





Original Research

In-office tooth bleaching effectiveness with different soft-tissue barriers – randomized controlled trial



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ABSTRACT

Objectives: To evaluate the tooth bleaching effectiveness of a 6% hydrogen peroxide paint-on varnish with two different types of soft-tissue protection materials.

Methods: Twenty patients were screened according to inclusion and exclusion criteria, submitted to professional dental prophylaxis, and randomly allocated to one of the two groups. An in-office bleaching technique protocol was performed (VivaStyle Paint On Plus, Ivoclar-Vivadent®, Liechtenstein) with two different soft-tissue protection materials: Group 1 – Vaseline; Group 2 – block-out resin. Bleaching effectiveness was evaluated with ΔE_{00} and ΔWI_D , calculated from the CIE $L^*a^*b^*$ values obtained by spectrophotometry analysis (SpectroShade). Appropriate statistical tests were performed to analyze intragroup differences in CIE $L^*a^*b^*$ and WI_D values and intergroup differences in ΔE_{00} and ΔWI_D with $\alpha=0.05$.

Results: Both groups presented statistically significant ($P<0.01$) differences in CIE $L^*a^*b^*$ and WI_D . Both ΔE_{00} and ΔWI_D surpassed the acceptability threshold ($\Delta E_{00} > 1.8$; $\Delta WI_D > 2.60$), and the ΔWI_D was mostly classified as hardly acceptable differences. Group 2 presented higher statistically significant ($P<0.01$) mean values with $\Delta E_{00} = 3.5 \pm 1.5$ and $\Delta WI_D = 8.6 \pm 4.2$.

Conclusions: The 6% hydrogen peroxide paint-on varnish tooth bleaching technique showed clinical effectiveness. However, effectiveness varied with the soft-tissue protection material used, with better results when applying a block-out resin, thus suggesting its clinical recommendation. (Rev Port Estomatol Med Dent Cir Maxilofac. 2021;62(3):141-149)

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Eficácia do branqueamento em consultório com diferentes barreiras de tecidos moles – ensaio clínico aleatorizado

R E S U M O

Palavras-chave:

Cor
Peróxido de hidrogénio
Verniz
Vaselina
Espectrofotometria
Dente

Objetivos: Avaliar a eficácia do branqueamento dentário de técnica *in-office paint-on* com peróxido de hidrogénio a 6% com dois tipos diferentes de materiais de isolamento relativo.

Métodos: Vinte pacientes foram selecionados de acordo com os critérios de inclusão e exclusão, submetidos a profilaxia dentária profissional e alocados aleatoriamente num de dois grupos. Foi realizado o protocolo de técnica de branqueamento *in-office* (VivaStyle Paint On Plus, Ivoclar Vivadent®, Liechtenstein) com dois materiais de isolamento relativo: Grupo 1 – Vaselina; Grupo 2 – resina *block-out*. A eficácia de branqueamento foi avaliada com ΔE_{00} e ΔWI_D , calculados a partir dos valores CIE $L^*a^*b^*$ obtidos por análise espectrofotométrica (SpectroShade). Testes estatísticos apropriados foram realizados para analisar diferenças intragrupo nos valores CIE $L^*a^*b^*$ e WI_D e diferenças intergrupo em ΔE_{00} e ΔWI_D com $\alpha=0,05$.

Resultados: Ambos os grupos apresentaram diferenças estatisticamente significativas ($P<0,01$) no CIE $L^*a^*b^*$ e WI_D . Tanto ΔE_{00} quanto ΔWI_D ultrapassaram o limite de aceitabilidade ($\Delta E_{00} > 1,8$; $\Delta WI_D > 2,60$). O Grupo 2 apresentou valores médios estatisticamente significantes superiores ($P<0,01$) com $\Delta E_{00} = 3,5 \pm 1,5$ e $\Delta WI_D = 8,6 \pm 4,2$.

