BMC Oral Health

RESEARCH

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Color evaluation of a one-shade used for restoration of non-carious cervical lesions: an equivalence randomized clinical trial

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Abstract

Background Obtaining a perfect color match with resin composite presents a significant challenge. The chameleon effect has enabled resin composite to mimic the color of the adjacent tooth structure in vitro. This double-blind, split-mouth and equivalent randomized clinical trial evaluated the color matching of one-shade resin composite with chameleon effect versus multi-shade resin composite in non-carious cervical lesion restorations (NCCLs).

Methods One hundred twenty restorations were performed on NCCLs with two restorative materials ($n=60$). After prophylaxis, the teeth were isolated with rubber dam and one universal adhesive was applied in the selective enamel etching strategy. For both groups, the restorations were inserted incrementally. The values of ΔE_{ab} and ΔE_{00} in the cervical and middle third were evaluated using a digital spectrophotometer before vs. after the restorations. The restorations were evaluated at baseline and after 7 days, 6-, 12- and 18-month of clinical performance according to the FDI criteria (Word Federation Criteria). Statistical analysis was performed using Chi-square test for all parameters. Color change was analyzed by two one-sided t-tests for paired samples ($\alpha=0.05$).

Results Regarding the color measurement no significant difference was observed when Vittra APS (FGM Dental Products, Joinville, SC, Brazil) was compared to Vittra Unique (FGM Dental Products, Joinville, SC, Brazil) for any of the comparisons performed ($p>0.05$). However, the ΔE_{ab} and ΔE_{00} values for the cervical third, both before and after the restorations, were higher compared to the ΔE_{ab} and ΔE_{00} values observed when comparing the cervical and middle thirds after the restorations. After 18 months, five restorations exhibited minimal discrepancies in terms of marginal adaptation or marginal discoloration ($p>0.05$). In all other criteria, including retention rate, no changes were detected at the 18-month recall.

Conclusions The one-shade resin composite used achieve the same color match when compared to a multi-shade resin composite after a period of 7 days in NCCLs. Overall, the restorations scored clinically very good (FDI) at baseline and after 18 months for all outcomes.

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Clinical Significance The use of a one-shade resin composite in NCCLs can be recommended because it has the ability to simplify the restoration procedure and maintaining an excellent clinical performance.

Registration of clinical trials RBR-8txr4fw: 26/05/2022.

Keywords Resin composite, Color, Optical properties, Clinical trial

Background

Resin composites are now widely utilized as restorative materials owing to their excellent aesthetic properties and clinical performance [1, 2]. The industry undergoes continuous technological advancements, enhancing these restorative materials and solidifying resin composite as the primary choice for direct restorations in both anterior and posterior teeth [3].

Despite its excellence as a material, resin composite poses challenges in achieving precise results, notably in accurately identifying the correct color match between the restoration and natural tooth structure [4]. Due to the inherent polychromatic nature of human teeth, achieving a perfect color match with resin composites represents a potentially difficult goal [4]. In the development of resin composites, pigments of diverse chroma, hues, and values have been incorporated to create color through the interplay of chemical energy between pigments and light [5, 6], resulting in what are known as multi-shade resin composites [7]. However, employing these multi-shade composites proves time-consuming for both the clinician and the patient. Attaining aesthetic "success" necessitates the involvement of a highly skilled professional, rigorous adherence to detailed clinical protocols, and a meticulous approach [4, 7].

Currently, materials engineered to blend or create a chameleon effect have empowered resin composite with the ability to mimic the color of the adjacent tooth structure [4, 8, 9]. This phenomenon, termed color blending [8, 10], demonstrates that, under optimal conditions, the composite seamlessly merges with the surrounding tooth, achieving what is known as a "single-shade" or "one-shade" resin composite [9, 10].

Extensive evaluations have been conducted on all optical properties of these innovative materials, encompassing translucency, opalescence, iridescence, and their potential for color adjustment [8, 11–14]. Yet, when comparing one-shade composites with multi-shade composites, conflicting results have emerged [8, 11–14]. Subsequently, some clinical trials [10, 15, 16] evaluate single-shade composites for applications such as diastema closure and direct veneers for permanent anterior restorations [10] and caries lesions in primary teeth [15], after 24 and 12 months, respectively [10, 15]. However, in both studies, the color change was only evaluated subjectively [10, 15]. More recently, single-shade composites have been employed to restore non-carious cervical lesions (NCCLs) compared to multi-shade composites, with objective color evaluation [16]. However, only short-term follow-ups (7 days) were presented. Therefore, it is evident that more clinical studies are needed to assess the disparities between one-shade and multi-shade composites, along with longer clinical follow-ups. The present study is the first to objectively evaluate the color of this resin composite and to clinically assess restorations during an 18-month service period in NCCLs.

The aim of this two-arm double-blind, equivalent, randomized clinical trial was to compare the clinical performance of the one-shade resin composite Vittra Unique (FGM Dental Products, Joinville, SC, Brazil) with the multi-shade resin composite Vittra APS (FGM Dental Products, Joinville, SC, Brazil) in restoring NCCLs. The first null hypothesis of this study is that there will be no difference in color matching between the resins used. The second null hypothesis of this study is that there will be no difference in other clinical parameters between the resins used.

Methods

Ethics approval and protocol registration

The clinical investigation was approved (protocol # 5.344.060) by the scientific review committee and by the committee for the protection of human participants of the Tuiuti University of Paraná (Curitiba, PR, Brazil). The study methodology was conducted in agreement with the Helsinki Declaration guidelines. All participants were informed of the nature and objectives of the study and the informed consent was obtained from all subjects before beginning of the study. This means that all subjects signed and agree to participate of the present clinical trial. It was registered in the Brazilian Clinical Trials Registry (RBR-8txr4fw; Registration Date: 26/05/2022). The description of the experimental design followed the Consolidated Standards of Reporting Trials (CONSORT) [17] with extension of equivalence study designs [18].

