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CLINICAL RESEARCH

Does the use of a 3-mm extended tray during an at-home bleaching treatment increase gingival irritation? A randomized clinical trial

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ABSTRACT

Statement of problem. Gingival irritation is a common side effect of at-home bleaching, but how the design of the bleaching tray affects its occurrence is unclear.

Purpose. The purpose of this randomized clinical trial was to determine whether a direct relationship is present between the design of bleaching trays and the risk of gingival irritation during at-home bleaching treatments.

Material and methods. This clinical trial was registered at ClinicalTrials.gov. (NCT06371664). Seventy-two participants were randomly assigned to 2 experimental groups: extended bleaching tray (3 mm) and nonextended bleaching tray (1 mm). Over a period of 3 weeks, participants underwent a nightguard dental bleaching treatment (6 to 8 hours) using 16% carbamide peroxide gel. Gingival irritation was evaluated subjectively by participants daily and objectively by clinicians at each visit. Tooth sensitivity was recorded daily using a 5-point numerical scale. Tooth color measurements were also made with a dental spectrophotometer. The risk of gingival irritation and the risk and intensity of tooth sensitivity were analyzed with the Pearson chi squared test and Fisher exact test. The color analysis was conducted with the Student *t* test (α=.05).

Results. Subjectively, the risk of gingival irritation was 66.7% in the extended group and 47.2% in the nonextended group, showing no statistically significant difference ($P>.05$). However, objectively, the risk of gingival irritation was significantly higher in the extended group (88.9%) compared with the nonextended group (63.9%) ($P=.01$(95% CI 1.06 to 1.83). Tooth sensitivity intensity was significantly higher in the extended tray group ($P<.001$), although the design did not significantly influence the risk of tooth sensitivity ($P>.05$). No significant differences were found between groups regarding color change ($P>.05$).

Conclusions. The use of an extended bleaching tray design increases the risk of gingival irritation and the intensity of tooth sensitivity. Therefore, the nonextended tray is recommended to minimize adverse reactions. (J Prosthet Dent 2025;133:1277-1283)

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Clinical Implications

The use of an extended bleaching tray design is associated with an increased risk of gingival irritation and higher intensity of tooth sensitivity. Therefore, the use of a nonextended tray is recommended to reduce adverse reactions.

At-home dental bleaching has been popular since Haywood introduced it in 1989. His technique, night-guard vital bleaching (NGVB), consists of an overnight bleaching treatment with a custom tray and 10% carbamide peroxide (CP) for between 3 days and 6 weeks.[1–4] This technique has been extensively studied and demonstrated to be safe and effective and to yield high patient satisfaction.[5–10] Nevertheless, at-home dental bleaching does come with potential side effects, including tooth sensitivity with a risk of 51%[11] and gingival irritation with recently reported rates ranging from 57.5% to 75%.[12,13] Gingival irritation can may be associated with factors that include the concentration and application time of the bleaching agent and the design of the tray.[14–19]

European legislation allows concentrations of 0.1% to 6% of hydrogen peroxide and 0.3% to 17% of carbamide peroxide.[6] A meta-analysis, published in 2016, reveals no significant differences between CP and HP regarding tooth sensitivity and gingival irritation. However, tray-delivered CP produces a greater whitening effect than HP bleaching agents.[20] Additionally, the use of a 16% concentration of CP during an NGVB has been demonstrated to be as safe as a 10% concentration but produces more gingival irritation.[21]

The optimal tray material has been reported to be soft with a 1-mm thickness.[4] However, as a consensus on the optimal tray design is lacking, the choice has been based on the personal preference and convenience of the dentist.[22] Nonscalloped trays have been reported to be associated with gingival irritation because of their direct contact with soft tissues, and the use of scalloped trays that avoid gingival contact has been recommend.[14,20] However, both designs have been reported to result in similar gingival irritation.[12,23] Haywood and Sword[4] suggested that for concentrations of 10% CP, a nonscalloped tray that extends 1 to 2 mm over the soft tissue should be used. However, for concentrations greater than 16%, a scalloped tray and the reduced application of the whitening agent have been recommended.[4]