Conclusões: A técnica de branqueamento dentário *in-office* do tipo *paint-on* a 6% peróxido de hidrogénio apresentou eficácia clínica, porém dependente do material de isolamento, com melhores resultados na aplicação de resina *block-out*, sugerindo a sua recomendação clínica. (Rev Port Estomatol Med Dent Cir Maxilofac. 2021;62(3):141-149)

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Introduction

Whiter teeth have been associated with a perception of beauty, health, and fitness. Thus, tooth color is considered one of the most important components in smile evaluation and facial esthetics, and tooth bleaching techniques have gained a major clinical relevance.^{1,2}

Nowadays, tooth bleaching products usually have peroxide-releasing agents, such as hydrogen peroxide (HP) or carbamide peroxide.^{3,4} In fact, initially, HP percentages were commonly high. However, peroxide-releasing agents have known adverse effects on biological tissues that can increase with higher concentrations.^{3,5} For this reason, manufacturers and clinicians searched for effective techniques with low HP concentrations, which resulted in the nightguard vital bleaching technique gaining popularity over the years.³ Although *in-office* bleaching techniques are associated with higher HP concentrations, a new protocol was described in 2006 consisting of two sixty-minute sessions (six ten-minute applications each session), with a week interval, of a paint-on whitening varnish with a lower HP percentage (6% HP).⁶ Nowadays, using lower HP techniques has even more relevance since the European Council Directive 2011/84/EU decreed tooth bleaching products as cosmetics and prohibited the use of concentrations higher than 6% HP.⁷

In-office bleaching effectiveness depends on appropriate field isolation since peroxide-releasing agents can be inactivated when in contact with saliva due to cellular enzymes and diffusion in water environments.^{8,9} Additionally, the use of a

physical barrier is essential for soft-tissue protection since contact with the agents can lead to organic tissue damage.¹⁰ In the previously described 6% HP paint-on varnish technique, a Vaseline barrier is indicated as a soft-tissue protection material due to its known occlusion effect and use in dentistry as a gingival barrier.^{3,6,8,11-13} Despite Vaseline's isolating properties, its semi-solid consistency increases solubility in the presence of fluids, which hinders isolation in the oral environment. An alternative soft-tissue protection material is the light-curing resin, which grants insolubility in water and superior adhesion to various surfaces, including the gingival tissue; however, it entails a higher economic cost.¹⁴⁻¹⁸

Although the properties of different soft-tissue protection materials are well known, their influence on the bleaching effectiveness is yet to be assessed. Therefore, this clinical study aimed to evaluate the effectiveness of a 6% HP paint-on whitening varnish used with two different types of soft-tissue protection materials. The following null hypothesis was established: there are no differences in the bleaching effectiveness of an *in-office* 6% HP paint-on varnish technique when used with two different soft-tissue protection materials.

Material and methods

A randomized clinical trial was performed at the Faculty of Dentistry of Universidade de Lisboa after the local ethics committee's approval. This trial is part of an undergoing tooth-bleaching research registered at the U.S. National Li-

Table 1. Inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
Be at least 18 years old	Restored or non-vital anterior teeth
Absence of smoking habits	Presence of periodontal disease or caries lesions
Willing to sign a consent form	Being under orthodontic treatment
Have at least one anterior tooth (maxillary or mandibular) equal or darker than A3,5 in VITA Classic shade guide measurable by a spectrophotometry	Allergy to one of the components
	Pregnancy or lactating women
	Anomalies of tooth development or presence of severe tooth discoloration
	History of any medical disease that may interfere with the study or require special consideration
	Poor oral hygiene

library of Medicine ClinicalTrials.gov website under the reference number NCT03588871, in full compliance with the Helsinki World Medical Association Declaration's most recent amendments. Patients were recruited consecutively, screened according to inclusion and exclusion criteria (Table 1), signed an informed consent form, and received professional dental prophylaxis. Then, they were randomly allocated to one of two study groups (GraphPad QuickCals, <http://www.graphpad.com/quickcals/randomize1.cfm>), according to different soft-tissue protection materials, for an in-office technique protocol with a paint-on varnish at 6% HP concentration (VivaStyle Paint On Plus, Ivoclar Vivadent®, Liechtenstein): Group 1 – Vaseline (Purified Vaseline, Continente, SonaeMC, Maia, Portugal); Group 2 – block-out resin (OpaldamTM, Ultradent Products, Inc, USA).

Two previously calibrated experienced dentists conducted in-office tooth bleaching using the 6% HP paint-on varnish technique, following the described clinical protocol: an Optragate retractor was placed in the patient's mouth (Optragate, Ivoclar Vivadent®, Liechtenstein); soft-tissue protection materials (Vaseline or block-out resin) were applied to the gingival margin to prevent contact with the peroxide varnish; one thin and uniform layer of the paint-on varnish was applied to the buccal surface of maxillary and mandibular anterior teeth (first pre-molar to first pre-molar); after 10 minutes, the varnish was easily removed using an ultrasonic scaling device; and paint-on layers were applied five additional times (10 minutes each), resulting in a total whitening procedure time of approximately 60 minutes per session.⁶ The clinical protocol was performed in two appointments with a one-week interval and is illustrated in Figures 1 to 6 for Group 1 and Figures 7 to 14 for Group 2. Additionally, the presence or absence of soft-tissue lesions was recorded.