Trial design, settings, locations of data collection and recruitment

The present study is a double-blind, equivalence and randomized and controlled clinical trial. It was performed between June 2022 to September 2022, and the 18-month data collection occurred between December 2023 to February 2024. The study was carried out at the clinics of the Faculty of Dentistry of the Tuiuti University of Paraná

(Curitiba, PR, Brazil), where patients were recruited as they sought treatment at the University's clinics. Participants were enrolled based on the sequence of their registration for the screening session, resulting in a convenience sample.

Eligibility Criteria

All participants were examined by two calibrated dentists to assess inclusion and exclusion criteria before the study's commencement. Assessments were performed using an intraoral clinical mirror, an exploratory probe, and a periodontal probe. The eligibility criteria for this study were modeled after those outlined by Miranda et al. [15] and are summarized as follows: Participants were required to be in good general health (ASA I, a normal healthy patient; and ASA II, a patient with mild systemic disease without significant functional limitations), at least 18 years old, and maintain acceptable oral hygiene as per the Simplified Oral Hygiene Index (OHI-S) [19]. They needed to have at least 20 teeth in occlusion and present with at least two NCCLs that were adjacent and with similar size, shape, and dimensions were included. This typically involved selecting either two anterior or two posterior teeth positioned side by side.

The study employed a split-mouth design to facilitate direct comparison of two different interventions within the same hemiarch of a single participant. Each NCCL had to be large enough to allow the spectrophotometer's tip to measure the initial color of the lesion and must have been non-retentive. Each NCCL was required to have a depth greater than 1 mm, involving both enamel and dentin, with no mobility [15]. Additionally, the margin at the cavo-superficial angle had to involve more than 50% of enamel [20].

Exclusion criteria included: poor oral hygiene (OHI-S score greater than 3), use of orthodontic appliances, severe or chronic periodontitis (evidenced by probing pocket depth greater than 4 mm with bleeding on probing and clinical attachment loss exceeding 3 mm in more than 4 teeth), severe bruxism (characterized by significant masticatory muscle pain, temporomandibular joint pain, or extreme tooth wear), allergies to resin materials or any materials used in the study, and pregnant or lactating women. Such individuals were excluded to ensure they received necessary treatments before participating in the restorative procedures as describe by Miranda et al. [15]

Sample size calculation

The sample size calculation focused on color matching, measured using the CIELab ΔE_{ab} scale, with an acceptability limit of 2.7 [21]. In a preliminary study involving 10 participants (data not shown), the mean ΔE_{ab} before and after using the universal-shade resin composite was 8.0 ± 4.0. This suggests that a ΔE_{ab} difference greater than 2.7 would be considered significantly noticeable when comparing two different resin composites. To achieve a significance level of $\alpha = 0.05$ and a statistical power of 90%, with an equivalence threshold of 2.7, a minimum of 48 restorations per group was required to detect equivalence. To account for potential patient dropouts, an additional 20% was added, resulting in a final sample size of 60 restorations per group.

Random sequence generation and allocation concealment

The randomization process was conducted on an intra-individual basis, with each patient receiving two restorations. This process was managed using tools from the website (http://www.sealenvelope.com). A staff m ember not involved in the research protocol handled the randomization. Details of the allocated groups were recorded on cards placed in black, sealed, opaque, and sequentially numbered envelopes. These envelopes were only opened on the day of the restorative procedure to maintain blinding of the randomization sequence. For each patient, the tooth with the higher number (according to the FDI numbering system) was treated first, while the tooth with the subsequent number received the second treatment [15].

Blinding

The evaluators, who were not involved in the restorative procedures, were blinded to the group assignments to ensure unbiased assessments. To maintain blinding, the resin tubes were not left exposed. Instead, the operator extracted the resin increment from each tube and enclosed it within a resin cocoon, placing the tubes on a bench behind the dental chair. This method prevented the patient from identifying which resin was being used. Additionally, since the patient lacked the knowledge to distinguish between the two techniques, they were also considered blinded to the group assignments. This setup fulfills the criteria for a double-blind study. However, due to the distinct differences between the materials used, it was not feasible to blind the operators, as pointed out by Miranda et al. [15].

Evaluation of the characteristics of the NCCLs and objective color evaluation

In the initial session, selected patients underwent dental prophylaxis using a pumice-based paste and water applied with a rubber cup (ref #8040RA and #8045RA, KG Sorensen, Barueri, SP, Brazil). This was followed by rinsing and drying. The degree of dentin sclerosis in the NCCLs was assessed based on the scoring criteria established by Heymann and Bayne (1993) [22], later modified by Swift et al. (2001) [23]. Measurements included cavity dimensions (height, width, and depth), cavity geometry

(evaluated through profile photography and categorized as <45°, 45°-90°, 90°-135°, and >135°) [24], the presence of antagonistic forces, and any wear or friction facets [25]. Preoperative sensitivity was assessed by applying air for 10 s using a triple dental syringe positioned 2 cm from the tooth surface, as well as with an explorer. These baseline analyses were recorded for comparison with post-treatment results [15].

Color evaluation was performed using a digital spectrophotometer (VITA Easyshade, VITA Zahnfabrik, Bad Säckingen, Germany) under controlled artificial lighting to avoid interference from external light. Teeth were kept hydrated during the assessment. The color of the cervical and middle thirds of the facial surface of each NCCL was measured (Fig. 1A). To standardize measurements, two impressions (Fig. 1B and F) of the tooth were made using dense silicone (Perfil, Vigodent, Rio de Janeiro, RJ, Brazil). These impressions served as a matrix for the spectrophotometer's shade measurements. Each impression was fitted with a circular metallic device with a 6 mm radius (the diameter of the spectrophotometer tip), creating a "window" for color measurement in the cervical third (Fig. 1C, D, G and H) and just below the cavity restoration interface/enamel in the middle third (Fig. 1E and I).

