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Clinical evaluation of a new chemically-cured bulk-fill composite in posterior restorations: 6-month multicenter double-blind randomized clinical trial

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ABSTRACT

Objective: To evaluate the postoperative sensitivity (POS), as well as the clinical performance of posterior restorations using a new chemically-cured bulk-fill composite (Stela Automix and Stela Capsule, SDI) comparing with a light-cured bulk-fill composite after 6 months.
Methods: Fifty-five participants with at least three posterior teeth needing restoration were recruited. A total of 165 restorations were performed on Class I or Class II cavities. After the application of Stela primer, the chemically-cured composite (Stela Automix or Stela Capsule) was inserted. For the light-cured composite group, a universal adhesive (Scotchbond Universal) was applied with a bulk-fill composite (Filtek One). Participants were evaluated for spontaneous and stimulated POS in the baseline, after 48 h, 7 days, and 6 months. Additionally, each restoration was assessed using the updated version of FDI criteria after 6 months. The differences in the proportions of the groups were compared by Cochran test statistics ($\alpha = 0.05$).
Results: Both chemically-cured composites showed a lower risk of POS compared to the light-cured composite at baseline and up to 48 h ($p < 0.04$). A significantly lower surface luster and texture was observed for the Stela Capsule composite compared to the light-cured bulk-fill composite (baseline and 6 months; $p = 0.03$). A significant color mismatch was observed for the light-cured bulk-fill composite compared to the chemically-cured composites (baseline and 6 months; $p = 0.03$). No significant differences were observed in any other item evaluations ($p > 0.05$).
Conclusion: Chemically-cured composites exhibit lower postoperative sensitivity and less color mismatch compared to a light-cured bulk-fill composite after 6 months of clinical service.
Clinical significance: The chemically-cured composites appear to be an appealing option for restoring posterior teeth, as they exhibit lower postoperative sensitivity compared to a light-cured bulk-fill composite, both at baseline and up to 48 h, and less color mismatch.

1. Introduction

Although the significant decrease of caries as a disease worldwide, the majority of cavitated dentin carious lesions in posterior teeth remain unrestored in several poor communities throughout the world [1]. In addition to the above, despite the increasing use of resin composites in posterior teeth [2,3], amalgam continues to be the preferable restorative material for filling cavities in posterior teeth in public health, mainly in low- and middle-income countries due to its effectiveness and relatively low cost [4].

Although the use of dental amalgam is widespread, dental and scientific communities generally believe amalgam is safe and effective, though concerns have been raised about the adverse effect on human health and the environment, based on the United Nations Minamata Convention on Mercury [5]. Due to all these facts, the demand for a true amalgam alternative kept on increasing. Although modern restorative

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materials, particularly resin composites, are reasonable alternatives to amalgam, it is difficult for them to compete with the beneficial characteristics of amalgam, such as easy handling, no requirement for expensive equipment like light-curing devices, and extended durability [6,7]. Despite many attempts to develop an alternative to amalgam [8], currently, no "perfect" alternative is available [9].

Recently, a chemically-cured (self-cured), bulk-fill restorative material has been introduced in the market (Stela, SDI, Victoria, Australia). This product is offered in two application forms (Stela Automix and Stela Capsule) and features an adhesive feature that does not require light-curing, as it polymerizes upon contact with the restorative material. A few in vitro studies have evaluated this new material with promising results [10–12].

However, the most appealing aspect of chemically cured composite materials is their ability to generate minimal shrinkage stress [13–15]. This is due to their low shrinkage, prolonged pre-gel phase, and gradual polymerization, which can reduce stress development at the adhesive interface, and minimize the formation of voids and gaps [13,16]. These characteristics can be crucial, since increased postoperative sensitivity (POS) may clinically manifest as a result of such issues. Indeed, a recent in vitro study indicates that employing chemically-cured composites leads to a resin-dentin interface less prone to gaps and voids when compared to light cured bulk-fill composite, even following extended storage in artificial saliva [11]. Nevertheless, the authors acknowledged that, due to the limitations of in vitro studies, clinical trials are necessary for a more comprehensive evaluation of the clinical behavior of this new material [17,18].This is the objective of the present study.

The aim of this double-blinded, randomized controlled trial was to compare the clinical performance, which focused on postoperative sensitivity, and posterior restorations placed with chemically-cured bulk-fill composite (Stela Automix and Stela Capsule), to light-cured bulk-fill composite after 6 months of clinical service. The null hypotheses tested were: 1) the use of chemically-cured composite (Stela Automix and Stela Capsule) does not influence the spontaneous postoperative sensitivity (POS) of posterior composite resin restorations; 2) the use of chemically-cured composites (Stela Automix and Stela Capsule) does not influence the stimulated postoperative sensitivity (POS) of posterior composite resin restorations; 3) the use of chemically-cured bulk-fill composites (Stela Automix and Stela Capsule) does not influence any evaluated clinical parameter of posterior resin composite restorations.

2. Method and materials

2.1. 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, Chile), reviewed and accepted the proposed protocol, and gave its consent for the participation of people in this study (protocol #5.972.758 and #CEC2024049, respectively). All participants were informed of the study's objectives and nature, and signed a consent form before their acceptance in the study. This clinical study was registered in the Brazilian Clinical Trials Registry (RBR-255jzz9) and was conducted and reported, following the Consolidated Standards of Reporting Trials (CONSORT) statement [19].

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

This was a multicenter, double-blinded (patient and examiner), split-mouth randomized clinical trial. This study was conducted in the Schools of Dentistry clinics of two Universities from October 2023 to December 2023. A 6-month follow-up was performed from April 2024 to June 2024.

2.3. Participants recruitment

All participants were recruited during screening sessions at the both universities' dental clinics, and from written notices on the internal bulletin boards. Participant recruitment was fairly rapid and convenient.

2.4. Eligibility criteria

One hundred and fifty participants were examined by two fully trained and experienced dental residents in each center to validate that they met the inclusion criteria, using an explorer, an intra-oral mirror, and a periodontal probe. Afterward, 55 participants (age range 27–73 years) were selected after accepting the terms of the research (Fig. 1). All participants had to be in good general health, be older than 18 years old, have an acceptable oral hygiene level according to the Simplified Oral Hygiene Index (OHI-S) [20], and have at least 20 permanent teeth under occlusion with at least three needing Class I or Class II restorations in vital teeth.

Participants with extremely poor oral hygiene (OHI-S more than 3) [20], severe or chronic periodontitis (teeth with probing pocket depth more than 4 mm with bleeding on probing and clinical attachment loss of more than 3 mm in more than 4 teeth) [21], dental prostheses, severe bruxism, parafunctional habits, or continuous use of anti-inflammatory or analgesic medication were excluded from the study. Also, participants with known allergies to resin-based materials or any other material used in this study, undergoing bleaching treatment, and pregnant or breast-feeding women were excluded. Consequently, each one of the selected participants signed a consent form accepting his/her role in the study.

2.5. Characteristics of the teeth cavities to be included

The teeth intended for restoration had to be in occlusion with their natural antagonist tooth and adjacent teeth. Primary caries, deficient existing amalgam or resin composite, were the criteria for resin composite restoration. (Fig. 2A). Dental cavities had to be Class I or Class II (involving the occlusal surface) with a depth of 3 mm or greater. Measurement was carried out using a bitewing radiograph and a ruler. Teeth requiring endodontic treatment, evaluated by radiography and cold pulpal sensitivity tests, (Roeko-Endo-Frost, Coltene/Whaledent, Langenau, Germany) were excluded.