Tooth color was evaluated by spectrophotometry with a proper device: SpectroShade micro (SS) (MHT Optic Research, Niederhasli, Switzerland; serial number HDL3973).¹⁹⁻²¹ The device was operated according to the manufacturer's instructions by an independent investigator, who performed three measuring rounds in upper and lower anterior teeth (canine to canine – 12 teeth). Results were registered before and after the tooth bleaching treatment in the CIE L*a*b* tooth color coordinates

system (CIE L*a*b* values of the buccal tooth surface), and the difference (ΔE_{00}) was calculated to determine bleaching effectiveness. Tooth whiteness was evaluated with a whiteness index (WI_D) specifically established for dentistry and based on the CIELAB color notation system. The whiteness index was assessed before (WI_{D1}) and after (WI_{D2}) the bleaching treatment, and then its difference was calculated (ΔWI_D).²²

$$\Delta E_{00} = \sqrt{\left(\frac{L_2 - L_1}{K_L S_L}\right)^2 + \left(\frac{C_2 - C_1}{K_C S_C}\right)^2 + \left(\frac{H_2 - H_1}{K_H S_H}\right)^2} + R_T \left(\frac{C_2 - C_1}{K_C S_C}\right) \left(\frac{H_2 - H_1}{K_H S_H}\right)$$

The CIEDE2000 formula, from the Commission Internationale De l'Eclairage (International Commission on Illumination) (CIE), was used to calculate ΔE_{00} . Computations with this color difference formula were performed according to the following equation:²³

Parametric factors were set to 1. The whiteness index was calculated before and after tooth bleaching with the following formula: $WI_D = 0.511L^* - 2.324a^* - 1.100b^*$.²⁴ Color and whiteness difference perception was assessed according to two major thresholds: perceptibility threshold (PT for ΔE_{00} ; WPT for ΔWI_D) at $\Delta E_{00} = 0.8$ and $\Delta WI_D = 0.72$; and acceptability threshold (AT for ΔE_{00} ; WAT for ΔWI_D) at $\Delta E_{00} = 1.8$ and $\Delta WI_D = 2.60$.²⁴⁻²⁶ ΔWI_D evaluation followed Perez et al.'s classification system presented in Table 2.²⁶

The sample size was previously determined based on our pilot study's data, using an online calculator (<http://powerand-sample-size.com>).¹⁸ Considering a mean ΔWI_D for teeth equal to or darker than A3.5 in VITA Classical (9.9 for Group 1 and 12.9 for Group 2) with a 3.2 standard deviation, we established that 20 patients (10 per group) would be needed for a two-sam-

Table 2. ΔWI_D classification system.

Visual grading	ΔWI_D 50:50% Threshold values
0: No difference	0.70
1: Small difference	1.57
2: Fairly acceptable difference	2.96
3: Hardly acceptable difference	5.69



Figure 1. Clinical protocol for Paint-On Plus Viva Style with Vaseline: 1) An Optragate retractor was placed in the patient's mouth (Optragate, IvoclarVivadent®, Liechtenstein).



Figure 4. Application of one thin and uniform layer of the paint-on varnish to the buccal surface of maxillary and mandibular anterior teeth (canine to canine).



Figure 2. Vaseline was applied to the gingival margin to prevent contact with the peroxide varnish.



Figure 5. 10-minute waiting period after paint-on application.



Figure 3. The final appearance of Vaseline in the gingival margin to prevent contact with the varnish.



Figure 6. After 10 minutes, the varnish was easily removed using an ultrasonic scaling device, and steps presented in Figures 4, 5, and 6 were repeated five additional times (10 minutes each), giving a total whitening procedure time of 60 minutes.



Figure 7. Clinical protocol for Paint-On Plus VivaStyle with Opal dam® (Opaldam™, Ultradent Products, Inc, USA): 1) An Optragate retractor was placed in the patient's mouth, and Opal Dam was applied with the appropriate syringe to the gingival margin to prevent contact with the peroxide varnish.



Figure 10. Opal Dam was light-cured for 20 seconds in the mandibula.



Figure 8. Opal Dam was light-cured for 20 seconds in the maxilla.