The spectrophotometer was calibrated before each measurement. The device's tip was placed into the holes of the silicone guide, and color parameters L*, a*, and b* [26, 27] were recorded for both the cervical and middle thirds. The L* value represents luminosity, the a* value indicates the red-green axis, and the b* value measures the yellow-blue axis.

Restorative procedures

To ensure that restorations were conducted with well-established criteria, the study advisor performed a restoration for each group, detailing all necessary steps for the restorative technique. Following this demonstration, two operators with over five years of clinical experience executed one restoration from each group under the advisor's supervision. This process allowed any deficiencies in the restorations to be addressed and corrected before the study commenced. The operators were only deemed calibrated to perform the restorative procedures after this review, and they were responsible for all restorations throughout the study [15].

At the beginning of the second session, the color selection for the restorative procedure was made. Dental prophylaxis was performed using a pumice-based paste and water applied with a rubber cup (ref #8040RA and #8045RA, KG Sorensen, Barueri, SP, Brazil), followed by the initial color measurement. For the multi-shade group, a Vita Classical shade guide (VITA Classical, Vita Zahnfabrik, Bad Säckingen, Germany) was used to identify the shade that most closely matched the color of the teeth. Subsequently, the resins were selected, and a chromatic map was created around the area to be restored. In restorations using multi-shade resin composites, at least one combination of enamel and dentin resin composite was utilized. This step was not necessary for the one-shade experimental group, which used only a single resin composite.

Restorations were carried out under local anesthesia with a 3% mepivacaine solution (Mepisv, Nova DFL, Rio de Janeiro, RJ, Brazil). After applying a rubber dam, master clamps were placed on the most posterior teeth, such

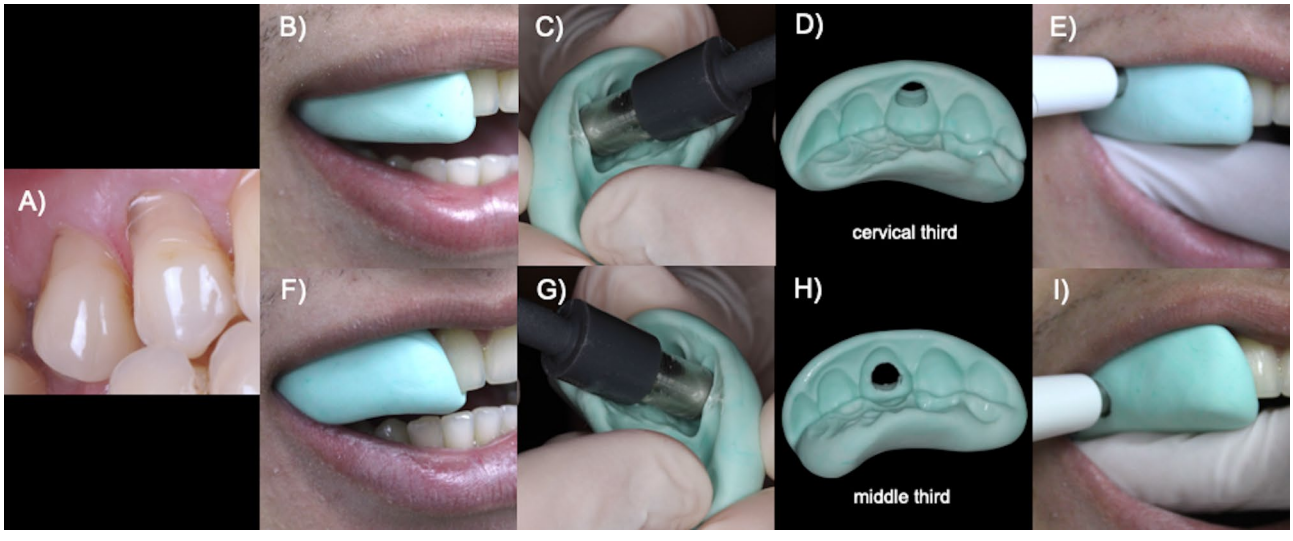

Fig. 1 Initial appearance of the non-carious cervical lesions to be evaluated (**A**). Two impressions of the tooth to be restored (**B** and **F**). Window created, using a circular metallic device, in the cervical third (**C** and **G**). Window created, in the middle third (**D** and **H**). The spectrophotometer tip inserted into the holes of the silicone guide, in the cervical third (**E**). The spectrophotometer tip inserted into the holes of the silicone guide, in the middle third (**I**)

as clamp 26 for molars and clamps 208/209 for premolars, to stabilize the isolation. Retractor clamps, including 212, 212 L, 212 R, and B4, were used on NCCLs. The universal adhesive system, Ambar Universal APS (FGM Dental Products, Joinville, SC, Brazil), was applied in selective enamel etching mode using Condac (37% phosphoric acid, FGM Dental Products, Joinville, SC, Brazil), following the manufacturer's guidelines.

The cavities were restored according to the following protocol: a multi-shade resin composite, Vittra APS (FGM Dental Products, Joinville, SC, Brazil), was inserted in increments of up to 2 mm and light-cured with an irradiance of 1,200 mW/cm² (Bluephase, Ivoclar Vivadent, Schaan, Liechtenstein) for 20 s. For multi-shade resin composite restorations, a standard layering protocol was followed: the initial increment layers replicated dentin, adjusted based on cavity depth, while the final layer mimicked enamel. Since the cervical region has a thicker dentin layer relative to enamel, this anatomical pattern was consistently maintained throughout the restoration process. Consequently, more dentin increments were applied than enamel. A single-one-shade resin composite, Vittra Unique (FGM Dental Products, Joinville, SC, Brazil) was then applied in increments of up to 2 mm, following the same light-curing procedure. For the group restored with single-shade resin composite, the number of increments depended on cavity size. In smaller cavities, one or two increments, each 2 mm thick, were sufficient. The irradiance was checked with a radiometer (Bluephase Meter II, Ivoclar Vivadent, Schaan, Liechtenstein) for every four restorations. Additional details on the materials used are provided in Table 1. After cavity filling, restorations were finished immediately with fine and extra-fine #2200 diamond burs (KG Sorensen, Barueri, SP, Brazil) and polished with OptraPol NG (Ivoclar Vivadent, Schaan, Liechtenstein) under continuous water cooling. Patients were instructed to resume their normal activities, including diet and oral hygiene practices.