2.6. Sample size

The 5-year failure rate of posterior composite restorations in the item fracture is reported to be 5 % in a previous systematic review [22]. Assuming there is no significant difference between the standard treatment (Filtek One Bulk Fill, 3M Oral Care, St. Paul, MN, USA) and the new treatments (Stela Automix or Stela Capsule, SDI), 165 restorations (55 per group) are needed to ensure a 95 % confidence level, that the limits of a two-sided "90 % confidence" interval will not exceed a 15 % deviation between the standard and the new treatments.

A second sample size was calculated for postoperative sensitivity (POS) after posterior resin composite restoration. Sample size calculation was based on the risk of POS of 30 % in deep and large restorations [23–29]. If there is truly no difference between standard (Filtek One Bulk fill, 3M Oral Care) and new (Stela Automix or Stela Capsule, SDI) treatments, then 165 restorations (55 for each group) are required to be 95 % certain that the limits of a two-sided 90 % confidence interval will exclude differences between standard and new treatments of more than 130 %.

2.7. Randomization sequence, allocation, and blinding

The randomization process was performed using the software on the website http://www.sealedenvelope.com, by a staff member who did not participate in the research protocol. The randomization was done on

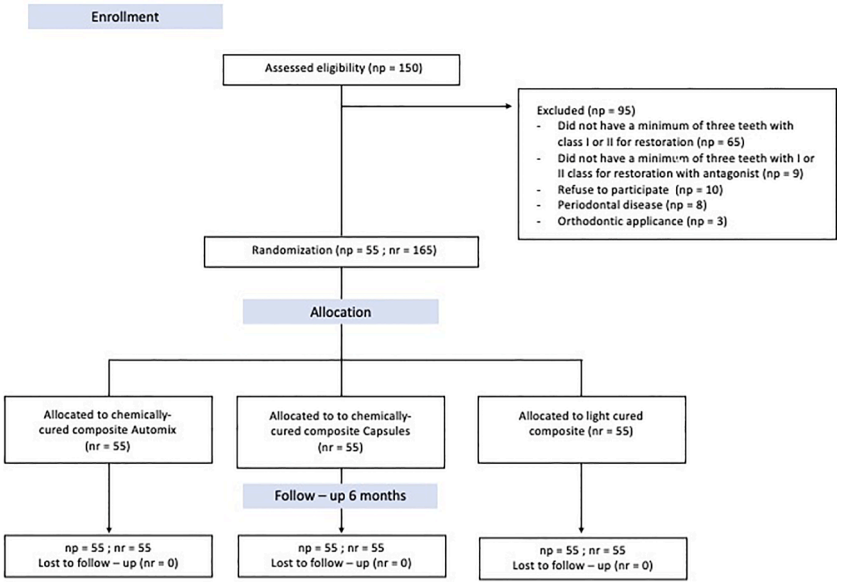

Fig. 1. Flow chart of the experimental design.

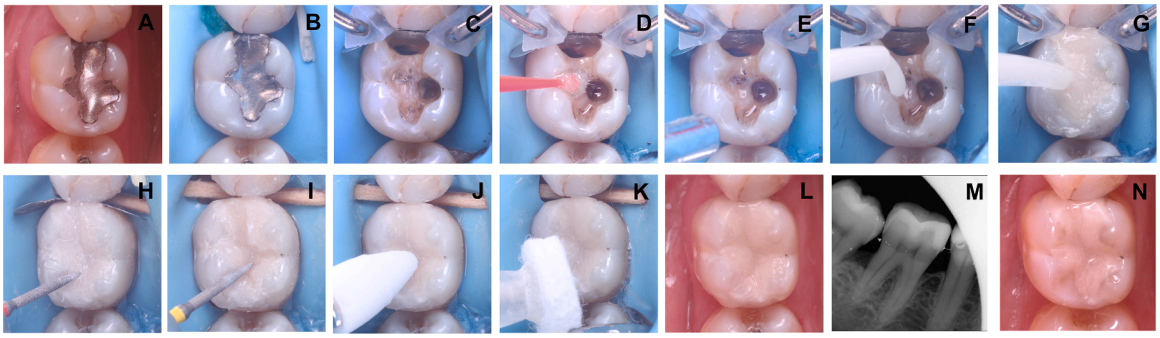

Fig. 2. Restorative procedure. In A, a lower left first molar is shown with a defective mesion-occusal amalgam restoration. In B depicts the tooth after rubber dam installation, and in C, the restotation has been removed and the matrix has been placed in position. Stela primer was applied (D), followed by solvent evaporation (E), and insertion of Stela Capsules (F and G). Sculpting began with coarse (H) and fine (I) diamond tips, followed by finishing (J) and polishing (K). In L shows the final restoration after 1-week of evaluation (baseline), as well as the final radiography (O). In the final picture (P), it is possible to see the clinical performance after 6 months.

an intra-individual basis so that each subject ended up with three restorations, one from each research group. Details of the allocated groups were recorded on cards inside opaque sequentially numbered sealed envelopes. Each envelope was opened on the day of the restorative procedure, guaranteeing the concealment of the random sequence, and preventing selection bias.

The clinician who performed each participant's restoration, was the only one aware of the procedure because he needed to know details on how to perform each restoration. This meant that participants and examiners were unaware of the group allocation in this double-blinded, randomized clinical trial design.

2.8. Baseline characteristics of the selected teeth and calibration procedure

Prior to restoration placement, the characteristics of posterior restorations were assessed. These included observations and documentation of features such as antagonist presence and attrition facets. Patient evaluations encompassed caries risk assessment and the estimation of parafunctional habits like bruxism, utilizing clinical and sociodemographic data. This assessment considered factors such as incipient caries lesions, history of caries, and parafunctional habits. The posterior teeth features are described in the 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. Air sensitivity was measured by air-drying for 10 s using a dental syringe positioned 2 cm from the tooth surface. Percussion sensitivity was evaluated by applying vertical and horizontal percussive loads on the occlusal and buccal aspects of the tooth, respectively, using the blunt end of a mouth mirror handle, as well as on the contralateral tooth. Cold sensitivity was induced by applying Endo Ice (Maquira, Maringá, PR, Brazil) to the cervical region of the vestibular face of the restored tooth. Heat sensitivity was assessed by applying heat to the tooth surface using a gutta-percha stick (Dentsply, Petrópolis, RJ, Brazil) [30]. Spontaneous preoperative sensitivity was assessed using the Visual Analogue Scale (VAS) and Numerical Rate Scale (NRS) to measure the intensity of tooth sensitivity. The VAS comprises of a 10-cm linear scale ranging from 'no pain' to 'unbearable pain'. The NRS comprises five verbal points, with 0 indicating "no pain" and 4 indicating "severe pain".

As two centers participated in this study, clinicians from each center visited the other center to calibrate the placement of the restorations. For this process, the study director initially performed one restoration for each group to outline all protocol steps in a laboratory setting.

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	4	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

Subsequently, all clinicians inserted 3–4 restorations of each material and described all the difficulties related to the procedure. Afterward, all clinicians performed an additional four restorations for each group in a clinical setting under the supervision of the study director. Throughout this process, all discrepancies were addressed and resolved prior to the initiation of the study. At this stage, the clinicians were deemed fully trained and qualified to carry out the restorative procedures. Once this step was completed, the clinicians were considered proficient in performing the restorative procedures.

2.9. Interventions: restorative procedure

Before undertaking restorative procedures, the clinicians cleaned all the teeth to be restored with pumice and water in a rubber cup (ref #8040RA and #8045RA, KG Sorensen, Barueri, SP, Brazil). Subsequently, local anesthesia (3 % mepivacaine Mepisv 3 %, Nova DFL, Rio de Janeiro, RJ, Brazil) was applied and the rubber dam isolation was performed (Fig. 2B). No additional retention or bevel was performed in the cavities.

