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ORIGINAL ARTICLE

Colorimetric evaluation after in-office tooth bleaching with violet LED: 6- and 12-month follow-ups of a randomized clinical trial

Matheus Kury[1] · Erica Eiko Wada[1] · Samuel da Silva Palandi[1] · Mayara Zaghi Dal Picolo[1] · Marcelo Giannini[1] · Vanessa Cavalli[1]

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Abstract

Objectives To evaluate the long-term outcomes of in-office bleaching with violet LED light (LED) alone or combined with carbamide (CP) or hydrogen (HP) peroxides.

Methods Volunteers of a previous short-term study were recalled for 6- and 12-month follow-ups, according to the following interventions ($n = 18$/group): LED, CP, LED/CP, HP, and LED/HP. The objective color (ΔE_{ab}, ΔE_{00}) and whiteness index (ΔWI_D) changes were calculated applying the CIELab coordinates' values obtained using a spectrophotometer. A visual shade guide determined the tooth's subjective color change (ΔSGU). Data were submitted to one-way ANOVA or Welch's ANOVA, following appropriate post hoc tests ($\alpha = 5\%$).

Results The LED and CP groups exhibited the lowest ΔE_{ab}, ΔE_{00}, and ΔSGU ($p < 0.05$), but the LED group displayed a significantly lower ΔWI_D. After 12 months, the LED/CP group presented a higher ΔE_{ab} and ΔE_{00} than the CP group ($p < 0.05$). ΔE_{ab}, ΔE_{00}, ΔSGU, or ΔWI_D means did not differ statistically between the LED/CP and HP groups. The LED/HP group presented a higher ΔE_{00} than the HP group, regardless of the time.

Conclusions The bleaching efficacy of LED alone was significantly lower compared to the LED/CP and HP-containing protocols. After 12 months, the LED/CP and HP groups did not differ in bleaching efficacy. LED irradiation only increased the objective color change of bleaching gels.

Clinical relevance LED alone promoted a long-term perceptible bleaching, but not compatible with that of high-concentrated HP. The bleaching outcomes of violet irradiation to 37% CP were maintained over time, with LED/CP demonstrating comparable results to HP even after 12 months.

National Clinical Trials Registry (REBEC) RBR-5t6bd9

Keywords Tooth bleaching · Hydrogen peroxide · Carbamide peroxide · Light · Follow-up

Introduction

In-office dental bleaching is one of the most frequent esthetic treatments performed by dentists and is often indicated for fast chromatic and perceptible changes in the anterior teeth [1–4]. The bleaching gels available for in-office bleaching are composed of highly concentrated hydrogen (HP) or carbamide (CP) peroxides [5]. The main difference between these two gels is the composition of CP, which presents carbamide peroxide with urea. When these compounds come into contact with water, they break down into hydrogen peroxide and ammonium and, later, in oxygen-free radicals and water. Therefore, the CP gel contains only one-third of the total hydrogen peroxide concentration compared to the HP gel [6]. As a consequence, HP may display a higher bleaching efficacy than CP, taking into consideration the same application time [7].

In recent decades, several types of light sources have been used to attempt to increase the efficacy of in-office bleaching gels [8]. The rationale behind this approach is to heat the peroxide gels through the thermal energy generated from the light. As a consequence, the increase in the release of free radicals could enhance the bleaching effects [8, 9]. Researchers have shown controversial bleaching

✉ Vanessa Cavalli
vcavalli@yahoo.com

1 Department of Restorative Dentistry, Piracicaba Dental School, University of Campinas, 901 Limeira Avenue, Areião, Piracicaba, SP 13414-903, Brazil

outcomes in regard to the use of the argon laser, halogen lamp, blue LED, or diode laser [10–12]. Such divergent outcomes could be explained based on the differences between irradiation protocols, time of use, or irradiance and power stability of the different light sources. Also, differences in the bleaching gel's type, concentration, or application regimen hinder the comparison among studies [10, 13]. However, systematic reviews concluded that no light irradiation source was able to enhance the efficacy of in-office bleaching gels [8, 13–15].

Some clinical reports have suggested the use of a new violet LED light for in-office dental bleaching [16–20]. In these clinical case reports, the violet LED was used in combination with CP and HP. However, the violet LED light manufacturer also recommends the irradiation of violet light without any peroxide or chemical agent [21]. Based on the lower light penetrability of the violet wavelength [22], some authors have speculated that the violet light alone possibly degrades the extrinsic staining molecules adhered to the enamel surface by a photocatalyst process [18, 20].

It is worth mentioning that the violet LED bleaching protocols, combined or not with peroxide agents, have been applied without sufficient evidence to support their efficacy and safety. Only three randomized clinical trials assessed the efficacy of violet LED and its effect on tooth sensitivity, either alone or combined with at least one type of peroxide agent (CP or HP) [23–25]. The effect of violet LED alone on tooth sensitivity was minimum. Also, the combination of violet light with 37% CP gel presented the same efficacy as that of the non-irradiated 35% HP gel, but with reduced tooth sensitivity [25].