One week after the restorative procedure, a second color measurement was performed using the same method as previously described. The device was recalibrated before each measurement. The spectrophotometer tip was inserted into the silicone guide's holes to obtain color parameters L*, a*, and b* [26, 27] for both the cervical and middle thirds of the restoration. Two measurements were performed: the first compared color changes in the cervical third before and after restoration, while the second compared color changes between the cervical and middle thirds after restoration.

Color difference before and after each was given by the difference between two color measurements measured with the spectrophotometer – calculated using the following formula CIELAB, 1978: $\Delta E_{ab} = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)2]^{1/2}$ and CIEDE 2000: $\Delta E_{00} = [(\Delta L\ /kLSL)^2 + (\Delta C/kCSC)^2 + (\Delta H/kHSH)^2 + RT\ (\Delta C^*\Delta H\ /SC^*SH)]^{1/2}$ [27–29].

Calibration for clinical evaluation procedure

Two experienced and calibrated examiners reviewed 10 photographs for each score associated with every criterion. Over two consecutive days, each examiner evaluated 10 to 15 patients who had NCCL restorations but were not included in the study sample. Agreement levels between intra-examiner and inter-examiner evaluations needed to be at least 85% before the evaluations were considered reliable [30, 31].

Table 1 Name, manufacturer, batch numbers, composition and application technique of the restorative materials used in the present study

Materials (Manufacturer)	Composition	Application technique
Vittra APS (FGM, Joinville, Santa Catarina, Brazil)	Monomeric matrix containing UDMA (Urethane Dimethacrylate) and TEGDMA (Triethylene Glycol Dimethacrylate) type monomers, photoinitiator composition (advanced polymerization system; APS), co-initiators, stabilizer and silane. Zirconia filler, silica and pigments (72–80%wt).	1. The resin composite is placed in increments of 2 mm. 2.Light-curing of each increment is performed with an irradiance of 1200 mW/cm² for 20 s.
Vittra Unique APS (FGM, Joinville, SC, Brazil)	UDMA, TEGDMA, photoinitiator composition (APS), co-initiators, stabilizer and silane. Nanospheres of a complex of silica-zirconia (72–80%wt)	1. The resin composite is placed in increments of 2 mm. 2.Light-curing of each increment is performed with an irradiance of 1200 mW/cm² for 20 s.
Ambar Universal APS (FGM, Joinville, SC, Brazil) (201123)	MDP (10-methacryloyloxydecyl dihydrogen phosphate), methacrylate monomers, photoinitiators complex (APS), co-initiators, stabilizers. Inactive Ingredients: inert load (silica particles) and vehicle (ethanol).	1.Apply phosphoric acid 37% only on enamel for 15 s. Wash the surface with water and dry the cavity until it is moist, not dehydrated. 2. Dispense Ambar Universal APS in a Dappen pot or directly onto a disposable micro applicator. Apply two layers of adhesive – one drop for each- on the slightly moistened tooth surface. The first layer should be applied vigorously by rubbing the adhesive microapplicator saturated with the product for 10 s. Next, the second layer of adhesive – with a new drop – is applied for another 10 s and then the area is air blasted gently for 10 s to evaporate the solvent. Light cure adhesive with mW/cm2 for 10 s.

Clinical Evaluation

A standardized paper form was used for each evaluator during follow-up assessments to ensure blinding. The primary clinical outcome was objectively measured color match, and the restorations were evaluated as described earlier. Additionally, restorations were assessed according to World Federation (FDI) criteria [31–33] both at baseline and 7 days, 6-, 12- and 18-month later, focusing on the following aspects:

1. Color stability and translucency.
2. Surface gloss/luster.
3. Surface color.
4. Anatomical form (esthetic properties).
5. Fracture and retention.
6. Marginal adaptation.
7. Marginal discoloration.
8. Patient perception (functional properties).
9. Postoperative hypersensitivity.
10. 10. Tooth vitality.
11. Recurrence of initial pathology.
12. Tooth integrity (enamel cracks).
13. Periodontal response (always compared to the reference tooth) (biological properties).

Variables were classified according to FDI criteria into categories of clinically very good, clinically good, clinically sufficient/satisfactory, clinically unsatisfactory but repairable, and clinically poor (replacement required) [31–33]. Each examiner independently evaluated all restorations once. In cases of disagreement, the examiners discussed and reached a consensus before finalizing the evaluation.

Statistical analysis

Statistical analyses adhered to the intent-to-treat principle as outlined by CONSORT [17]. Descriptive statistics were employed to summarize the distribution of the evaluation criteria. Each assessment criterion, based on revised FDI criteria [31–33], was analyzed individually. To compare differences between the two groups at each time point, the Chi-square test was used ($\alpha = 0.05$). Inter-examiner agreement was assessed using Cohen's kappa statistic. For objective color evaluations, t-tests for paired samples were conducted for each parameter (ΔE_{ab} and ΔE_{00} for cervical third before vs. after restoration, and ΔE_{ab} and ΔE_{00} for cervical vs. middle third after restorations). Equivalence between study groups was tested using two one-sided t-tests for paired samples (TOST-P) at different assessment points (baseline vs. 1-week). This method involved a right-sided test for the lower margin of the equivalence limit and a left-sided test for the upper margin, both with a significance level of 0.025. The overall p-value was determined as the larger of the two p-values from the lower and upper tests. Equivalence was not upheld if treatments differed by more than 2.7 units for ΔE_{ab} or 1.8 units for ΔE_{00} in either direction. Additionally, Pearson correlation analysis was used to examine the relationship between cavity characteristics (such as angle, cervico-incisal height, mesio-distal width, depth, degree of sclerotic dentin) and objective color parameters. All other secondary outcomes based on FDI criteria were analyzed using the Chi-square test. The significance level for all statistical tests was set at $\alpha = 0.05$.