After rubber dam isolation, the cavity design (restricted to the elimination of carious tissue or defected restorations) was prepared using stainless steel burs (# 329, 330 and/or 245; KG Sorensen, Barueri, SP, Brazil) placed on a high-speed handpiece with air-water irrigation. Only caries-infected dentin (according to selective carious tissue removal techniques) and defective restorations were removed (Fig. 2C).

For Class II cavities, a sectional matrix system Palodent (Dentsply Caulk, Milford, DE, USA) was used and proximal wedges were placed and adapted to obtain the proximal contour of the restoration (Fig. 2C). No liner nor base was placed in these prepared cavities. The cavity dimensions were measured in the proximal (Class II) or occlusal (Class I), in millimeters (height, width, and depth) using a periodontal probe (#6 Satin Steel Handled). After these were completed, the envelopes were opened, and the clinicians were made aware of which restorative material they would use for each cavity. All participants received each of the three restorations as part of the following combination:

1. For Stela Automix group: Stela primer was applied and then, the Stela Automix was applied with a syringe following the manufacturer's instructions (Table 2).
2. For Stela Capsule group: The Stela primer was applied and then, (Fig. 2D and E), the Stela used in capsules was employed following the manufacturer's instructions (Fig. 2F and G; Table 2).
3. For the control group (Filtek One Bulk fill): the Scotchbond Universal (3M Oral Care, St. Paul, MN, USA) was applied in the self-etch mode and then, the Filtek One Bulk fill resin (shade A2B), was applied with a syringe following the manufacturer's instructions. For this group, the light-curing procedure was performed making use of a Radii Xpert (SDI, Victoria, Australia) using the monowave point for 10 (adhesive) and 40 s (composite; 1,000 mW/cm^2), as per the manufacturer's directives. The irradiance was evaluated before each restoration with 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. Once, restorations were finished, occlusal adjustment was executed with a final polishing, using fine (F) and extra fine-grained (FF) diamond tips (Fig. 2H and I; KG Sorensen, Barueri, SP, Brazil), Optimize rubber cups, (Fig. 2J) and Polimax felt discs (Fig. 2K; TDV, Pomerode, SC, Brazil). In Fig. 2L, it is possible to see the final results. Proximal contacts were checked with dental floss and adjusted with sanding strips (3M Oral Care, St. Paul, MN, USA) and, if the clinician had some doubts, a new radiography was taken (Fig. 2M). Batch numbers, composition of materials, and adhesive/restorative procedures used in the study are described in Table 2.

2.10. Clinical evaluation

Once again, as two centers participated in this study, individuals from each of the centers visited the other center to calibrate the evaluation of the restorations. Four fully trained and experienced blinded dentists, [two in each center], who did not participate in the restoration procedure, examined each restoration. For calibration of the evaluation criteria, the examiners reviewed 10 photographs, representative of each score from FDI criteria [31]. These examiners evaluated 10–15 teeth on two occasions. To ensure examiner calibration before starting the evaluation, an intra-examiner and inter-examiner agreement of at least 85 % was required. For a proper evaluation, examiners performed dental prophylaxis with pumice and water over the teeth's surface before the evaluation. Clinical evaluation was performed using a dental explorer and an intraoral mirror. The proximal marginal adaptation of Class II restorations was evaluated using dental flossing and bitewing radiography when examiners considered it necessary.

The standardized procedure for examination included intraoral digital photographs of each restoration, and a paper case report at each recall time, ensuring they were kept blind to previous evaluations during the follow-up recalls. The restorations were assessed for spontaneous POS at baseline (up to 24 h), up to 48 h, after 7 days, and at 6 months.

For the assessment of the POS, participants were instructed to

Table 2
Material composition, adhesive, and restorative procedures.

Material [Batch Number]	Composition (*)	Adhesive and restorative procedures
Stela Primer (SDI, Victoria, Australia) [1,210,131]	Methyl ethyl 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) [1,210,270]	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. Wait four min, after mixing, to Stela polymerised; 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) [1,210,270]	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; 7. Wait four min, aafter mixing, to Stela polymerised; 8. Finish and polish the restoration.
Single Bond Universal Adhesive (3 M Oral Care, 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 5 s 4. Light cure for 10 s (1,000 mW/cm^2)
Filtek One Bulk Fill Posterior Restorative (Light-cured composite; 3 M **Oral Care, St. Paul, MN, USA) Shade A3 [N68566]**	Organic Matrix: 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 (1,000 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. Accessed 07, May 2024.
(***) Stela Product brochure (2023). Available in: https://www.sdi.com.au/pdfs/brochures/en-us/stela_sdi_brochures_en-us.pdf. Accessed 07, May 2024.
(****) Stela Automix, Stela Capsule. MSDS (2022). Available in: https://www.sdi.com.au/pdfs/sds/au/stela%20automix_sdi_sds_au.pdf. Accessed 07, May 2024.

describe their level of sensitivity using a Visual Analog Scale (VAS) ranging from 0 to 10, where participants were required to mark a line perpendicular to a 10-mm line, with one end representing 'no sensitivity' and the other end representing 'unbearable sensitivity.' Additionally, the participants were required to fill a Numerical Rating Scale (NRS) ranging from 0 to 4 (0 = none, 1 = mild, 2 = moderate, 3 = considerable, and 4 = severe). In both scales, participants were asked to complete the pain scale forms 24 h after the restorative procedure and daily for up to seven days.

Additionally, stimulated POS was evaluated at 7 days. Each evaluation included assessing restoration sensitivity to air application, palpation, vertical and horizontal percussion, and cold and heat stimulations, consistent with the initial evaluation protocol. Final values of spontaneous POS were categorized into two groups: the percentage of patients reporting POS at least once during the treatment (absolute risk) and the overall intensity of POS over 48 h, 7 days, and 6 months.

All other clinical parameters indicated in the updated version of the FDI were used (Table 3) and were evaluated at baseline and after 6 months of clinical service. The parameters have functional (F1. Fracture of material and retention; F2. Marginal adaptation; F3: Contact point/food impact; F4. Form and contour; F5. Occlusion and wear), biological (B1. Recurrence of caries; B2. Dental Hard tissues defects at the restoration margin) and aesthetic (A1. Surface luster and surface texture; A2. Marginal staining; A3. Color match) properties. These variables were ranked according to FDI criteria into clinical ratings; excellent/very good [VG], clinically good [CG], clinically satisfactory [SS], clinically unsatisfactory [CU], and clinically poor) [PO][32] (Table 3). The two

Table 3
Updated FDI criteria set utilized for clinical assessment (1st. part) [33].