Even though some clinical trials attest to the limited ability of violet LED to bleach without peroxides or to increase the efficacy of peroxide agents, these reports are part of short-term evaluations only (up to 14-day follow-up) [23–25]. Besides, there is no evidence for the clinical efficacy of violet LED irradiation protocols using updated colorimetric systems. None of the clinical trials reported the color change based on the CIEDE2000, a system that corrects discrepancies in the CIELab color change formula [26]. Moreover, the clinical application of the whiteness index for dentistry, an index developed specially to detect the whiteness levels of teeth and is more suitable to visual perception, ought to contribute to the understanding of the topic [27].

Therefore, this study determined the long-term colorimetric evaluation (6 and 12 months from bleaching procedures) from a randomized and controlled clinical trial of violet LED in-office bleaching protocols. The null hypotheses tested were that after 6 and 12 months from bleaching, (1) violet LED light alone would not present the same bleaching efficacy as CP or HP gels, (2) violet irradiation would not increase the color and/or whiteness changes promoted by CP and HP, and (3) irradiation of CP with violet LED would not result in a bleaching efficacy similar to that observed for high-concentrated hydrogen peroxide.

Material and methods

Ethical aspects

The ethical aspects of this clinical trial were approved under the registration numbers: 72879717.7.0000.5418 (Issuing authority: *Plataforma Brasil*) and 2.229.061 (Issuing authority: Local Ethical Committee). An amendment was also approved by the Local Ethical Committee (3.776.209). This research was registered in the National Clinical Trials Registry (REBEC—RBR-5t6bd9) and followed the CONSORT guidelines. This is a long-term evaluation of a previously short-term published study [25]. Patients included in this study signed an informed consent in accordance with the Declaration of Helsinki before the first clinical session.

Recruitment of volunteers

The patients were recruited from the University through announcement signs distributed into a few facilities of the building. Patients of dental clinics, dental students, faculties, and staff were able to enroll for the initial appointment, which checked the eligibility criteria. Before signing the consent form, potential patientswere clinically evaluated and wereselected based on the inclusion or exclusion criteria found in Table 1.

The number of patients was determined by a sample size calculation, using color change values from a published study [28]. Adopting a 5% level of significance, an 80% power, and a 0.50 effect size *(f)*, the calculation indicated a minimum of 16 patients to detect differences among groups (BioStat, AnalystSoft, Walnut, CA, USA). Twenty volunteers were recruited, taking into consideration a further possibility of drop-out. The short-term study conducted by Kury et al. (2020) showed that 18 patients from each intervention group concluded the bleaching treatments and returned for the 14-day follow-up [25].

Randomization, blinding, and allocation

A research member, not responsible for either treating or evaluating the patients, performed the randomization and allocation concealment of the volunteers (V.C.). A code written in an opaque and sealed envelope was assigned to each participant. Then, the envelopes were randomly distributed into the five intervention groups [24, 28, 29]. The randomization was open only to the operator, before the beginning of the bleaching intervention. Two members were directly involved with the clinical appointments: one

Table 1 Inclusion and exclusion criteria

Inclusion	Exclusion
Age: 18 to 60 years old	Enamel cracks
Absence of carious lesions	Previous dentin hypersensitivity
Healthy gingival conditions	Pregnancy
Vital teeth	Smokers
Color of the canine's cervical/middle third should be at least A2	Endodontically treated teeth and/or with extensive restorations (minimal restorations accepted)
It was mandatory to report availability to attend follow-up appointments	Previous allergy to one of the materials planned to be used in the dental procedure
Absence of edentulous space between maxillary and mandibular premolars	Volunteers who have undergone bleaching during the last 3 years

operator (E.E.W) and one evaluator (M.K.). The operator was informed of which group each participant was allocated to because of the bleaching agents and light characteristics. However, the evaluator of the colorimetric analysis was blinded to the procedures. The volunteers were not aware of either the type or the concentration of the bleaching gel they were exposed to. For this purpose, any label, brand logo, or packaging that would enable identification of the products was removed [30]. The evaluator was previously calibrated during the in-office bleaching appointments of five participants excluded from the clinical trial. This calibration was performed by measuring the color of the cervical and middle third from the buccal surface of the upper canines after each training bleaching session [29]. The operator was responsible for recording the data. Another research member, also blinded, was in charge of scheduling the follow-up appointments (S.S.P.).

Interventions (bleaching procedures)

The bleaching protocols were defined according to the bleaching gel (HP, CP, or none) and light irradiation method (violet LED or none) used, and patients were randomly allocated into five different groups (n = 20/group): LED, CP, LED/CP, HP, and LED/HP. Table 2 displays the composition of the bleaching gels and the technical specification of violet LED. The bleaching protocols were as follows.

LED

The complete LED irradiation cycle totals 30 min (twenty 1-min irradiations with consecutive 30-s intervals). The gingival tissues were protected with a gingival barrier of flowable composite resin (Top Dam, FGM, Joinville, SC, Brazil) light-cured for 20 s (Valo, Ultradent, South Jordan, UT, USA). The violet LED device (MMOptics, São Carlos, SP, Brazil) was permanently positioned 8 mm away from the arches throughout the irradiation cycles. The teeth were kept hydrated with moist gauze during the intervals. The protocol was repeated for eight sessions at 4-day intervals.