Results

Overview

The restorative procedures were executed exactly as planned, with no modifications (Fig. 2). All baseline details regarding the characteristics of the restored lesions are presented in Table 2. A total of 120 restorations were placed, with 65 in the maxillary arch and 55 in the mandibular arch. Approximately 60% of the restorations were placed in premolars. It's worth noting the number of colors used in each multi-shade resin composite restoration, with 19 restorations performed using three or more shades and 41 restorations utilizing two shades, typically a combination of enamel and dentin resin composite.

Out of the 105 patients assessed for eligibility, 45 were not enrolled in the study due to not meeting the inclusion criteria (Fig. 2). Consequently, a total of 60 subjects (32 male and 28 female) were selected, with more than half of the participants being over 49 years of age. A total of 120 restorations were placed, evenly distributed with 60 in each group (Fig. 2). The procedures were performed according to the protocol without any modifications. Table 2 provides the baseline participant details and characteristics of the treated lesions, demonstrating an equal distribution of lesion features between groups. Observe in the Table 2 that, due to the randomization process employed, there was a balanced distribution of individual cavity and/or tooth characteristics across the treatment groups. This balanced distribution allowed us to directly assess the effect of the composite materials while controlling for potential confounding factors.

The overall Cohen's kappa statistics (0.87) indicated a high level of agreement among the examiners at the 6-month, 12-month, and 18-month follow-ups. All research subjects were assessed at baseline and during the 7 days, 6-month, 12- month, and 18-month follow-up visits, with a recall rate of 100%.

Objective color measurement

Regarding the objective color measurement, the results can be observed in Table 3; Fig. 3. The TOST test demonstrated the equivalence of color change for ΔE_{ab} and ΔE_{00} in the cervical third before and after the restorative

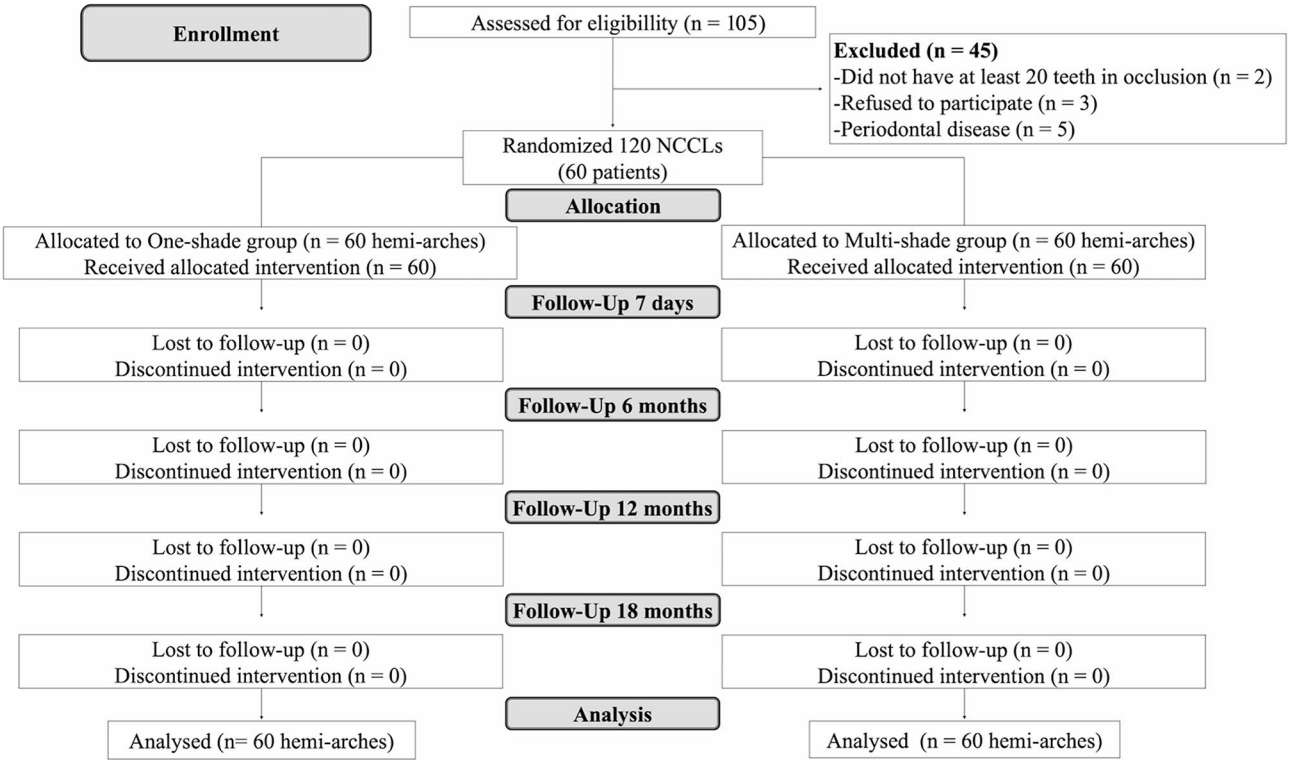

Fig. 2 CONSORT Flow Diagram

procedure, as well as in the cervical vs. middle third after the restorative procedure. The two-sided 90% confidence intervals (CI) of the difference of the means are within the predetermined equivalence margins of -2.7 and +2.7 for ΔE_{ab} and −1.8 and +1.8 for ΔE_{00}. The reported p-value is the larger of the two p-values from the upper and lower one-sided tests (TOST). All comparisons for all instruments were equivalent between protocols (Fig. 3, $p<0.001$). No significant difference was observed when one-shade was compared to multi-shade for any of the comparisons performed ($p>0.05$). However, it is worth mentioning that the values of ΔE_{ab} and ΔE_{00} in the cervical third before vs. after the restorations were higher when compared with ΔE_{ab} and ΔE_{00} observed when cervical vs. middle third after restorations were compared.