	Functional properties (domain F*)				
	F1. Fracture of material and retention	F2. Marginal adaptation	F3. Contact point/food impact	F4. Form and contour	F5. Occlusion and wear
Criteria	Visual examination and short air drying	Visual examination, short air drying, and 250-μm probe	Visual examination and 25-/ 50-/100-μm blades	Visual examination	Visual examination and articulation paper
1. Clinically excellent/very good (sufficient)	Restoration is completely present without deficiencies detectable after air drying. No crack, chipping/ delamination, or material bulk fracture	Ideal marginal adaptation of the restoration at the dental hard tissue after air drying. No marginal gap detectable by gentle probing	Ideal contact point: 25-μm metal blade can pass through proximal contact and no inflammation of the gingiva/ periodontium due to the proximal restoration. No food impaction	Outline, contour, convexity, embrasure, and/or marginal ridges are restored ideally in comparison to the individual, age-related and functional anatomy. No marginal step detectable by gentle probing	Ideal individual and age-related static and dynamic occlusion with multiple antagonistic contact points. No premature contacts, non-/ hyper-occlusion, and/or balancing interferences
2. Clinically good (sufficient)	Restoration is completely present with minor deficiencies detectable after air drying, e.g., insignificant material chipping or one hairline crack	Slight deficiencies of marginal adaptation after air drying. Minor, superficial marginal gap(s) or ditching	Slightly weak contact point: 50-μm metal blade can pass through proximal contact and no inflammation of the gingiva/periodontium due to the proximal restoration. No food impaction	Minor deviations in outline, contour, convexity, embrasure, and/or marginal ridges in comparison to the individual, age-related and functional anatomy, AND/OR minor marginal steps, overhangs detectable by gentle probing	Minor deviations in individual and age-related static and dynamic occlusion with at least one antagonistic contact point per tooth. No premature contacts, non-/ hyper-occlusion, and/or balancing interferences
3.Clinically satisfactory (sufficient)	Restoration is present with deficiencies detectable without air drying, e.g., hairline cracks or distinct material loss (chipping). Material loss can mainly be corrected by refurbishment if needed	Distinct deficiencies of marginal adaptation without air drying: marginal gap(s) or ditching (width < 250 μm and/or depth < 2 mm)	Oversized contact point or excessive material: 25-μm metal blade cannot pass through proximal contact and inflammation of the gingiva/ periodontium due to the proximal restoration. Refurbishment is possible. OR Severely weak contact point: 100-μm metal blade can pass through proximal contact but no inflammation of gingiva or discomfort	Outline, contour, convexity, embrasure, and/or marginal ridges are distinctly misshaped but clinically acceptable and/ or distinct negative/positive steps, overhangs. Refurbishment (removal of overhangs/steps) to some extent is possible	Hyper-occlusion, premature contacts, and/or balancing interferences that can be eliminated by refurbishment
4. Clinically unsatisfactory (partially insufficient)	Localized but severe deficiencies regarding fracture and retention, e.g., chipping/ delamination which cannot be refurbished, bulk fracture, or partially loose/lost restoration. Repair is possible.	Localized but severe deficiencies of marginal adaptation: width ≥ 250 μm and/or depth ≥ 2 mm marginal gap(s). Partially loose/lost restoration. Repair is possible	Severely weak contact point: 100-μm metal blade can pass through proximal contact or unintended interlocked contact point. Inflammation of the gingiva/ periodontium due to the proximal restoration and/or food impaction. Repair is possible	Outline, contour, convexity, embrasure, and/or marginal ridges are in parts severely undersized in comparison to the individual, age-related, and functional anatomy AND/ OR prominently negative marginal steps. Repair is possible	Localized, flat occlusal structure with severe non-occlusion AND/OR severely worn restoration. Repair is possible
5. Clinically poor (entirely insufficient)	Generalized severe deficiencies, e.g., extensive delamination, multiple bulk fractures, or (nearly) completely loose/lost restoration. Repair not possible/reasonable	Generalized and severely compromised marginal adaptation: width ≥ 250 μm and/or depth ≥ 2 mm. Complete loose/lost restoration. Repair not possible/ reasonable	Severely weak contact point: 100-μm metal blade can easily pass through proximal contact or unintended interlocked contact point (impossible to pass). Inflammation of the gingiva/periodontium due to the proximal restoration and/or food impaction. Repair not possible/reasonable	Outline, contour, convexity, embrasure, and/or marginal ridges are generally and severely under- or oversized in comparison to the individual, age-related, and functional anatomy. Repair not possible/ reasonable	Generalized, severe non-occlusion AND/OR extensively worn restoration. Repair not possible/ reasonable
Not applicable	This code is used if examination for any reason is not possible				
Additional comments	1) Should be included without exception in any study that requires restoration assessment. 2) If a restoration is graded as entirely insufficient (F1/ score 5) or completely lost all other functional (except F2) and aesthetical categories become not applicable	1) Evaluate gap formation at the restoration margin only. 2) If any loss of restoration material or dental hard tissue is evident, these findings have to be scored in the categories F1 and B2. Caries at the restoration margin has to be scored in category B1. 3) If a restoration is graded as entirely insufficient or completely lost (F2/score 5), all other functional and aesthetical categories become not applicable	1) Not applicable in case of missing adjacent teeth, gap-toothed/flared/mobile dentition, or atypical individual tooth form, e.g., microdens or diastema. 2) Do not mix-up with F1	1) Describes in particular the dentist's or dental technician's ability to restore the tooth in comparison to contralateral (unrestored) teeth. 2) Do not mix-up with F1, F2, or F3	1) Not applicable in case of irregular individual tooth form or malocclusion, e.g., microdens or missing antagonistic teeth. 2) In case of severe and generalized fracture and retention deficiencies of a restoration (F1/score 5), score 5 (F5) is becoming not applicable. 3) Do not mix-up with F1