The primary objective of this study was to assess the direct relationship between tray design and gingival irritation during NGVB with 16% CP by comparing whether the use of a 3-mm nonscalloped tray leads to a higher prevalence of gingival irritation than a 1-mm scalloped tray. The secondary objectives included evaluating potential differences in the risk and severity of tooth sensitivity, as well as assessing variations in the degree of tooth bleaching. The null hypothesis was that the tray design would not significantly affect the prevalence of gingival irritation during NGVB.

MATERIAL AND METHODS

A randomized, parallel, double-blind clinical trial was designed comprising 2 study groups with both the investigator and analyst being blinded to the group assignments. The study had been approved by the Galician Drug Research Ethics Committee (registration code 2022/491) and was registered at ClinicalTrials.gov. (registration number NCT06371664). Conducted from March to April 2023 at the Faculty of Dentistry of Santiago of Compostela (Spain), the study followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines and adhered to the ethical principles of the World Medical Association (Declaration of Helsinki). Each participant received trial information and a written informed consent was obtained before taking part.

Faculty volunteers who asked about bleaching treatment were informed about the study and invited to participate. To be eligible, participants had to be over 18 years, have no oral or systemic pathology, be periodontally healthy (Silness and Löe plaque index and gingival index <1[24]), have no carious lesions, and have maxillary and mandibular canines with a color of A2 or darker as measured with a shade guide (Classical A1-D4 shade guide; VITA Zahnfabrik). Participants with adhesive restorations or prostheses in the anterior region, enamel or dentin alterations, smokers, pregnant women, or those who had undergone prior bleaching treatment were excluded from the study.[25,26]

The sample size was determined based on data from a previous study where the absolute risk of gingival irritation using a conventional bleaching tray was reported as 75% and the standard deviation was obtained.[13] The calculation was performed automatically by using the !NSize.sps macrodata developed for statistical software packages (IBM SPSS Statistics, v29.0; IBM Corp). Considering a standard deviation of 60%, a minimum expected effect size of 24%, an alpha risk of 5%, a power of 80%, and the incorporation of a 20% buffer for potential participant losses, 72 participants were needed, 36 per group.

An independent researcher (B.M.-B.), uninvolved in the evaluation and analysis, oversaw the randomization sequence. Block randomization was calculated with a statistical software package (IBM SPSS Statistics, v29.0; IBM Corp). Figure 1 presents the flow diagram of the study.