When evaluating the characteristics of the cavities, including cervico-incisal height, mesio-distal width, depth, and degree of sclerotic dentin, no significant differences were observed for (ΔE_{ab} and ΔE_{00} evaluated cervical third before vs. after) for each group, usually with a weak correlation. ($p>0.06$; 'r' ranging from – 0.03 to 0.28; Table 4). The unique exception was for 'degree of angle' that showed a significant difference ($p<0.04$; Table 4), despite a weak correlation ('r' < 0.29).

Other clinical secondary outcomes

According to the FDI criteria, after 18 months, two restorations (one single-shade and one multi-shade) exhibited minimal discrepancies in marginal adaptation. Additionally, three restorations (one for one-shade and one for multi-shade) showed minimal marginal discoloration. However, no significant difference was detected between the groups ($p>0.05$; Table 5). In all other criteria, no changes were detected at the 18-month recall.

Discussion

The present clinical study evaluated the color adjustment potential of a one-shaded resin composite compared with a multi-shaded resin composite. Although several universal resin composites are available in the market, only a few of them are one shade, such as Omnichroma (Tokuyama Dental Corp., Japan), Admira Fusion X-tra (Voco, GmbH, Cuxhaven, Germany), and Vittra Unique (FGM Dental Products, Joinville, SC, Brazil) [33]. Omnichroma (Tokuyama Dental Corp., Japan) was the first bona fide one-shaded resin composite. According to the manufacturer, the uniform spacing and arrangement of the spherical Omnichroma particles produce light transmission throughout the restoration. Additionally, the translucency of Omnichroma increases after polymerization due to the difference in the refractive index of the monomers before and after polymerization [9, 34].

For the one-shaded composite used in the present study (Vittra Unique), there is no clear explanation from the manufacturer about the mechanism of the material's color shifting. However, several recent studies have

Table 2 Characteristics of the non-carious cervical lesions per each restorative group

Characteristics of NCCLs lesions	Number of Lesions	
	One-shade	Multi-shade
Shape (degree of angle)		
< 45	1	2
45–90	23	25
90–135	18	15
> 135	18	18
Cervico-incisal height (mm)		
< 1.5	7	8
1.5–2.5	13	13
2.5-4.0	33	29
> 4.0	7	10
Mesio-distal width (mm)		
< 2.5	11	13
2.5–3.5	15	12
3.5-4.0	13	20
> 4.0	21	15
Depth (mm)		
1.0-1.5	43	43
1.5-2.0	9	59
2.0-2.5	1	0
> 2.5	7	8
Degree of sclerotic dentin		
1	15	16
2	23	20
3	16	14
4	6	10

Table 3 Color evaluation (ΔE_{ab} and ΔE_{00}) of restorations evaluated before and after performed the restorative procedure (*)

	Cervical third before vs. after		Cervical vs. middle third after	
	ΔE_{ab}	ΔE_{00}	ΔE_{ab}	ΔE_{00}
One-shade	5.7 ± 2.5	3.9 ± 1.8	8.9 ± 7.3	6.9 ± 5.8
Multi-shade	6.1 ± 2.7	4.5 ± 2.3	9.8 ± 6.2	7.4 ± 5.0
p-value*	0.51	0.35	0.47	0.5

(*) Test-t Student showed not significant difference for any comparisons ($p > 0.05$)

shown that Vittra Unique presented lower opacity compared to other composites [12, 35]. Therefore, the color adjustment potential of Vittra Unique seems to be related to its higher translucency after light-cure [35].

However, recent studies showed that Vittra Unique has shown similar color adjustment potential in comparison with Omnichroma [12, 36]. For instance, Altınışık, Özyurt [36] evaluated the color adjustment potential of several one-shade composites (Omnichroma, Charisma Diamond One [Kulzer, Hanau, Germany], Vittra Unique, and Essentia Universal [GC Corporation, Tokyo, Japan]). The results of this study indicate that the values for visual color adjustment potential ranged from 0.43 to 0.53, while those for instrumental color adjustment potential ranged from 0.34 to 0.43, with no significant difference between them [36].

The main focus of the present study was to compare the blending effect of the one-shade versus the multi-shade composite, primarily because previous studies discovered controversial results in terms of color adjustment potential when both types of resin composite were compared in vitro [5, 6, 34, 36]. Despite all the advantages of in vitro evaluations [37, 38], this type of study does not necessarily predict the clinical performance of any material or protocol, underscoring the importance of conducting clinical studies.

In the present study, because the color match was evaluated based on the revised FDI criteria, all restorations were considered clinically excellent/very good. This means there was "no deviation in shade, translucency/opacity between restoration, and neighboring dental hard tissue/adjacent teeth" [31]. These results align with previous ones that showed that one-shade resin composites produce similar color matches as the multi-shade resin composites evaluated [10, 15].

Unfortunately, color matching is a relative measure that does not produce an absolute of a restoration's instantaneous color [38]. Therefore, clinical trials must utilize a more objective mode to measure the color match. This was the main reason why the authors of this study tried to measure the way the color of restorations should match the surrounding tooth structure and to evaluate the real "blending effect" of one-shade resin composites with adjacent dental tissue.

In the first part of this method, the color evaluation was performed to evaluate the color change observed in the cervical third before and after the restorative procedure. Based on this measure, it was expected that one-shade resin composites would improve their color adjustment potential with the tooth structure [34, 36]. In the second part of this method, the color evaluation was performed to evaluate the color change observed in the cervical vs. middle third after the restorative procedure. While the color among different thirds of teeth is not the same [39], we expected that the one-shade resin composites would exhibit some level of similarity across both thirds, matching the color of the substrate.