	Biological properties (domain B*)			Aesthetic properties (domain A)		
	B1. Recurrence of caries	**B2. Dental hard tissue defects at the restoration margin**	**B3. Postoperative hyper sensitivity and pulpal status**	**A1. Surface luster and surface texture**	**A2. Marginal staining**	**A3. Color match**
Criteria	Visual examination, short air drying, and 250-μm probe	Visual examination	Tooth hypersensitivity reported by patient; pulp sensitivity tested with cold stimulus	Visual examination and short air drying	Visual examination and short air drying	Visual examination
1. Clinically excellent/very good (sufficient)	No caries/ demineralization at the restoration margin detectable after air drying	Intact dental hard tissue without crack lines and fractures at the restoration margin	No postoperative hypersensitivity or pain on chewing and/or cold/warm food items reported by the patient. Normal (short) reaction to sensitivity test on cold	Surface luster and surface texture comparable to dental hard tissue/ adjacent teeth after air drying	No marginal staining detectable after air drying	No deviation in shade, translucency/opacity between restoration, and neighboring dental hard tissue/adjacent teeth
2. Clinically good (sufficient)	First visible signs of a non-cavitated caries lesion at the restoration margin detectable after air drying	Minor vertical/horizontal hairline crack lines in enamel at the restoration margin	Patient reports minor postoperative hypersensitivity or minor pain on chewing and/or cold/warm food items reported by the patient for a limited period of time (< 1 week). Normal (short) reaction to sensitivity test on cold	Slightly dull surface luster and/or surface texture with minor deviations, e.g., isolated/small marks, pores, and/or voids detectable compared to dental hard tissue/ adjacent teeth after air drying	Minor marginal staining detectable after air drying	Minor deviation in shade, translucency/ opacity between restoration, and neighboring dental hard tissue/adjacent teeth detectable
3.Clinically satisfactory (sufficient)	Established, non-cavitated caries lesion or microcavity at the restoration margin detectable without air drying	Distinct enamel chipping or enamel fracture at the restoration margin. If necessary, deficiencies can be corrected by refurbishment	Patient reports distinct postoperative hypersensitivity or distinct pain on chewing and/or cold/warm food items reported by the patient for a prolonged period of time (> 1 week). Normal (short) or more intense reaction to sensitivity test on cold	Dull surface luster and/or surface texture with distinct deviations, e.g., marks, pores, and/or voids detectable compared to dental hard tissue/ adjacent teeth detectable without air drying. Refurbishment is possible	Distinct marginal staining detectable without air drying but not displeasing. Refurbishment is possible	Distinct deviation in shade, translucency/ opacity between restoration, and neighboring dental hard tissue/adjacent teeth detectable but not displeasing
4. Clinically unsatisfactory (partially insufficient)	Localized dentin cavity (width > 250 μm, depth > 2 mm) at the restoration margin. Repair is possible	Severe marginal (enamel) fracture, partially fractured cusp or ridge at the restoration margin. Repair is possible	Patient reports severe/ persistent, postoperative hypersensitivity or persistent pain on chewing and/ or cold/warm food items reported by the patient for a prolonged period of time (> 1 month) AND/OR intense reaction to sensitivity test on cold. Both symptoms indicate irreversible pulpitis. Endodontic treatment requires access cavity only	Localized, displeasing dull surface luster and/or rough surface texture with substantial deviations/ multiple pores/voids detectable compared to dental hard tissue/ adjacent teeth which can be repaired	Localized, displeasing deep marginal staining. Marginal staining can be removed/ improved by repair	Localized, displeasing deviation in shade, translucency/ opacity between restoration, and neighboring dental hard tissue/adjacent teeth which can be improved by repair
5. Clinically poor (entirely insufficient)	Extensive dentin cavity at the restoration margin. Repair not possible/ reasonable	Cusp or tooth fracture, e.g., involving enamel, dentin, and cementum possible with mobile fragments/pain when biting OR cracked tooth syndrome related to restoration. Repair not possible/reasonable	Irreversible pulpitis, nonvital tooth, pulp necrosis with or without periapical periodontitis after restoration placement. Endodontic treatment requires replacement of the restoration	Generalized, displeasing dull surface luster and/ or rough surface texture with substantial deviations/ multiple pores/voids compared to dental hard tissue/adjacent teeth. Repair not possible/ reasonable	Generalized, displeasing deep marginal staining. Repair not possible/ reasonable	Generalized, displeasing deviation in shade, translucency/opacity between restoration, and neighboring dental hard tissue/adjacent teeth. Repair not possible/reasonable
Not applicable	This code is used if examination for any reason is not possible					
Additional comments	1) Do not confuse caries with marginal staining (A2). 2) Consider only caries lesions that are located directly at the restoration margin. 3) If any loss of restoration material or dental hard tissue is evident, these findings have to be scored in the corresponding categories F1 and B2	1) Do not misdiagnose attrition, erosive tooth wear, etc. in this category. 2) If loss of restoration material or CAR is evident, these entities have to be scored in the corresponding categories F1 and B1	1) This category can only be evaluated in vital teeth that are monitored from the time the restoration is placed. 2) Refurbishment, repair, or replacement cannot be related to a possible endodontic treatment procedure; therefore, possible restorative interventions are not used for categorization	1) The evaluation of aesthetic properties is relevant for decision making on tooth-colored restorations in visible tooth surfaces only. 2) Evaluation can be performed from a standard examination distance under operating light (~ 40 cm) or from speaking distance (~ 80–100 cm) with the operating light switched off. This has to be defined and reported later. If surface luster and surface texture have to be taken in account, the worse characteristic determines the grading		
				If surface luster and surface texture have to be taken in account, the worse characteristic determines the grading	Do not confuse marginal staining with CAR (B1)	Evaluation of tooth-colored restorations only

(*) Part referent to indirect restoration was removed of the description.

criteria that were not evaluated as recommended by FDI were post-operative hypersensitivity and pulpal status (B3), solely due to a more comprehensive evaluation conducted in the present study.

Also, two criteria categorized as miscellaneous were evaluated: patient's view (M1) and assessment of dental restoration on radiographs (M2). After 7 days of the restorative procedure, participants filled out a 5-point Likert scale to measure satisfaction from the patient's perspective. The scale was structured as follows: 1. Very satisfied; 2. Satisfied; 3. Neither satisfied nor dissatisfied; 4. Dissatisfied and; 5. Very dissatisfied. Participants selected the option that best reflected their level of satisfaction with the procedure.

In cases of dissatisfaction, a detailed report was provided on aspects such as pain, hypersensitivity, chewing comfort, occlusion, proximal contacts, cleanability, contours, and aesthetics. In the case of M2, a radiographic examination was conducted, only if the patient had a complaint or if the contact point/food impaction (F3) was clinically assessed as unsatisfactory or poor [32]. Examiners evaluated all the restorations and gave their scores individually. If any disagreement occurred, examiners had to reach a consensus before the participant left.

All restorations scored as clinically unsatisfactory or poor by updated FDI criteria, were immediately counted/considered as a cumulative failure in the next follow-up evaluation [32]. Each failed restoration was replaced with a new composite resin restoration [32]. These new restorations were not included as part of the study for further evaluation. Participants' restorations whose evaluations were not possible to be performed, as well as excluded restorations, were considered lost in the follow up.

2.11. Statistical analysis

The statistician was blinded to the type of study groups. The statistical analysis followed the intention-to-treat protocol, according to CONSORT's suggestion [19]. Descriptive statistics were used to describe the distributions of the evaluated criteria.

Participants who experienced at least one episode of POS at each evaluation time (48 h, 7 days, and 6 months) were considered to have POS. The risk of spontaneous and stimulus-induced (air, cold, heat, horizontal, and vertical percussion) POS between the groups at each time point (48 h, 7 days, and 6 months) was compared using the Cochran test. The risk of spontaneous POS across different time points (48 h, 7 days, and 6 months) for each group was compared using the Cochran test. The intensity of spontaneous POS was assessed using the Kruskal-Wallis and Mann-Whitney tests. Additionally, the risks of POS according to cavity characteristics were compared using the Chi-square or Fisher exact test.

For all other outcomes, the differences between the three groups' ratings in the baseline and after 6 months were analyzed using the Friedman repeated measures analysis of variance by rank ($\alpha = 0.05$), while differences in ratings within each group at baseline and after 6 months were assessed using the McNemar test (Statistica StatSoft Inc., Tulsa, Ok, USA; $\alpha = 0.05$).

3. Results

In total, one hundred and fifty (150) participants were screened for eligibility, and 95 participants were excluded from the study for not meeting the inclusion criteria (Fig. 1). Therefore, one hundred and sixty-five restorations were performed on 55 participants, 20 males and 35 females (Table 1). Each participant had three restorations within the experimental groups ($n = 55$) in a split-mouth design. The restorative procedure was applied precisely as planned, and no modification was performed. All baseline cavity characteristics were considered for all restorations, as described in Table 1. In each one of the follow-ups, restorations were examined, and pictures taken (Fig. 3). The level of agreement between inter and intra-examiners was calculated using the Cohen *kappa* statistics showing 0.86 and 0.85, respectively. All participants attended a one-week and 6-month recall (Fig. 1). The final picture of the clinical case after 6 months of clinical evaluation (Fig. 1N), as well as some examples of the restorations performed were outlined in Fig. 3. Tables 4 to 7 display all the data regarding follow-up times.

The four clinicians chronicled several details regarding the handling of each composite after performing the restorations – e.g. difference between capsule vs syringe, ease of use, setting time, polishing/finishing, etc. The four clinicians observed that the restorations made with the chemically-cured composite inserted Automix was easier to use due to its flowability. However, the chemically-cured composite inserted as Automix exhibited a longer and somewhat inconsistent polymerization time (4–8 min). Because of this, the clinicians found it somewhat challenging to sculpt. Some concerns were reported by the clinicians regarding the completion of the finishing/polishing procedures when the chemically-cured composite inserted as Automix was applied.

Regarding the chemically-cured composite inserted as Capsule, the clinicians observed a lower curing time, typically around 30–60 s from the start of the application of the mixture. Consequently, the sculpting was usually performed during the finishing procedures. Additionally, all clinicians noted that it was more difficult to achieve good polishing when the chemically-cured composite inserted as Capsule was used.