CP or LED/CP

The gingival tissue was protected with a barrier as previously described. The 37% CP gel (FGM, Joinville, SC, Brazil) was applied directly on the teeth's buccal surface. The CP gel was applied for 30 min without refreshing and either combined with the irradiation of the violet LED light as described above (LED/CP), or without the use of the light source (CP). At the end of the session, the bleaching gel was removed and rinsed from the teeth. The protocol was repeated for three sessions at 7-day intervals.

Table 2 Bleaching agents' composition and light source technical specification

Bleaching agents and light source	Specification/composition
Hydrogen peroxide (HP) Whiteness HP (FGM, Joinville, SC, Brazil)	35% hydrogen peroxide, glycol, deionized water, dyes, inert filler, thickener, pH = 7.0
Carbamide peroxide (CP) Whiteness HP (FGM, Joinville, SC, Brazil)	37% carbamide peroxide, glycol, deionized water, inert filler, neutralized Carbopol, pH = 7.0
Violet LED (LED) Bright max whitening (BMW) (MMOptics, São Carlos, SP, Brazil)	Eight light emitting diode lamps (401.82 nm = violet wavelength) Illumination area of the curved acrylic tip = 10.7 cm^2. Total power = 1.2 W. Irradiance at the position corresponding to the right upper incisor = 8.0 mW/cm^2

HP or LED/HP

The thickener and 35% hydrogen peroxide (FGM, Joinville, SC, Brazil) were mixed in a container. This mixture was applied on the entire buccal surface from premolar to premolar with a micro brush after protecting the gingival tissues with a gingival barrier, as previously described. Initially, the gel showed a reddish color, changing to transparent within the first minutes. The HP gel was applied for 30 min without refreshing and either combined with the irradiation of the violet LED light as described above (LED/HP) or without the use of the light source (HP). The protocol was repeated for three sessions at 7-day intervals.

Colorimetric evaluation

A digital spectrophotometer (Easy Shade, Vita Zahnfabrik, Bad Säckingen, Germany) evaluated the upper right canine color. A custom-made silicon barrier (Zhermak, Kouigo, Italy) of each patient's superior arch was obtained. A hole in the cervical/middle region of the upper right canine standardized the position of the spectrophotometer's tip for readings on the buccal enamel surface [28].

The baseline/initial L* (luminosity: black—/ white+), a* (red+/ green -), b* (yellow+/ blue -), H (hue), and C (chroma) values were recorded after dental prophylaxis and before the first bleaching session (T_0) [25] and after 6 (T_{6m}) and 12 (T_{12m}) months from the last bleaching application. The patients were not submitted to dental prophylaxis at T_{6m} and T_{12m}, but they were required to brush their teeth before the follow-up sessions. During the appointment intervals, the patients were directed to not brush their teeth with whitening toothpaste. The coordinates (L*, a*, b*) were recorded and used to calculate objective color change, which was the primary outcome of the research. ΔE_{ab} and ΔE_{00} (color change) calculations were performed using the CIELab and CIEDE2000 formula, respectively, as follows [26]:

$$\Delta E_{ab} = \sqrt{\Delta(L)^2 + \Delta(a)^2 + \Delta(b)^2}$$

$$\Delta E_{00} = \sqrt{\left(\frac{\Delta L'}{K_L S_L}\right)^2 + \left(\frac{\Delta C'}{K_C S_C}\right)^2 + \left(\frac{\Delta H'}{K_H S_H}\right)^2 + RT.\left(\frac{\Delta C'}{K_C S_C}\right).\left(\frac{\Delta H'}{K_H S_H}\right)}$$

The S_L, S_C, and S_H are weighting functions that adjust the final color change in the location of L*, a*, and b* coordinates. K represents parametric correction factors, and R is a rotation function that establishes interaction among hue and chroma differences in the blue area. Two Δ values were obtained considering two time points ([$T_{6m} - T_0$] and [$T_{12m} - T_0$]). The 50:50% perceptibility threshold (PT) for the adopted values were 1.2 ΔE_{ab} and 0.8 ΔE_{00} units [31].

Moreover, Δ values considering the same time points above were calculated for the whiteness index for dentistry (ΔWI_D), based on the CIELAB system [27]:

$$WI_D = 0.55L^* - 2.32a^* - 1.100b^*$$

The 50:50% perceptibility threshold for the whiteness index change (WPT) was considered 0.61 ΔWI_D units [32]. Finally, a visual shade guide (ΔSGU – Vita Zahnfabrik, Bad Säckingen, Germany) evaluated the subjective color change of the upper right canine [33]. The tabs of the shade guide system were sorted in terms of lightness values. According to Table 3, the numbers 1 through 16 were assigned to each value in a decreasing order. The numbers recorded in each appointment were used to calculate the subjective color change. The subjective assessment considered the same time intervals, and the evaluator was previously calibrated and blinded in terms of which group each patient belonged.