Figure 11. Application of one thin and uniform layer of the paint-on varnish to the buccal surface of maxillary and mandibular anterior teeth (canine to canine).



Figure 9. Opal Dam was applied in the mandibula.



Figure 12. Opal Dam in the mandibula was removed using a clamp.



Figure 13. Opal Dam in the maxilla was removed using a clamp.



Figure 14. After 10 minutes, the varnish was easily removed using an ultrasonic scaling device, and the step presented in Figure 11 was repeated five additional times (10 minutes each), giving a total whitening procedure time of 60 minutes. In the end, Opal Dam was totally removed.

ple comparison test with a superiority limit at a WPT value of 0.72. Calculations were performed with a power of 80% and α of 5%.

All collected data were analyzed using IBM SPSS version 25 (IBM Statistics, Inc. Chicago, IL, USA). Results were presented as mean and standard deviation (SD) of CIE $L^*a^*b^*$ color parameters and WI_D , with the respective ΔE_{00} and ΔWI_D , for all 12 anterior teeth and teeth darker than A3.5. Sample normality was evaluated with the Kolmogorov-Smirnov test, resulting in a normal distribution. Statistical analysis was performed by parametric tests with a paired t-test conducted to analyze intragroup differences in CIE $L^*a^*b^*$ and WI_D values and an independent t-test conducted to determine intergroup differences in ΔE_{00} and ΔWI_D . A statistical significance level of $\alpha=0.05$ was considered.

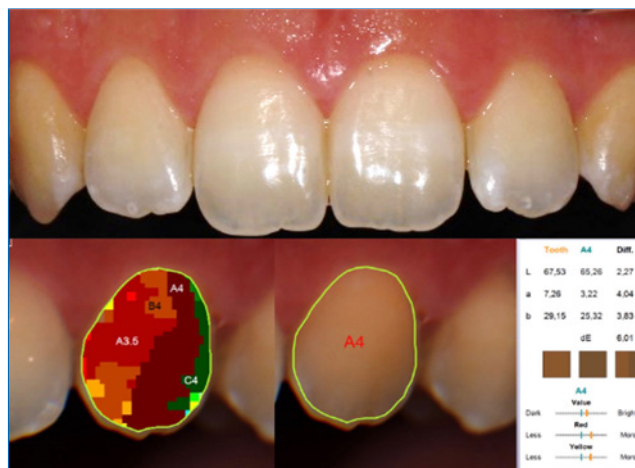


Figure 15. Pre-treatment of a Group 1 case – with Spectroshade images on tooth 23.

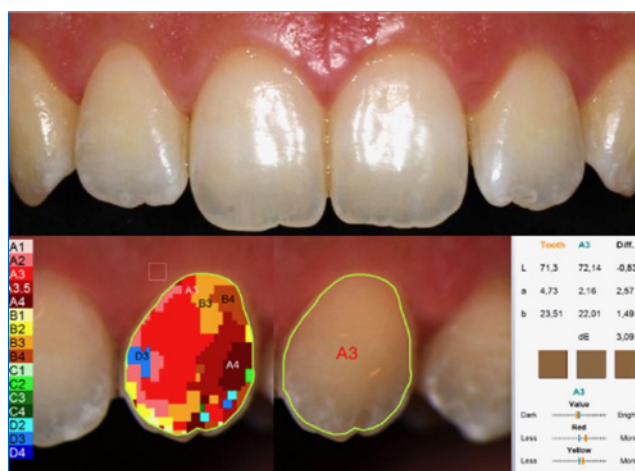


Figure 16. Post-treatment of a Group 1 case – with Spectroshade images on tooth 23.

Results

A total of 20 patients were selected and randomly assigned to each group (three males and seven females per group), with a mean and SD of 23.3 ± 2.3 and 21.6 ± 3.0 years of age for Groups 1 and 2, respectively. There were no statistically significant differences in color coordinates and WI_{D1} mean values before the bleaching treatment (results depicted in Table 3).