3.1. Postoperative (hyper-) sensitivity

A higher risk of spontaneous POS were observed for all groups up to 48 h after restoration placement, with statistically significant differences among the groups ($p = 0.04$ at baseline and $p = 0.03$ up to 48 h; Table 4). The light-cured composite showed significantly higher spontaneous POS than the chemically-cured composite inserted in Capsule at baseline, and the chemically-cured composite inserted using Automix up to 48 h. (Table 4).

On the other hand, although no significant differences were observed when both chemically-cured composites were evaluated across all time points ($p = 0.11$ and $p = 0.03$, respectively for Automix and Capsule; Table 4), a significant difference among evaluation times was observed for the light-cured composite when comparing baseline and up to 48 h to 7 days and 6 months ($p = 0.007$; Table 4).

Regarding intensity of spontaneous POS, no statistically significant difference was found in each period when comparing among groups (Tables 5; $p > 0.18$). It is noteworthy to mention that during the 1-week evaluation period, the intensity of spontaneous POS was considered mild when measured using the VAS and NRS scales (Table 5).

After 1 week, only a few participants reported experiencing stimulus-induced POS, with no statistically significant difference observed when different groups were compared (Table 6; $p > 0.36$). Moreover, none of the participants required oral medication to alleviate POS. However, it is also worth highlighting that after 6 months of clinical evaluation, no patients reported spontaneous tooth sensitivity.

When evaluating cavity characteristics, such as the type of cavity, number of surfaces, and cavity depth, no significant differences were observed (Table 7; $p > 0.60$).

3.2. General evaluation: functional properties

No restorations exhibited any issues regarding material fractures or retention loss (F1), loss of contact point/food impaction (F3), deviation of form and contour (F4), or occlusion and wear (F5) in the current recall assessment (Table 8). Only a few restorations showed minor deviation in the marginal adaptation after 6-month recall, with no significant differences among materials ($p = 0.92$; Table 8).

3.3. General evaluation: biological properties

No restorations were ranked with recurrence of caries (B1) or dental hard tissues defects at the restoration margin (B2; Table 8). The evaluation of POS (item B3) was described earlier.

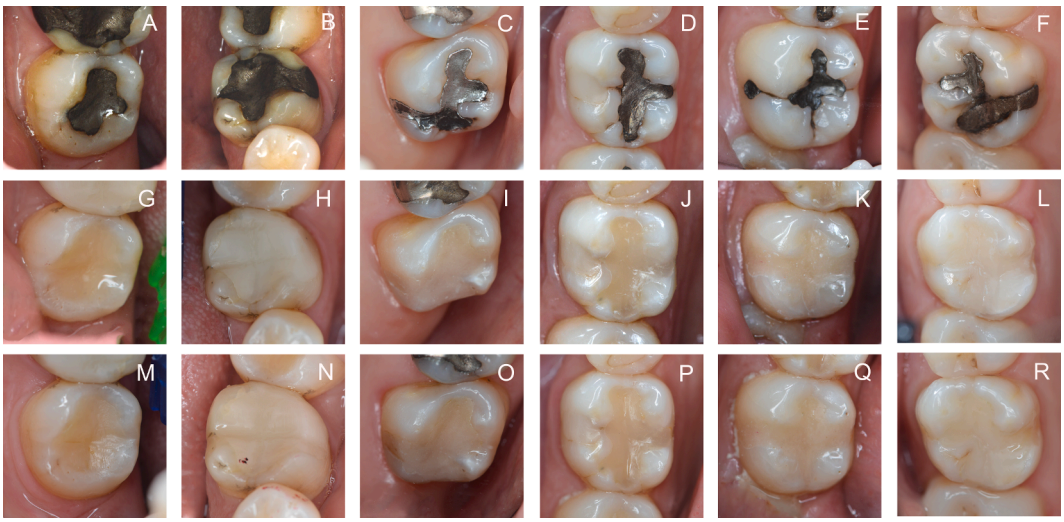

Fig. 3. Examples of posterior restorations conducted in the present study. In A to F illustrate amalgam restorations, indicated for defect substitution or esthetic reasons (based on patient complaints). In G to L display the appearances of the restorations after one week of evaluation (baseline). In M and P exhibit light-cured restorations assessed as 'B' in color match. In N and Q demonstrate the opacity (N) and challenges in polishing (Q) observed when using chemically-cured composite in Capsules. In O and R present two examples of chemically-cured composite in Automix, rated 'A' in all clinical criteria.

Table 4
Number of participants with spontaneous postoperative sensitivity (POS)/total during 06 months of follow-up, as well as the absolute risk of POS (*).

Time Assessment		Chemically cured composite				Light-cured composite		
Time Assessment		Automix		Capsule				
		Number of Participants with POS/ Total	Absolute Risk (95 % CI)	Number of Participants with POS/ Total	Absolute Risk (95 % CI)	Number of Participants with POS/ Total	Absolute Risk (95 % CI)	*p*-value*
Postoperative	**Baseline**	5 / 55 A,Ba	9.0 (3.9–19.6)	3 / 55 Aa	5.4 (1.9–14.8)	11 / 55 Bb	20.0 (11.6–32.3)	0.04
	Up to 48 h	2 / 55 Aa	3.6 (1.0–12.3)	3 / 55 A,Ba	5.4 (1.9–14.8)	9 / 55 Bb	16.4 (8.9–28.3)	0.03
	7 days	2 / 55 Aa	3.6 (1.0–12.3)	1 / 55 Aa	1.8 (0.3–9.6)	2 / 55 Aa	3.6 (1.0–12.3)	0.88
	6 months	0 / 55 Aa	0.0 (0.0–0.07)	0 / 55 Aa	0.0 (0.0–0.06)	0 / 55 Aa	0.0 (0.0–0.07)	1.0
p*-value		0.11		0.26		0.007		

(*) Cochran test.

Table 5
Intensity of spontaneous postoperative sensitivity experienced by participants during 7 days of follow-up (*).

Time assessment	Visual analogue scale			*p*-value	Numerical rate scale			*p*-value
	Chemically cured composite		Light-cured composite		Chemically cured composite		Light-cured composite	
	Automix	Capsule			Automix	Capsule		
Up to 48 h	0.6 ± 2.0	0.4 ± 1.4	0.8 ± 2.1	0.95	0.5 ± 1.1	0.2 ± 0.5	0.9 ± 1.4	0.18
7 days	0.1 ± 0.1	0.1 ± 0.2	0.1 ± 0.1	1.00	0.2 ± 0.2	0.1 ± 0.4	0.2 ± 1.2	0.92

(*) Kruskall-Wallis and Mann-Whitney tests.

3.4. General evaluation: aesthetic properties

No restorations were ranked with marginal staining (A2) during the present clinical evaluation (Table 8). However, some restorations were ranked as GO in the surface luster and surface texture (A1) and color match (A3; Table 8). In terms of surface luster and surface texture (A1), thirty restorations were ranked as clinically good (10 for chemically-cured composite inserted Automix (Fig. 3), 14 for chemically-cured composites used in Capsule and 06 for light-cured composite) in the baseline and after 6 months of recall rate. A significant difference was detected between Capsule and light-cured composite (Fig. 3; $p = 0.03$; Table 8).

Thirty-two restorations were ranked as clinically good in color match (A3; 08 for chemically-cured composite inserted as Automix, 07 for chemically-cured composites used in Capsule and 17 for light-cured composite) in the baseline and after 6 months of recall rate. A significant difference was detected among both chemically-cured composites and light-cured composite (Fig. 3; $p = 0.03$; Table 8).