Statistical analyses

The normality and the equal variances of the data obtained in the objective colorimetric evaluation were explored using the Shapiro–Wilk and Levene tests (SPSS 23, IBM, Chicago, IL, USA). The data attending both the normality and equal variance assumptions ($p > 0.05$) were submitted to one-way ANOVA and Tukey's test. Because the normality distribution of the ΔE_{ab} [$T_{6m} - T_0$] and ΔWI_D [$T_{12m} - T_0$] was confirmed, but the equality of variance assumption failed, data were assessed using Welch's ANOVA, followed by the post hoc Games-Howell test. The data from the subjective color change (ΔSGU) were analyzed using the non-parametric Kruskal–Wallis and Dunn multiple comparisons' tests. The significance level was set at 5%.

Results

The bleaching procedures and the 14-day follow-up appointments occurred in 2018 [25]. The 6-month and 1-year follow-ups assessed the long-term efficacy of the bleaching protocols during 2019. The flow of the patients throughout the clinical trial and the drop-off numbers per intervention group are illustrated in Fig. 1. Table 4 presents the demographic data of the volunteers.

The observed post hoc power values were above 0.95 for all the outcomes evaluated. Table 5 and Figs. 2 and 3 display

Table 3 Numeric scores of VITA Classical shade guide in decreasing order of value

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
B1	A1	B2	D2	A2	C1	C2	D4	A3	D3	B3	A3.5	B4	C3	A4	C4

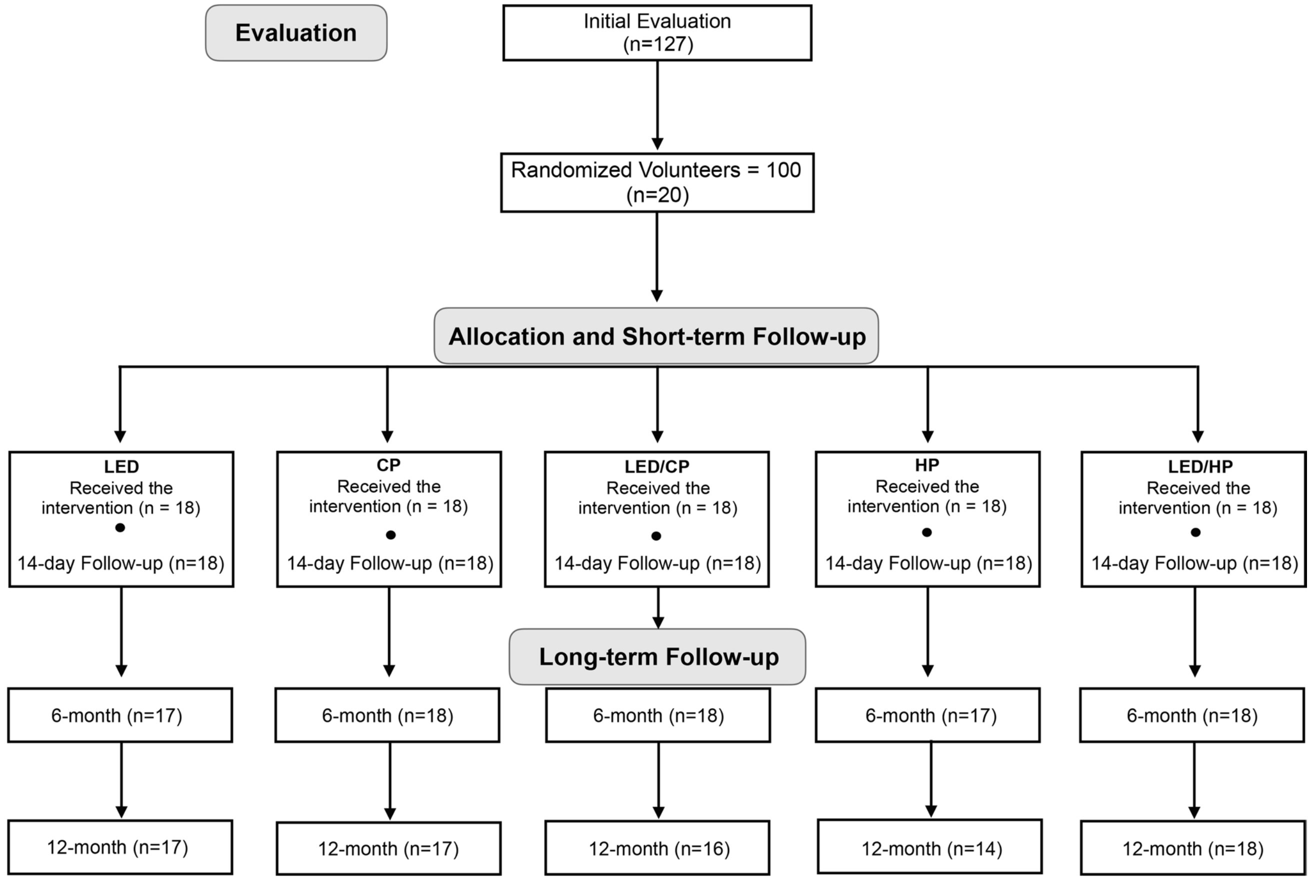

Fig. 1 Flow chart including the long-term evaluation of the volunteers

the mean objective (ΔE_{ab} and ΔE_{00}) and median subjective (ΔSGU) color change values 6 and 12 months from each protocol. After 6 months ($T_{6m} - T_0$), violet LED exhibited the lowest ΔE_{ab} among the groups ($p < 0.001$), with no color differences compared to CP (ΔE_{00} and ΔSGU; $p > 0.05$). No differences were observed among CP, LED/CP, and HP according to the objective (ΔE_{ab} and ΔE_{00}) and subjective parameters (ΔSGU) ($p > 0.05$). LED/HP exhibited the highest ΔE_{ab} and ΔE_{00}, but its ΔSGU was comparable to those of LED/CP and HP.