All treatments occurred without drop-outs, and both groups presented statistically significant differences ($P < 0.01$) for tooth color coordinates after bleaching procedures, with an increase in L^* mean value and a decrease in a^* and b^* mean values. Additionally, the whiteness index results were statistically significant ($P < 0.01$), presenting higher mean values after treatment in both groups. Bleaching effectiveness was verified with the ΔE_{00} surpassing the AT in 81.7% of cases (90 teeth in Group 1; 106 teeth in Group 2) while the ΔWI_D was

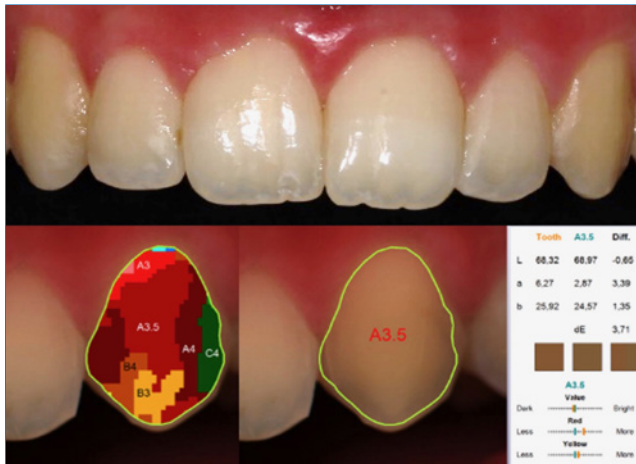


Figure 17. Pre-treatment of a Group 2 case – with Spectroshade images on tooth 23.

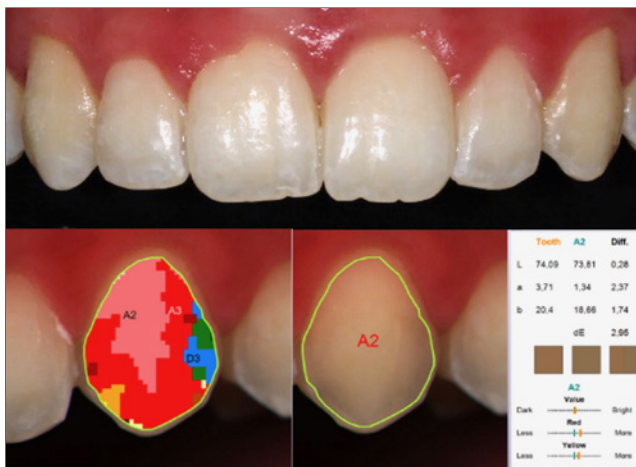


Figure 18. Post-treatment of a Group 2 case – with Spectroshade images on tooth 23.

higher than the WAT in 93.3% of cases (110 teeth in Group 1; 114 teeth in Group 2). The ΔWI_D classification was rated as “hardly acceptable differences” in most cases: 89.2% in Group 1 and 94.2% in Group 2.

When assessing intergroup differences, statistically significant differences were detected in both ΔE_{00} and ΔWI_D ($P < 0.01$). Group 2 presented a ΔE_{00} global mean of 3.5 ± 1.5 , equating to approximately 0.9 units above Group 1. The whiteness index presented similar results, with the ΔWI_D being significantly higher in Group 2 with a global mean of 8.6 ± 4.2 compared to the 6.7 ± 3.1 values in Group 1. When analyzing teeth darker than A3.5, these differences were more pronounced, with Group 2 presenting 1 unit of ΔE_{00} and 2.5 units of ΔWI_D above Group 1 (Table 3).

Five patients from Group 1 and three from Group 2 presented symptomatic small white lesions in the mandibular gingival papilla (symptoms disappeared shortly after the appointment). Figures 15 to 18 depict illustrative clinical cases of each group with before and after treatment photos.

Table 3. Descriptive statistics, before and after tooth bleaching, by study group. Mean values and standard deviation of color coordinates $L^*a^*b^*$, WI_D , ΔE_{00} , and ΔWI_D are presented for each group regarding all teeth and only teeth classified as equal or darker than A3.5 by VITA Classical. [1 – Before treatment; 2 – After treatment; * – Intergroup statistically significant differences for independent t-test ($P < 0.01$) with $\alpha = 0.05$.]

	Group 1 – Vaseline n=10		Group 2 – Block-out n=10	
	All teeth n=120	Teeth VITA ≥ A3.5 n=28	All teeth n=120	Teeth VITA ≥ A3.5 n=28
L1	72.5±2.5	69.8±1.3	72.8±2.7	70.2±1.8
a1	3.5±1.4	5.4±0.8	3.6±1.3	5.2±0.8
b1	19.7±3.8	24.7±1.8	19.8±3.5	24.2±1.4
L2	74.9±1.9	73.3±1.1	75.8±1.7	74.4±1.4
a2	2.8±1.0	4.0±0.6	2.6±0.8	3.4±0.8
b2	16.8±2.9	20.6±1.5	15.5±3.0	18.6±1.8
WI_{D1}	6.9±8.0	-4.6±3.3	7.1±7.5	-2.9±2.7
WI_{D2}	13.6±5.9	5.6±3.1	15.7±5.0	9.8±3.2
ΔE_{00}^*	2.6±1.1	3.6±0.9	3.5±1.5	4.6±1.4
ΔWI_D^*	6.7±3.1	10.2±2.1	8.6±4.2	12.7±3.3