In general, it was possible that the one-shade resin composite used showed similar ΔE_{ab} and ΔE_{00} values in both measurements compared to the multi-shade resin composite. Therefore, the authors accept the first null hypothesis. However, the most important result of the present study is that no significant differences in color match were observed when applying the revised FDI criteria [31]. This means that one-shade composites have a similar shade-matching ability as multi-shade composites, which aligns with Zulekha et al.'s (2022) results when

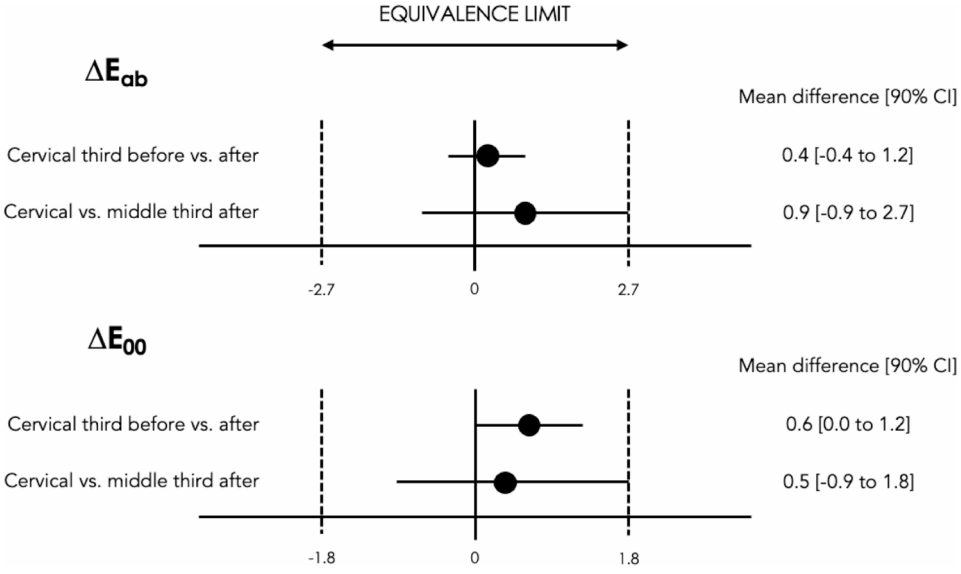

Fig. 3 Mean differences of color change measured with different instruments (ΔE_{ab} and ΔE_{00}) between in the cervical third before and after the restorative procedure or in the cervical vs. middle third after the restorative procedure groups at the baseline vs. 7 days procedure. Horizontal bars indicate two-sided 90% confidence interval (CI) of the mean difference between treatment groups. The zone between the dashed lines indicates the equivalence limit margin

Table 4 Correlation between characteristics of NCCLs lesions and color evaluation (ΔE_{ab} and ΔE_{00}) of restorations evaluated before and after performed the restorative procedure (*)

		Cervical third before vs. after				
		Shape (degree of angle)	**Cervico-incisal height (mm)**	**Mesio-distal wight (mm)**	**Depth (mm)**	**Degree of sclerotic dentin**
ΔE_{ab}	One-shade	*r* = 0.29; p-value 0.04	*r* = 0.15; p-value 0.31	*r* = 0.18; p-value 0.21	*r* = 0.12; p-value 0.40	*r* = -0.05; p-value 0.71
	Multi-shade	*r* = 0.33; p-value 0.02	*r* = 0.12; p-value 0.39	*r* = 0.19; p-value 0.19	*r* = 0.26; p-value 0.07	*r* = -0.03; p-value 0.84
ΔE_{00}	One-shade	*r* = 0.16; p-value 0.28	*r* = 0.27; p-value 0.06	*r* = 0.12; p-value 0.39	*r* = 0.07; p-value 0.62	*r* = 0.12; p-value 0.40
	Multi-shade	*r* = 0.19; p-value 0.20	*r* = 0.28; p-value 0.06	*r* = 0.10; p-value 0.48	*r* = 0.00; p-value 0.99	*r* = 0.10; p-value 0.48

(*) Person correlation between paired data

restorations performed in primary maxillary incisors were evaluated [16].

It is important to mention that the authors observed very good results for the multi-shade composites used. However, the operators of the present study could be considered experienced, as they had been trained to layer restorations with various shades prior to the study, ensuring good results in terms of color matching. This training, however, was not necessary for one-shade resin composite restorations, as the reduction in the number of shades simplified the creation of almost imperceptible restorations using fewer shades [15].

It is worth noting that higher values of ΔE_{ab} and ΔE_{00} were observed for both composites. The ΔE_{ab} values ranging from 5.7 to 6.1, whereas the ΔE_{00} values ranging from 4.5 to 3.9. All of the values were higher than the acceptability threshold of 50:50, which is 2.7 for ΔE_{ab} and 1.8 for ΔE_{00} [21]. Taking the acceptability parameter into account allows researchers to assess how perceptible the color change was for evaluators [21]. These values indicate that more than 50% of observers noticed some color change and believed the dental restoration required color correction [21]. However, this contradicts what was observed in the subjective evaluation, where both evaluators described all restorations as excellent/very good for color match. In addition, the patients answered that there were "entirely satisfied" with the quality of the final restoration [31].