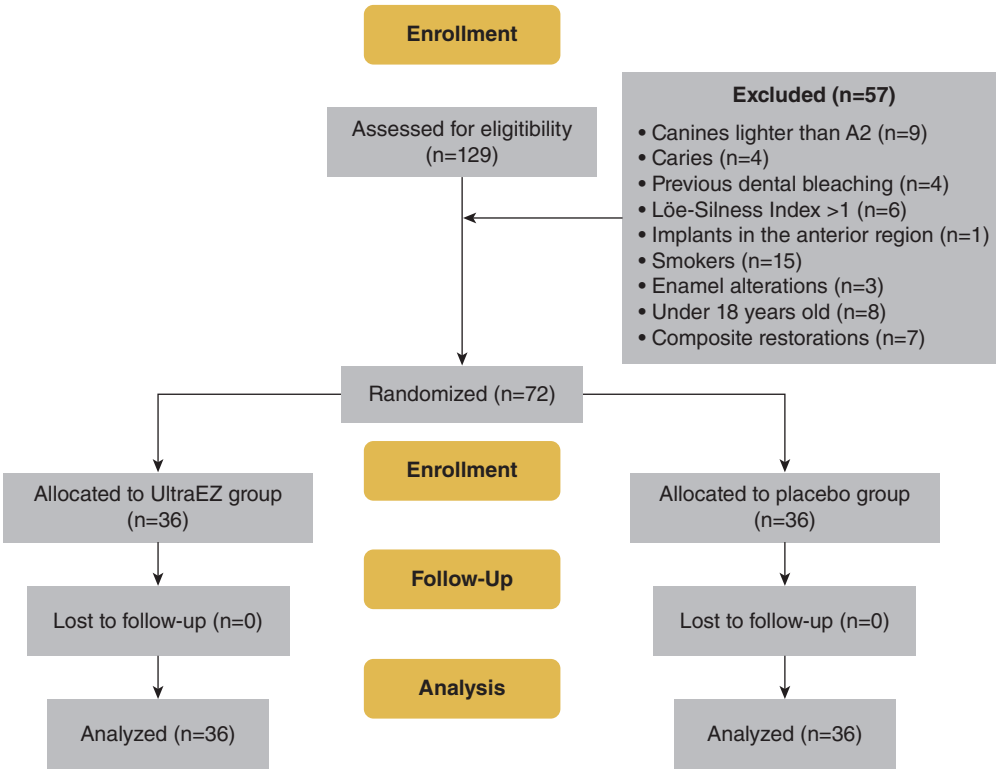

Figure 1. CONSORT flow diagram.

During the screening visit, 2 experienced evaluators (P.P-L., T.G-G.) conducted general examinations and recorded personal information. The interrater reliability was over 80% (kappa index). Bitewing radiographs were made to exclude interproximal caries. Extrinsic stains were removed through dental scaling and polishing with paste (Detartrine Z; Septodont). The gingival status was evaluated with a periodontal probe, and participants were classified based on the Löe and Silness gingival index.[24] Alginate impressions (Orthoprint; Zhermack) of both dental arches were made, poured in gypsum (Elite Model Fast; Zhermack), and cut into a horseshoe form.

Two clinicians (P.A-N., I.V.-A.), who had no prior contact with the participants, fabricated the bleaching trays with a vacuum system (Econo-Vac Vacuum Forming System; Buffalo Dental Manufacturing Co) making 1-mm soft maxillary and mandibular trays (Mouthguard 040; Dentaflux) without reservoirs. The trays were trimmed 1 mm (conventional) or 3 mm (extended) apically to the gingival margin based on assignment.

On the next visit (week 0), 1 week after the screening, each participant received a sealed, opaque plastic bag containing their trays and 3 syringes of bleaching agent (Opalescence 16% PF; Ultradent Products, Inc). Before opening the plastic bags, evaluators recorded the color of each tooth using the position-finder and spectrophotometer (Easyshade V; VITA Zahnfabrik). To maintain blinding, an independent clinician (P.C-B.) verified the proper tray fit. Participants were provided with a toothbrush and toothpaste (Colgate Total Original; Colgate Oral Pharmaceuticals) to standardize oral hygiene. They had to brush their teeth with the whitening agent (1 drop each tooth) and wear the trays overnight (8 to 6 hours) daily for 3 weeks. Written instructions for the procedure were also provided.

In the first and second week of treatment, a new gingival and color evaluation was performed, and 3 syringes of whitening agent were administered. Finally, in the third week, the gingival irritation and tooth sensitivity recording sheets were collected, and the final evaluation was done.

At each visit, an objective evaluation of gingival tissue was conducted through visual examination and the use of a periodontal probe. Participants were categorized according to the Löe and Silness gingival index as G0 (normal gingiva); G1(mild inflammation: slight change in color, slight edema; no bleeding on probing); G2 (moderate inflammation: redness, edema and glazing; bleeding on probing); or G3 (severe inflammation: marked redness and edema; ulceration; tendency to spontaneous bleeding).[21,24,27] Participants who reported a score of "0"during the treatment were categorized as individuals who did not experience gingival irritation due to bleaching. The highest recorded score served as a reference to determine the degree of gingival irritation of each participant.