After 12 months ($T_{12m} - T_0$), LED and CP groups exhibited the lowest ΔE_{ab} and ΔE_{00} ($p < 0.001$). CP, LED/CP, and HP exhibited no differences in terms of ΔSGU ($p > 0.05$). LED/CP presented significantly higher ΔE_{ab} and ΔE_{00} than that obtained with the CP group. LED/HP exhibited the highest color changes among the groups according to ΔE_{00} ($p < 0001$), but with no statistical differences to HP (ΔE_{ab} and ΔSGU) and LED/CP (ΔSGU).

All the groups presented mean ΔE_{ab} and ΔE_{00} values above the 50:50% perceptibility threshold. The differences among ΔSGU mean values presented the same statistical pattern over time, showing that LED and CP groups did not present statistical differences independently of the

Table 4 Demographic information of the selected patients per group as well as in an overall perspective

	Age (years)	Gender	Ethnicity
LED	22.4 (5.7)	M (30.0%); F (70.0%)	WT (90.0%); BK (10.0%); IND (0.0%); AS (0.0%)
CP	20.0 (2.3)	M (25.0%); F (75.0%)	WT (90.0%); BK (0.0%); IND (5.0%); AS (5.0%)
LED/CP	21.6 (2.4)	M (40.0%); F (60.0%)	WT (90.0%); BK (5.0%); IND (5.0%); AS (0.0%)
HP	21.7 (5.5)	M (40.0%); F (60.0%)	WT (90.0%); BK (5.0%); IND (0.0%); AS (5.0%)
LED/HP	21.2 (2.3)	M (30.0%); F (70.0%)	WT (85.0%); BK (5.0%); IND (0.0%); AS (10.0%)
Total	21.4 (4.1)	M (33.0%); F (67.0%)	WT (89%); BK (5.0%); IND (2.0%); AS (4.0%)

Abbreviations: *M* male, *F* female, *WT* white, *BK* black, *IND* indigenous, *AS* Asian

Table 5 Mean and standard deviation values of the objective (DEab and DE00) and median and interquartile range values of the subjective (DSGU) color changes after 6 and 12 months from the last bleaching session

	ΔEab ($T_{6m}-T_0$)	ΔEab—($T_{12m}-T_0$)
LED	4.1 (1.9) C	4.9 (2.4) C
CP	7.1 (2.9) B	5.5 (3.0) C
LED/CP	8.7 (2.9) B	8.3 (2.9) B
HP	10.2 (4.3) B	10.3 (5.4) AB
LED/HP	14.3 (2.8) A	14.0 (3.3) A
	ΔE00—($T_{6m}-T_0$)	ΔE00—($T_{12m}-T_0$)
LED	3.1 (1.2) C	3.1 (1.9) C
CP	4.1 (1.8) BC	3.0 (1.7) C
LED/CP	4.8 (1.0) B	5.1 (2.0) B
HP	5.3 (2.5) B	5.2 (2.5) B
LED/HP	8.5 (1.9) A	8.4 (2.3) A
	ΔSGU—($T_{6m}-T_0$)	ΔSGU—($T_{12m}-T_0$)
LED	0.0 (5.7) C	0.0 (1.7) C
CP	3.0 (7.0) BC	3.0 (5.5) BC
LED/CP	6.0 (5.0) AB	5.5 (6.0) AB
HP	7.0 (3.0) AB	7.0 (4.0) AB
LED/HP	8.0 (3.0) A	7.0 (2.0) A

Means and medians followed by different letters statistically differ at 5%. The uppercase letters compare the different bleaching protocols within the same period of evaluation

evaluation time. Violet LED did not increase the ΔSGU of the CP and HP gels (LED/HP = HP; LED/CP = CP).

Table 6 and Fig. 4 depict the mean ΔWI_D values after 6 and 12 months from bleaching. The LED group presented the lowest means ($p < 0.05$) within separate evaluation times. The irradiation of the CP and HP gels with the LED did not significantly increase the ΔWI_D means (LED/CP = CP; LED/HP = HP) within each evaluation time. LED/CP and HP showed no statistical differences in terms of the whiteness index, independently of the time point ($p > 0.05$). All the ΔWI_D means were above the 50:50% perceptibility threshold.

