lower risk of failure than Class II restorations. Since Class II restorations involve more complex stress distributions and are generally more prone to marginal degradation and secondary caries, future studies should include a greater proportion of Class II cases to better assess the material's performance under more challenging clinical conditions. Third, patient-related variables such as occlusal forces, parafunctional habits, or oral hygiene status were not controlled or stratified, which could influence clinical outcomes and should be considered in future trials. Finally, in the present study, both adhesive systems (Stela Primer and Scotchbond Universal) were applied in the self-etch mode primarily to avoid bias, given that Stela Primer is specifically indicated for use in this mode. Although it is commonly believed that selective enamel etching enhances adhesive longevity compared to self-etch application alone, a recent systematic review reached conclusions consistent with our findings when evaluating posterior composite restorations [59]. Nevertheless, further clinical studies are needed, particularly to assess the performance of Stela Primer with or without selective enamel etching.

5. Conclusion

A novel chemically-cured resin composite applied in two delivery forms, Automix and Capsule—appears to be a promising alternative for posterior restorations, considering that no clinical differences were observed in functional or biological outcomes when compared to a light-cured bulk-fill resin composite.

The minor differences observed, favorable to the chemically-cured resin composite in terms of color match, and to the light-cured bulk-fill resin composite in terms of surface luster and texture (Capsule), did not compromise the overall clinical performance or patient satisfaction of any group after 18 months of clinical evaluation.

Ethical approval and protocol registration

The ethics committee of the State University of Ponta Grossa (Ponta Grossa, PR, Brazil) and Universidad de los Andes (Santiago, RM, Chile) reviewed and approved the proposed protocol and authorized the participation of individuals in this study (protocol #5.972.758 and #CEC2024049 respectively). All participants were informed about the study's objectives and nature and provided written informed consent prior to their inclusion. This clinical trial was registered in the Clinical Trials Registry (RBR-255jzz9) and was conducted and reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement.

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CRediT authorship contribution statement

Alessandro D. Loguercio: Writing – review & editing, Writing – original draft, Visualization, Project administration, Funding acquisition, Conceptualization. **Byron Carpio-Salvatierra:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Conceptualization. **Romina Ñaupari-Villasante:** Writing – original draft, Methodology, Investigation, Conceptualization. **Ana Armas-Vega:** Writing – original draft, Resources, Conceptualization. **Sofia Cavagnaro:** Writing – original draft, Investigation, Conceptualization. **Antonia León:** Writing – original draft, Investigation, Conceptualization. **Romina Aliaga-Galvez:** Writing – original draft, Methodology, Conceptualization. **Carlos José Soares:** Writing – review & editing, Project administration, Conceptualization. **Mario Felipe Gutierrez:** Writing – review & editing, Supervision, Project administration, Methodology, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jdent.2025.106031.

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