Table 1. Subjective gingival irritation. Number of participants with gingival irritation, absolute risk, and relative risk

	Group	Gingival Irritation (n)		Absolute Risk (95% CI)	Relative Risk (95% CI)	P*
		Yes	No			
Week 1	1 mm	15	21	41.7% (27.1 to 57.8%)	1.47 (0.92 to 2.33)	.09
	3 mm	22	14	61.1% (44.9 to 75.2%)		
Week 2	1 mm	7	29	19.4% (9.8 to 35%)	0.7 (0.29 to 1.63)	.4
	3 mm	10	26	27.8% (15.8 to 43.9%)		
Week 3	1 mm	2	34	5.6% (1.5 to 18.1%)	3.5 (0.79 to 17.72)	.15
	3 mm	7	29	19.4% (9.8 to 35%)		
Overall Scenario	1 mm	17	19	47.2% (31.9 to 62.9%)	1.41 (0.93 to 2.14)	.09
	3 mm	24	12	66.7% (50.3 to 79.8%)		

CI, confidence interval; N, number of participants.
* Pearson chi-squared test

From a subjective perspective, all participants were provided with a gingival irritation recording sheet to complete daily throughout the 3-week treatment period. They were instructed to mark a "0" if their gingival tissue appeared normal or "1" if they observed gingival irritation, defined as the presence of a white or red layer on the gingiva.[28] Participants who scored "0" during the treatment were classified as individuals without gingival irritation.

Each participant received a sensitivity recording sheet and was instructed to complete it daily for the 3-week treatment period. To evaluate tooth sensitivity levels, a 5-point subjective numerical classification scale was employed (0=no sensitivity, 1=mild, 2=moderate, 3=considerable, and 4=severe).[29,30] Participants who reported a score of "0" during the treatment were categorized as individuals who did not experience tooth sensitivity. The highest recorded score was used as a reference to determine the degree of individual tooth sensitivity of each participant.

The color was measured objectively using a spectrophotometer (Easyshade V; VITA Zahnfabrik).[23,31] To standardize the color measurement, a 4-mm custom position-finder (Mouthguard 150; Dentaflux) was created. For accurate measurement, a hole was drilled at the mid cervical point, 2 mm from the cervical margin of each tooth under study (maxillary and mandibular right central incisors and canines).[30] The parameters L* (lightness), c* (chroma), and h* (hue) of each tooth were recorded.[32] To determine the color change between the initial visit and the evaluations at the first, second, and third week of treatment, the CIEDE2000 formula (ΔE^{00}) was used:

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

The absolute risk of gingival irritation in both groups was compared by using the Pearson chi-squared test (first, second, and third week and worst overall scenario). The relative risk and the corresponding confidence interval (95% CI) were also calculated. The Cochran test was used to evaluate gingival irritation in each group over time.

The absolute risk of tooth sensitivity was also compared using the Pearson chi-squared test. The intensity of tooth sensitivity was evaluated using the Pearson chi squared test and Fischer exact test with post hoc Bonferroni-adjusted *P* values. For the color analysis, the Kolmogorov-Smirnov test was performed to verify whether the sample followed a normal distribution. Intergroup comparisons in the first, second, and third weeks of treatment were conducted using the Student *t* test (α=.05 for all statistical tests). All analyses were executed using a statistical software package (IBM SPSS Statistics, v29.0; IBM Corp).

RESULTS

Out of 129 participants initially evaluated, 72 met all inclusion criteria and completed the study without any dropouts. The conventional tray group had a mean ±standard deviation age of 29.28 ±8.44 years, with 72.2% women. In the extended tray group, 69.4% were women, and the mean ±standard deviation age was 32.19 ±13.25 years. Statistical analysis revealed no significant differences between the groups in terms of age, sex distribution, baseline gingival status, or tooth shade.