In the present study, the ΔE_{ab} and ΔE_{00} were obtained for measurements performed by Vita Easyshade digital spectrophotometer, mainly because this device has been used to measure color change in several materials [40–42] Compared to the visual color measure, the digital spectrophotometer is considered the most precise, flexible, and helpful tool for color assessment in dentistry [43]. However, spectrophotometer used may not be the

Table 5 Number of evaluated restorations for each experimental group (*) classified according to the World Dental Federation (FDI) criteria

FDI Criteria	(*)	Baseline		7 days		6 months		12 months		18 months	
		One-shade	Multi-shade	One-shade	Multi-shade	One-shade	Multi-shade	One-shade	Multi-shade	One-shade	Multi-shade
Color stability and translucency	A	60	60	60	60	60	60	60	60	60	60
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Surface gloss/lustre	A	60	60	60	60	60	60	60	60	60	60
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Surface color	A	60	60	60	60	60	60	60	60	60	60
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Anatomical form	A	60	60	60	60	60	60	60	60	60	60
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Fractures and retention	A	60	60	60	60	60	60	60	60	60	60
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Marginal adaptation	A	60	60	60	60	60	60	59	59	59	59
	B	0	0	0	0	0	0	1	1	1	1
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Marginal discoloration	A	60	60	60	60	60	60	58	59	58	59
	B	0	0	0	0	0	0	2	1	2	1
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Patient perception	A	60	60	60	60	60	60	60	60	60	60
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Postoperative sensitivity	A	60	60	60	60	60	60	60	60	60	60
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Tooth vitality	A	60	60	60	60	60	60	60	60	60	60
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0

Table 5 (continued)

FDI Criteria	(*)	Baseline		7 days		6 months		12 months		18 months	
		One-shade	Multi-shade	One-shade	Multi-shade	One-shade	Multi-shade	One-shade	Multi-shade	One-shade	Multi-shade
Recurrence of initial pathology	A	60	60	60	60	60	60	60	60	60	60
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Tooth Integrity	A	60	60	60	60	60	60	60	60	60	60
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
Periodontal response	A	60	60	60	60	60	60	60	60	60	60
	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0

(*) A = Clinically very good; B = Clinically good; C = Clinically satisfactory; D = Clinically unsatisfactory; E = Clinically poor

best tool for evaluating the color adjustment potential. Indeed, several other devices are more adequate tools to perform this measurement, such as imaging colorimeters and spectrophotometers. Unfortunately, these devices are complex and more expensive than the spectrometer used in the present study [43, 44]. Therefore, researchers should use most adequate tools to evaluate the color match of these new one-shade composites in future clinical studies.

Although other clinical parameters were considered secondary outcomes, it is important to briefly highlight a few points. Both composites demonstrated excellent performance according to the revised FDI criteria [31], leading the authors do accept the second null hypothesis. The similar degree of conversion, mechanical properties (flexural strength, elastic modulus, and microhardness), as well as post-gel shrinkage and shrinkage stress of the one-shade composite used in the present study compared to the multi-shade composite [37, 38, 45–47], can explain these excellent clinical results, in terms of functional and biological properties [31].

A small number of restorations showed marginal discrepancies, and none exhibited loss of retention or fracture during the 18-month clinical evaluation. This can be attributed to the use of selective enamel etching combined with a universal adhesive. Previous observations have shown that selective enamel etching enhances the micromechanical retention of the adhesive to the tooth surface by creating a rougher surface and, consequently, improving the bonding performance at all [48, 49].

Regarding the adhesive system, the universal adhesive used has shown very good adhesive performance compared to other universal adhesives available on the market [50–53]. However, it is worth mentioning that clinical tests for its predecessor (Ambar Universal, FGM Dental Products, Joinville, SC, Brazil) in previous clinical studies showed a retention rate varying from 89 to 93% after 18 months of clinical evaluation [54, 55]. Indeed, the manufacturer claims that the addition of a more hydrophilic photoinitiator improves the polymerization process. Recent studies showed an increase in the immediate degree of conversion and, consequently, the bonding performance when the universal adhesive used in the present study was compared with its predecessor or other universal adhesives available on the market [56, 57]. This seems to explain the excellent retention rate and the few marginal discrepancies observed even after 18 months of clinical evaluation.

Some limitations of the present study should be described. One limitation of the present study is the 18-month clinical follow-up, which may not provide a complete picture of long-term performance, as previously observed [58, 59]. Therefore, extended follow-up studies are essential to fully understand their clinical efficacy over time. Due to the numerous differences among one-shade resin composites available in the market [60], it is impossible to extrapolate the current results for other one-shade resin composite of different brands. Therefore, it is important that other clinical studies be performed to evaluate all one-shade resin composites that advocate this "blending effect." Despite promising results, particularly in terms of color match, it is important to continue evaluating these restorations in the long-term follow-up.

Conclusions

After 18 months, the one-shade resin composite evaluated demonstrated a comparable color match to the multi-shade resin composite in non-carious cervical

lesions when assessed subjectively (by the human eye) or objectively (via digital spectrophotometer). Taking in account all other items of the clinical evaluation, the clinical performance of both resin composites evaluated should be consider excellent.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12903-024-05108-6.

Supplementary Material 1

Acknowledgements
This study partially supported by the National Council for Scientific and Technological Development (CNPq) under grants 304817/2021-0 and 308286/2019-7 and Coordenação de Aperfeiçoamento de Pessoal de Nível Superior - Brasil (CAPES) - Finance Code 001. The authors would like to thank FGM Dental Group for the generous donation employed in this study. The authors would like to thank Bleaching&Bond group (Brazil).

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Funding
No funding was receipt for the present study.

Data availability
The raw data from the study is accessible and can be requested directly from the authors by contacting corresponding author by email.

Declarations

Ethics approval and consent to participate
The clinical investigation was approved (protocol # 5.344.060) by the scientific review committee and by the committee for the protection of human participants of the Tuiuti University of Paraná (Curitiba, PR, Brazil). The study methodology was conducted in agreement with the Helsinki Declaration guidelines. All participants were informed of the nature and objectives of the study and the informed consent was obtained from all subjects before beginning of the study. This means that all subjects signed and agree to participate of the present clinical trial. It was registered in the Brazilian Clinical Trials Registry (RBR-8txr4fw; Registration Date: 26/05/2022).

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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Received: 10 June 2024 / Accepted: 23 October 2024
Published online: 04 December 2024

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