Discussion

Although there are few available clinical trials on the efficacy of violet LED for in-office bleaching [23–25], those studies demonstrated only the short-term effects on the colorimetric outcomes. The 6- and 12-month follow-ups of this study demonstrated that the violet LED alone produced color and whiteness changes significantly inferior to the HP groups. However, LED alone and CP exhibited no statistical differences concerning the ΔE_{ab} and ΔE_{00} at the 12-month evaluation. Therefore, the first null hypothesis was rejected

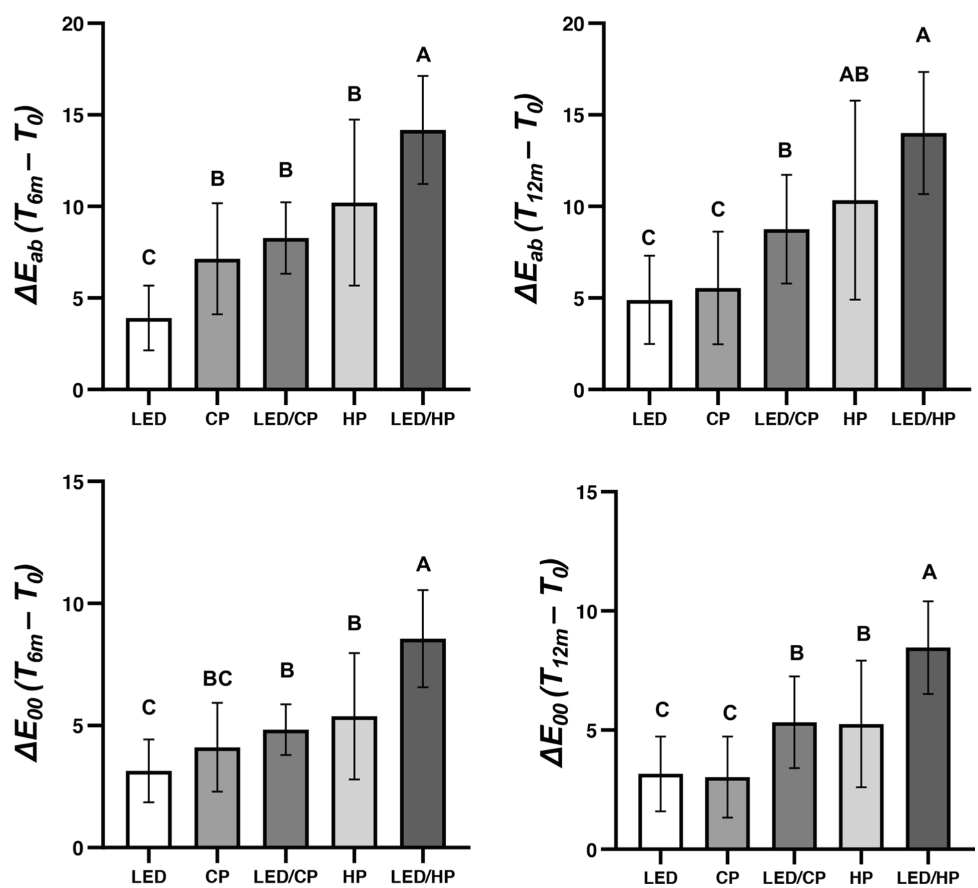

Fig. 2 Mean and standard deviation values of the objective color changes (ΔE_{ab} and ΔE_{00}) after 6 and 12 months from the last bleaching session. Means followed by different letters statistically differ at 5%. The uppercase letters compare different bleaching protocols within the same period of evaluation

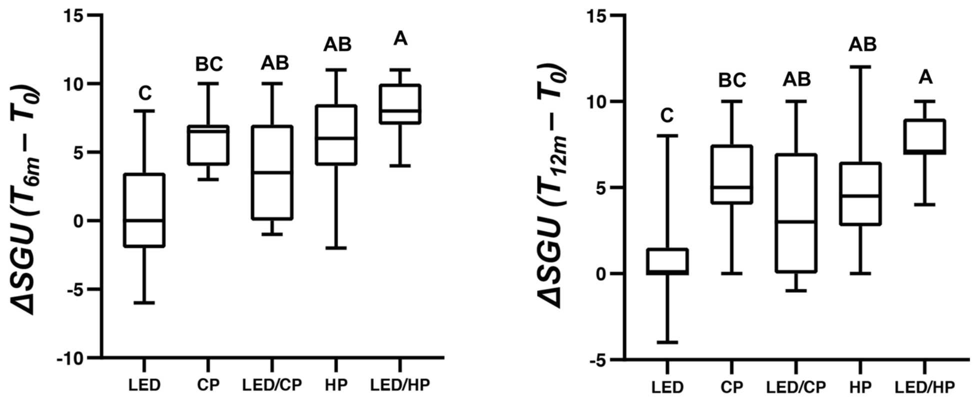

Fig. 3 Box plot of the subjective color changes (ΔSGU) showing the median, quartile ranges, and minimum and maximum values after 6 and 12 months from the last bleaching session. Medians followed by different letters statistically differ at 5%. The uppercase letters compare different bleaching protocols within the same period of evaluation

because the violet LED alone promoted color change comparable to those of the peroxide agents. It is possible to observe that the objective differences (ΔE_{ab}) between the LED and CP groups were maintained up to the 6-month follow-up. Nevertheless, the 12-month evaluation suggested a color rebound in the CP group, which could have favored the similarity among LED and CP. Interestingly, the subjective color change (ΔSGU) revealed no differences between these two groups throughout the study.