3.5. General evaluation: miscellaneous criteria

Regarding the patient's perspective (M1), although some patients reported POS, all of them expressed being very satisfied with the entire restorative procedure. Since there were no significant complaints or issues with the class II restorations (F3), additional radiographs (M2) were deemed unnecessary in this study.

Table 6
Number of participants who experienced provoked pre- and postoperative/total to different stimulus in the baseline and 7 days follow-up.

Time assessment		Chemically cured composite				Light-cured composite		
Time assessment		Automix		Capsule				
		Number of Participants with POS/Total	Absolute Risk (95 % CI)	Number of Participants with POS/Total	Absolute Risk (95 % CI)	Number of Participants with POS/Total	Absolute Risk (95 % CI)	*p*-value
Preoperative	**Air**	9 / 55	16.4 (8.9–28.3)	6 / 55	10.9 (5.1–21.8)	8 / 55	14.5 (7.5–26.2)	0.70
	Cold	21 / 55	38.2 (26.5–51.4)	21 / 55	38.2 (26.5–51.4)	26 / 55	47.3 (34.7–60.2)	0.53
	Heat	10 / 55	18.2 (10.2–30.3)	8 / 55	14.5 (7.5–26.2)	12 / 55	21.8 (12.9–34.4)	0.61
	Palpation	0 / 55	0.0 (0.0–0.07)	0 / 55	0.0 (0.0–0.07)	0 / 55	0.0 (0.0–0.07)	1.0
	Horizontal percussion	4 / 55	7.3 (2.9–17.3)	2 / 55	3.6 (1.0–12.3)	1 / 55	1.8 (0.3–9.6)	0.35
	Vertical percussion	3 / 55	5.4 (1.9–14.8)	2 / 55	3.6 (1.0–12.3)	2 / 55	3.6 (1.0–12.3)	0.86
Postoperative	**Air**	0 / 55	0.0 (0.0–0.07)	1 / 55	1.8 (0.3–9.6)	0 / 55	0.0 (0.0–0.07)	0.36
	Cold	8 / 55	14.5 (7.5–26.2)	12 / 55	21.8 (12.9–34.4)	14 / 55	25.4 (15.8–38.3)	0.35
	Heat	2 / 55	3.6 (1.0–12.3)	4 / 55	7.3 (2.9–17.3)	3 / 55	5.4 (1.9–14.8)	0.70
	Palpation	0 / 55	0.0 (0.0–0.07)	0 / 55	0.0 (0.0–0.07)	0 / 55	0.0 (0.0–0.07)	1.0
	Horizontal percussion	0 / 55	0.0 (0.0–0.07)	0 / 55	0.0 (0.0–0.07)	0 / 55	0.0 (0.0–0.07)	1.0
	Vertical percussion	0 / 55	0.0 (0.0–0.07)	0 / 55	0.0 (0.0–0.07)	0 / 55	0.0 (0.0–0.07)	1.0

(*) Cochran test.

Table 7
Number of participants who experienced spontaneous postoperative sensitivity at baseline (up to 24 h) Follow-Up.

Time assessment		Number of sensitive teeth (%)		*p*-value
		Yes	No	
Cavity depth	**3 mm**	6 (9.2)	59 (90.8)	0.61
	More of 3 mm	13 (13.0)	87 (87.0)	
Black Cavity	**Class I**	12 (10.5)	102 (89.5)	0.60
	Class II	7 (13.7)	44 (86.3)	
Number of Restored surfaces	**1 or 2 faces**	18 (11.7)	136 (88.3)	1.0
	3 or 4 faces	1 (9.1)	10 (90.9)	

(*) Chi-square test and Fisher exact test.

4. Discussion

The present randomized clinical trial evaluated the POS and the clinical performance of a new chemically-cured resin composite applied in two forms (Automix and Capsules) compared to light-cured resin composite restorations. The results of the study showed that the application of the chemically-cured resin composite, regardless of the form, significantly decreased the occurrence of spontaneous POS in resin composite posterior restorations compared to light-cured bulk-fill resin composite restorations. This led us to reject the first null hypothesis. To the best of the authors' knowledge, this is the first clinical study to evaluate this new chemically-cured resin composite in two forms (Automix and Capsule) compared to light-cured resin composite. Although this randomized clinical trial only evaluated short-term clinical performance, the inclusion of a new chemically-cured resin composite, belonging to a new category of composite for direct posterior restorations without extensive clinical data, justified the need for this short-term evaluation. Indeed, some interesting differences were observed among the groups immediately and after six months of clinical evaluation.

POS after placing posterior composite restorations has been a problem experienced by clinicians for a long time. Several factors can contribute to the generation of POS in posterior restorations, among them the mode of polymerization of composites [15,33]. The polymerization process of all methacrylate-based composites is actually accompanied by substantial shrinkage that occurs simultaneously with the bonding process to the tooth structure. This leads to higher constraint of the contraction, resulting in stress generation within the material and at the interface with the tooth. Clinically, composite strain is hindered by the confinement of the material bonded to the tooth, and as a result, shrinkage manifests itself as stress. Therefore, it is expected that the resultant stress may damage the bonding interface and is one of the main causes of internal or marginal gaps [14,15]. Additionally, enamel cracks or deflection of the surrounding tooth structure can occur [15,33]. All these factors can lead to potential POS.

However, the magnitude of polymerization shrinkage stress can be modulated according to the mode of polymerization. It is well known that light-cured composites generate faster and higher polymerization shrinkage stresses than chemically-cured composite [34]. This occur because, immediately after the light-curing process, the composite loses its ability to flow, its elastic properties increase, and consequently, higher residual shrinkage stresses are generated [15].

On the other hand, chemically-cured composites undergo a slower and delayed polymerization reaction, allowing the composites to flow due to their extended viscous phase compared to light-cured composites [14]. This reduces polymerization shrinkage and polymerization stress, preserving the adhesive interface [15,35]. Indeed, a recently published *in vitro* study showed that while the chemically-cured composite (Automix) demonstrated excellent adaptation and no presence of gaps at the resin-dentin interface of simulated class I restorations, the light-cured bulk-fill composite (the same used in the present study) was characterized by the presence of gaps and voids in all specimens [11].

Therefore, the slow and extended polymerization reaction of chemically-cured composites contributes to understanding why immediate POS, as well as POS up to 48 h, were lower compared to light-cured composites. It is important to note that, despite some differences in polymerization time when comparing the two chemically-cured composites, this did not significantly impact the generation of POS reported by participants.

It is worth mentioning that in the present study, participants were instructed to report any sensitivity they experienced. One review of clinical studies comparing the presence and intensity of POS in posterior composite resin restorations revealed that in around 50 % of the studies

Table 8
Number of evaluated restorations for each experimental group (*) classified according to the World Dental Federation (FDI) criteria for functional properties [33].