The analysis of gingival irritation, based on subjective participant-reported data during the assessments (first, second, third, and overall) showed no significant differences between the groups (*P*>.05). The absolute risk, the relative risk, and the number of participants with gingival irritation are presented in Table 1. Significant reduction in gingival irritation were observed in both groups across visits (*P*<.001).

Objective data compiled by clinicians revealed statistically significant differences in gingival irritation at the first week (*P*=.013), second week (*P*=.009), and in the worst overall scenario (*P*=.013). However, by the third week of treatment, no statistically significant differences were observed (*P*=.276). The absolute risk, the relative risk, and the number of participants with gingival irritation in the first week, second week, third week, and the worst overall scenario are presented in Table 2. After all examinations, no participant was

Table 2. Objective gingival irritation. Number of participants with gingival irritation, absolute risk, and relative risk

	Group	Gingival Irritation (n)		Absolute Risk (95% CI)	Relative Risk (95% CI)	P*
		Yes	No			
Week 1	1 mm	23	13	63.9% (47.6 to 77.5%)	1.39 (1.06 to 1.83)	.013**
	3 mm	32	4	88.9% (77.5 to 95.6%)		
Week 2	1 mm	10	26	27.8% (15.8 to 43.9%)	2.1 (1.16 to 3.8)	.009**
	3 mm	21	15	58.3% (42.2 to 72.9%)		
Week 3	1 mm	7	29	19.4% (9.8 to 35%)	1.57 (0.69 to 3.59)	.276
	3 mm	11	25	30.6% (18 to 46.9%)		
Overall Scenario	1 mm	23	13	63.9% (47.6 to 77.5%)	1.39 (1.06 to 1.83)	.013**
	3 mm	32	4	88.9% (77.5 to 95.6%)		

CI, confidence interval; N, number of participants.
* Pearson chi-squared test
** Statistically significant

Table 3. Number of participants with dental sensitivity, absolute risk, and relative risk

	Tooth Sensitivity (n)				
Group	Yes	No	Absolute Risk (95% CI)	Relative Risk (95% CI)	P*
1 mm	20	16	55.6% (39.5 to 70.4%)	1.25 (0.87 to 1.79)	.22
3 mm	25	11	69.4% (63.9 to 96.5%)		

CI, confidence interval; N, number of participants.
* Pearson chi-squared test

categorized with a Löe and Silness Index greater than G1. The data of the first week and the worst overall scenario were similar; with 76.4% of the participants experiencing gingival irritation. The 3-mm tray group exhibited a 25% (95% CI 6.2 to 43.7%) higher risk of gingival irritation than the 1-mm tray group. In the second week, 43.1% of the participants had gingival irritation. The 3-mm tray group had a 30.6% (95% CI 8.8 to 52.3%) higher risk of gingival irritation than the 1-mm tray group. Between visits, there was a statistically significant reduction in gingival irritation in both groups: 1-mm group ($P<.001$) and 3-mm group ($P<.001$).

Overall, 62.5% of the participants reported experiencing some degree of tooth sensitivity during the treatment. The absolute risk, the relative risk, and number of participants with tooth sensitivity is presented in Table 3. Upon comparing both groups, no statistically significant differences were observed ($P=.22$). Regarding the intensity of tooth sensitivity, the distribution of participants with varying grades of tooth sensitivity in each group is presented in Figure 2. A statistically significant difference among groups and grades of intensity was found ($P<.001$). Specifically, participants with the 1-mm tray were more likely to experience mild sensitivity, while participants with the 3-mm tray were more likely to experience considerable sensitivity.