In this context, the discrepancies among colorimetric outcomes could be credited to the method of data collection itself. The ΔSGU is considered a subjective method that lighting, age, gender, and eye fatigue might directly impact the decision of the teeth's value [34]. On the other hand, the ΔE_{00}, ΔE_{ab}, and ΔWI_D data are calculated based upon CIELab coordinates collected from precise instruments such as spectrophotometers. This equipment provides the coordinate values by means of a visible spectral reflectance process [35]. Even though subjective color determination is widely used because the visual shade guide is cost-effective, previous studies pointed out that the objective evaluations are more accurate than visual shade tabs [35, 36].

Researchers hypothesized that the mechanism of the action of violet LED alone is based on the interaction of

Table 6 Mean and standard deviation values of the whiteness index for dentistry changes (DWID) after 6 and 12 months from the last bleaching session

	ΔWID—($T_{6m}-T_0$)	ΔWID—($T_{12m}-T_0$)
LED	0.8 (2.6) C	1.3 (2.6) C
CP	9.6 (6.3) B	8.7 (6.8) B
LED/CP	10.9 (5.5) B	9.1 (4.8) B
HP	15.2 (8.8) AB	14.7 (12.4) AB
LED/HP	19.5 (5.4) A	19.0 (4.5) A

Means followed by different letters statistically differ at 5%. The uppercase letters compare the different bleaching protocols within the same period of evaluation

the visible wavelength (approximately 405 nm) with the extrinsic staining adhered to the surface of buccal enamel [18, 21]. Indeed, in vitro studies showed that the irradiation of artificially stained teeth by violet LED resulted in medium to high color or whiteness changes [19, 37, 38]. However, the outcomes obtained in the present clinical scenario suggested that the light effect alone is perceptible, but less efficient than high-concentrated hydrogen peroxide. Thus, the fact that patients exhibited teeth with lower staining and were submitted to prophylaxis before bleaching might have impacted the outcomes.

Since the whiteness index for dentistry calculation takes into account the CIELab coordinates [27], it makes sense that the WI_D changes promoted by violet LED were significantly lower than the CP and HP groups. The WI_D evaluation indicates changes in the teeth's spectral behavior that migrate to high lightness and low saturation [27]. Also, this index performs a greater correlation with visual color perception. Based on the ΔWI_D presented in this study, it is possible to infer that the impact of the light itself on the whiteness of teeth was significantly lower than that of peroxide-based agents.

The color change calculation based on the CIEDE2000 system is an important data that was also not used in the previous clinical trials on the violet LED in-office bleaching [23–25]. The differences among the ΔE_{ab} and ΔE_{00} calculations rely on the weighting functions that adjust the final ΔE_{00} in the location of the L*, a*, and b* coordinates. Applying the lightness, hue, and chroma, CIEDE2000 corrects the interaction of hue and chroma in the b* coordinate. It also alters the low influence of the a* coordinate, which is important only for colors with low chroma [39]. A recent review from Paravina et al. (2019) displayed the individual ΔE_{ab} and ΔE_{00} values compatible with visual perceptibility as well as with excellent efficacy of bleaching [40]. Therefore, the authors of this study believed that the inclusion of these three objective parameters (ΔE_{ab}, ΔE_{00} and ΔWI_D) would guarantee a more accurate and broader discussion.

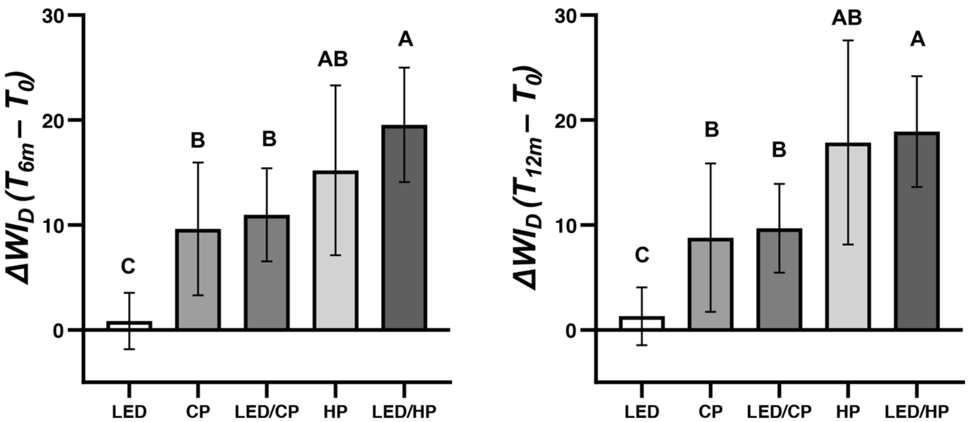

Fig. 4 Mean and standard deviation values of the whiteness index for dentistry changes (ΔWI_D) after 6 and 12 months from the last bleaching session. Means followed by different letters statistically differ at 5%. The uppercase letters compare the different bleaching protocols within the same period of evaluation

The violet LED irradiation increased the ΔE_{ab} and ΔE_{00} of the CP gel, but only at the 12-month evaluation. Thus, the second null hypothesis that bleaching gels irradiated by violet LED would not present higher changes than CP or HP alone was rejected. The decrease in the color change of the CP group (without light) after 12 months could be credited for the lower decomposition of the CP gel into hydrogen peroxide [6]. However, a 6% HP gel, which presents lower total hydrogen peroxide concentration than 37% CP, resulted in stable color change after 1 year [41]. Therefore, the presence of urea in the CP gel might have decreased the CP by-products (without LED irradiation) interaction in the dentin. Also, the characteristics and habits of each patient cannot be ruled out, because the patients' habits, such as the consumption of dark beverages or even toothbrushing, influence the color rebound [42].