Functional properties	Time	Baseline			6-months			Biological and aesthetic properties	Time	Baseline			6-months		
	(*;**)	AU	CA	CO	AU	CA	CO		(**)	AU	CA	CO	AU	CA	CO
F1. Fracture of material and retention	VG	55	55	55	55	55	55	**B1. Recurrence of caries**	VG	55	55	55	55	55	55
	GO	–	–	–	–	–	–		GO	–	–	–	–	–	–
	SS	–	–	–	–	–	–		SS	–	–	–	–	–	–
	CU/PO	–	–	–	–	–	–		CU/PO	–	–	–	–	–	–
F2. Marginal adaptation	VG	55	55	55	53	54	51	**B2. Dental hard tissue defects at the restoration margin**	VG	55	55	55	55	55	55
	GO	–	–	–	02	01	04		GO	–	–	–	–	–	–
	SS	–	–	–	–	–	–		SS	–	–	–	–	–	–
	CU/PO	–	–	–	–	–	–		CU/PO	–	–	–	–	–	–
F3. Contact point/food impact (*)	VG	18	19	14	18	19	14	**A1. Surface luster and surface texture**	VG	45	41	49	49	41	45
	GO	–	–	–	–	–	–		GO	10	14	06	6	14	10
	SS	–	–	–	–	–	–		SS	–	–	–	–	–	–
	CU/PO	–	–	–	–	–	–		CU/PO	–	–	–	–	–	–
F4. Form and contour	VG	55	55	55	55	55	55	**A2. Marginal staining**	VG	55	55	55	55	55	55
	GO	–	–	–	–	–	–		GO	–	–	–	–	–	–
	SS	–	–	–	–	–	–		SS	–	–	–	–	–	–
	CU/PO	–	–	–	–	–	–		CU/PO	–	–	–	–	–	–
F5. Occlusion and wear	VG	55	55	55	55	55	55	**A3. Color match**	VG	47	48	38	47	48	38
	GO	–	–	–	–	–	–		GO	8	7	17	8	7	17
	SS	–	–	–	–	–	–		SS	–	–	–	–	–	–
	CU/PO	–	–	–	–	–	–		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.

analyzed, POS assessment relied on patients' self-reports of sensitivity during specific time intervals [36]. Typically, this assessment method is derived from participants' everyday encounters with different stimuli rather than from a standardized, controlled stimulus. While employing a stimulus to evaluate the risk and intensity of POS has been observed in certain studies [28,29,37], it is important to note that these methods are particularly crucial when assessing pulp vitality rather than POS.

In the present study, no significant differences were observed in terms of all parameters evaluating stimulated POS, which led us to accept the second null hypothesis. Although there were some differences among composites, both spontaneous and stimulus-induced POS were minimal after one week, as previously demonstrated in recent clinical studies examining the same commercial brand [28,29,38–40].

Although previous studies have demonstrated an absolute risk range of 12.4–30 % for POS when light-cured resin composites are used for restoring posterior teeth, the average percentage of spontaneous POS in these studies is approximately 20 % [28,29,38–40], consistent with the findings observed in the present study. However, some studies report lower values of POS [38,41].This suggests that various factors can influence the risk of POS, including variables like the size and complexity of the cavity being treated, as well as the specific clinical environment where the restorative procedures are carried out.

In terms of the characteristics of the cavities (tooth distribution, cavity depth, and number of restored surfaces), no significant differences were noted in the present study when these factors were compared. While it is anticipated that more extensive cavities, particularly in molars, which involve more surfaces and are deeper, would exhibit higher instances of POS compared to simpler cavities, there is no consensus in the literature [23,25,26,28,29]. This ambiguity persists due to the limited number of studies evaluating a narrower range of restorations. Future clinical studies in posterior restorations need to evaluate the effect of these variables (tooth distribution, cavity depth, and number of restored surfaces) to confirm or refute this hypothesis.

Despite the present randomized clinical trial evaluating only short-term clinical performance of these materials, some interesting differences were observed among the groups, even after a short-term clinical evaluation, such as surface luster and surface texture, and color match.

The chemically-cured composite applied as Capsules exhibited a lower surface luster and a rougher surface texture compared to the light-cured composite. This challenge in achieving optimal polish can be attributed to the difficulty in polishing these restorations [42]. It's worth noting that while the chemically-cured composite in Capsule contains irregular fillers with a mean particle size of 4.0 μm, the light-cured composite features spherical filler with sizes ranging from 4 to 100 nm. As a result, the former can lead to the formation of large holes or pits on the surfaces during polishing due to the presence of larger fillers. In contrast, nanofill composites like the light-cured composite used in our study are known for their high polishability and ability to achieve better gloss after finishing/polishing [43–45].

It is also worth mentioning that despite both commercial presentations of the chemically-cured composite having the same name (Stela), the composition varies according to the form of presentation. While the Automix presentation contains two different types of fillers with mean sizes ranging from 2.8 to 4.0 μm, the Capsule presentation contains only one type of filler with a mean particle size of 4.0 μm. Additionally, the former has a lower filler loading (61.2 wt%) compared to the Capsules presentation (76.8 wt%). Therefore, despite the chemically-cured composite presented in Automix containing a mean filler size higher than the light-cured composite, the lower filler content seems not to affect their polishing [42].

Regarding color match, the light-cured composite showed a higher color mismatch (31 %) compared to chemically-cured composites (14 %). It is well known that bulk-fill composites have increased translucency compared to incrementally applied composites [46], which ensures adequate depth of cure and reduces light scattering. This is usually accomplished by the addition of larger filler sizes and a reduction in color pigments [46,47]. However, it was soon acknowledged that the heightened translucency might compromise the esthetic blending of the restorations. Occasionally, a noticeable gray tint was observed in the restoration, along with limited ability to conceal dark tooth discolorations. Considering that the majority of the restorations (74 %) were related to esthetic reasons associated with the substitution of amalgam

restorations, this outcome seemed foreseeable. Although this may not be a problem in molar restorations, it may have some impact when premolars are restored [48].

Interesting and controversial results have been observed in terms of color match when bulk-fill composites were clinically evaluated. For instance, some studies reported that all restorations performed with bulk-fill composite showed a perfect color match [41,49], while other studies reported color mismatch values as high as 15–22 % [39,50]. However, in the former studies, the reasons for changing the restorations were not clear. On the other hand, in the studies by Sekundo et al. and Loguercio et al. [39,48,50], the majority of the restorations were replacements for amalgam restorations, which justified the color mismatch reported in these studies.

Despite some differences among the materials regarding POS and certain aesthetic properties, these minimal discrepancies were not considered failures and were ranked as clinically acceptable, only requiring monitoring of the restoration [32]. It should be noted that all restorations were ranked as clinically excellent/very good when important aspects such as functional and biological properties were evaluated, with no significant differences observed among composites. A recent in vitro study [10] demonstrated that both materials (Automix and Capsule) of the new chemically-cured composite exhibited good results in terms of flexural strength, hardness, water sorption, and solubility, surpassing the ISO standards [51] limits and showing mechanical properties similar to those of light-cured composites recommended for posterior restorations [52].

In addition, the mechanical and physical properties of the bulk-fill composite in terms of degree of conversion, fracture strength, and polymerization stress, could be other factors for the low number of restorations with failures related to fracture [53]. It is worth mentioning that the fracture/retention rate of the current study was around 95 %, similar to the 93 % [54] and 90 % [39] after the same follow-up, when restorations of light-cured composites were performed.

An inherent limitation of the present study is its short-term evaluation (6-month clinical follow-up), which may be insufficient for comprehensively assessing the long-term clinical performance of these new chemically-cured composites. Hence, long-term follow-up remains necessary. Moreover, it is pertinent to note that over 60 % of the restorations in our study were Class I restorations. Considering that Class II restorations pose a higher risk of failure compared to Class I restorations when using regular viscosity composites, it is advisable for future clinical investigations to assess the performance of these new chemically-cured composites in cavities with increased complexity.

5. Conclusion

The chemically-cured composites appear to be an appealing option for restoring posterior teeth, as they exhibit lower postoperative sensitivity compared to a light-cured bulk-fill composite, both at baseline and up to 48 h, and less color mismatch. However, lower surface luster and texture were observed for the chemically-cured composites applied in Capsule compared to the light-cured composite.

Declaration of competing interest

The authors declare that they have no conflicts of interest.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jdent.2024.105246.

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