Discussion

This clinical study aimed to compare the influence of two different types of soft-tissue protection materials on the effectiveness of an in-office 6% HP paint-on whitening varnish. This technique presented bleaching effectiveness, with overall mean ΔE_{00} and ΔWI_D of 3.0 ± 1.4 and 7.7 ± 3.8 , respectively, which are above the respective AT and WAT values of 1.8 and 2.6. However, different results were detected between the evaluated soft-tissue protection materials, with the block-out resin presenting superior effectiveness compared to Vaseline, thus rejecting the established null hypothesis.

Regardless of the soft-tissue protection material, this in-office bleaching technique presented whiter and lighter-colored teeth compared to the initial clinical situation. This result was represented by an overall L^* increase (resulting in a lighter color) and a^*/b^* decrease (resulting in a whiter color), based on the CIE $L^*a^*b^*$ system color values' spectrophotometric analysis, thus reducing operator bias. This study's findings are in agreement with previous studies that evaluated the effectiveness of this in-office technique.^{6,14} Benbachir et al. evaluated tooth color by spectrophotometry but with a ΔE outdated formula.^(14,25) To our knowledge, this was the first study to assess efficacy with the CIEDE2000 formula and a new whiteness index based on the CIE $L^*a^*b^*$ system. As observed in previous studies, the detected white non-erosive lesions in soft tissues disappeared shortly after the clinical protocol, with low symptomatology.^{6,14} These mild and transient adverse effects may be related to the lower HP concentration.^{6,16,27}

Considering hydrogen peroxide's kinetics and petroleum jelly's transparent semi-solid characteristics, the Vaseline protection technique's inferior effectiveness may be explained by its isolation incapacity when HP is released into the crevicular fluid.^{10,11,28} Additionally, due to petroleum jelly's transparency, Vaseline can be overlooked in the tooth's vestibular surface, resulting in enamel areas where the bleaching varnish would have less effectiveness. On the other hand, the characteristics of the described block-out resin, which is made of light-curing methacrylate resin and adheres to the gingiva and tooth margins, may allow better isolation capacity from the oral fluids with an easily distinguishable color.¹⁷ This reasoning may explain the results suggesting that the clinical protocol for the paint-on varnish Paint On Plus in-office technique could be optimized by modifying the soft-tissue protection material from Vaseline to a block-out resin, increasing bleaching effectiveness. Although block-out resins have been applied in several bleaching studies, to the authors' knowledge, the effect of the protection technique itself has never been evaluated.^{3,14,15,29,30} The rationale for using Vaseline based on its lower treatment cost may not be justifiable if better detectable results (ΔE_{00} of 0.9, which suggests a tooth color difference detected by more than 50% individuals) are achievable using light-curing methacrylate resins.

This study was performed in a university setting, involving mostly younger patients with overall good oral hygiene and higher treatment compliance. However, in an older population with darker colored teeth, the bleaching effects could probably be even more noticeable since our results suggest an increase in color difference perception for teeth darker than VITA Clas-sical A3.5.

The influence of different materials or techniques for proper soft-tissue isolation on the effectiveness of in-office bleaching techniques still lacks evidence in the literature. While more clinical studies are always recommended, this study's results suggest that different soft-tissue protection materials may influence in-office bleaching effectiveness.

Conclusions

A 6% HP paint-on varnish tooth bleaching technique presented higher clinical effectiveness when a block-out resin was applied as a soft-tissue protection material compared to Vaseline. Thus, a clinical modification of the original protocol is suggested.

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Ethical disclosures

Protection of human and animal subjects. The authors declare that the procedures followed were in accordance with

the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki).

Confidentiality of data. The authors declare that they have followed their work center protocols on access to patient data and for its publication.

Right to privacy and informed consent. The authors have obtained the written informed consent of the patients or subjects mentioned in the article. The corresponding author is in possession of this document.

Conflict of interest

Bleaching materials supported by Ivoclar-Vivadent. The authors do not have any financial interest in the companies whose materials are included in this article.

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