On the other hand, the more stable LED/CP outcomes might be a result of the synergistic effect of the CP itself and the photolytic activity of the violet light [9]. Even though previous clinical trials concluded that the painful sensation during bleaching was lower for the CP protocol, CP did not attain the chromatic changes as observed for HP [7, 25]. Vaez et al. (2019) showed that the humidification with a damp gauze of enamel prior to the 37% CP application enhanced the efficacy of the in-office bleaching protocol [43]. Thus, activation methods could be appropriate to increase the 37% CP bleaching outcomes. LED/CP presented a color change significantly higher than CP only at the 12-month evaluation, but its similarity with HP was observed independent of the evaluation time. Therefore, the third null hypothesis that LED/CP and HP groups' changes would not be similar after 12 months was rejected. Clinically, this observation for LED/CP could be extrapolated to a stable and high-efficient [40] bleaching protocol with lower levels of tooth sensitivity [25] in comparison to 35% HP.

The significantly higher ΔE_{ab} and ΔE_{00} results of LED/HP compared to the HP protocol observed at the 6-month follow-up were only replicated for ΔE_{00} at the 12-month follow-up. An important limitation regarding these results was the different number of patients able to return to the last appointment in each group. The drop-off was justified because patients moved to long-distance cities. The highest drop-out rate in the HP group ($n=4$) at T_{12m} could have been responsible for the increase in the standard deviation, not resulting in statistical difference between the groups in the ΔE_{ab} evaluation. However, the CIEDE2000 system displayed a higher color change for LED/HP even under such circumstances. Regardless of the increase detected in ΔE_{00} for LED/HP, it is worth mentioning that the intensity of tooth sensitivity for this group during bleaching was overall higher in comparison to HP [25]. Also, the HP and LED/CP protocols exhibited excellent bleaching efficacy [39], thereby questioning the necessity of irradiating the HP gel.

It is important to highlight that the colorimetric analyses herein were only performed using the upper right canine. The decision to use the upper canine was based upon the fact that the chromophores are located in the dentin [6]. Also, a previous study in the literature showed that the esthetic outcomes on thicker teeth tend to saturate later than in thinner teeth, i.e., the upper central incisor [44]. However, further studies could attempt to evaluate if the bleaching outcomes with the present protocols would be different in other dental elements.

Since all the patients reported absence of tooth sensitivity symptoms after 1 week from the last bleaching appointment, no tooth sensitivity data was added to this study. No complaints regarding tooth sensitivity were reported at either the 6- and 12-month follow-ups. Also, further studies could evaluate other application times of the bleaching gels, as the present clinical trial applied the protocols recommended by the light manufacturer and published in previous studies [19, 20]. Following the American Dental Association (ADA) guidelines, effective and safe performance of bleaching in patients is dependent on an appropriate standard exam and the correct diagnosis of the dental discoloration prior to treatment [45].

To summarize, the colorimetric evaluation over time of patients showed that the color and whiteness changes caused by the violet LED alone is perceptible. However, this protocol did not translate into the high levels of bleaching efficacy and did require a longer treatment time. In other words, patients would be submitted to 8 sessions of violet LED bleaching without reaching the esthetic outcomes observed for peroxide-driven bleaching. On the other hand, the violet LED irradiation of CP promoted stable colorimetric changes and exhibited long-term similar efficacy to HP. At the 12-month follow-up, the ΔE_{00} was the only colorimetric parameter showing significant increase in efficacy for LED/HP.

Conclusion

Within the limitations of this study, the possible conclusions could be drawn as follows:

- The use of violet LED alone (without bleaching gels) resulted in perceptible long-term bleaching outcomes, but its efficacy was significantly lower than LED/CP and HP-containing protocols;
- The increase in the long-term efficacy of CP and HP gels irradiated with violet LED was dependent on the evaluation time and the colorimetric system. The combination of violet LED with gels tended to increase the long-term color change (ΔE_{ab} and ΔE_{00}) outcomes, but not the ΔWI_D results;
- LED/CP reached the efficacy (ΔE_{ab}, ΔE_{00}, and ΔWI_D) of the HP protocol even after 12 months from the bleaching procedures.

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Declarations

Ethics approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee (Piracicaba Dental School Ethical Committee—2.294.061 and 3.776.209) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Consent to participate Informed consent was obtained from all individual participants included in the study.

Conflict of interest M. Kury has received research grant (FAPESP #17–08625-0). E. E. Wada has received research grant (FAPESP #17–24847-3). V. Cavalli has received research grant (FAPESP #17–23841-1).

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