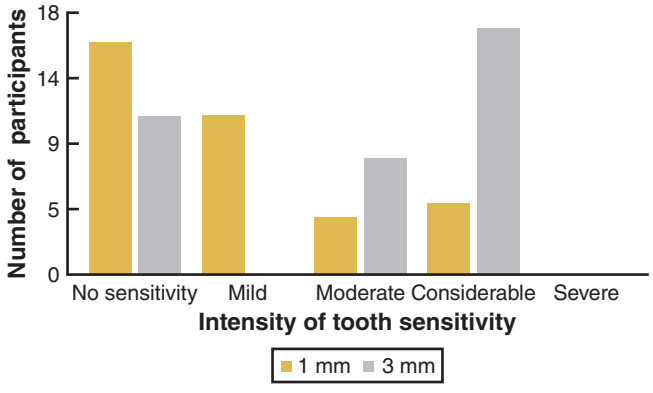

Figure 2. Intensity of tooth sensitivity.

The means and standard deviations of ΔE^{00} for the 1-mm and the 3-mm tray group are presented in Table 4. In the first week ($P=.59$, 95% CI −0.83 to −0.48), second week ($P=.71$, 95% CI −0.94 to 0.65), and third week ($P=.97$, 95% CI −0.86 to 0.83) of treatment, no statistically significant differences were found between the groups.

DISCUSSION

The null hypothesis that the tray design would not significantly affect the prevalence of gingival irritation during NGVB was rejected, as the results indicated that different tray designs influenced the occurrence of gingival irritation. The present double-blind clinical trial was designed to evaluate the prevalence of the gingival irritation of 2 different tray cutouts during an NGVB.

Gingival irritation resulting from at-home bleaching treatments is typically mild to moderate, transient, and localized in small areas.[25,27] It is primarily caused by trauma from poorly fitted bleaching trays or direct contact of the bleaching agent with gingival surfaces.[20,21] The thick and rigid tray materials used in the past contributed to trauma and subsequent gingival irritation, but contemporary tray materials are soft and thin, reducing the risk of gingival irritation.[18,19] However, direct

Table 4. Means and standard deviations of color change (ΔE^{00})

	Groups			
Evaluation	**1-mm Tray**	**3-mm Tray**	**Mean Difference (95% CI)**	***P****
Week 1	5.03 ±0.99	4.86 ±1.68	−0.18 (−0.83 to 0.48)	.59
Week 2	6.74 ±1.65	6.59 ±1.73	−0.15 (−0.94 to 0.65)	.71
Week 3	8.28 ±1.69	8.27 ±1.89	−0.01 (−0.86 to 0.83)	.97

CI, confidence interval.
* Student *t* test

and prolonged exposure of soft tissues to high concentrations of bleaching agents can lead to gingival burns and ulcerations.[4,25] This study used an overnight bleaching technique (6 to 8 hours) with 16% CP, representing a worst-case scenario for assessing gingival irritation.[21]

The absolute risk of general gingival irritation from subjective and objective data, was 56.9% and 76.4%, respectively, consistent with other studies.[12,13] The risk of gingival irritation in the objective analysis carried out by the clinicians was significantly higher than in the subjective one carried out by participants. Participants may not notice areas of redness or inflammation when they do not experience gingival discomfort or pain, accounting for the observed discrepancy.

Subjective data from participants suggested a 47.2% incidence of gingival irritation in the 1-mm tray group and 66.7% in the 3-mm tray group, although this difference was not statistically significant ($P>.05$); it was, however, consistent with that reported by Carneiro et al.[12] However, objective analysis in the worst-case scenario showed a significant relationship ($P=.013$), indicating a 25% higher risk of gingival irritation in the 3-mm tray group compared with the 1-mm group. These findings contrast with those of Carneiro et al,[12] who used 10% CP and relied on subjective data alone. The authors are unaware of a previous study that compared 2 different bleaching tray designs using both subjective and objective data collection methods.

By using an extended tray, the contact between the gel and saliva is significantly minimized. This limits inadvertent ingestion, with the extended tray acting as a protective barrier that prevents the gel from seeping out.[18,26] However, the drawback of this approach lies in the inability to eliminate excess gel easily, resulting in prolonged contact with the soft tissues and potentially leading to greater gingival irritation.[4] Using a non-extended tray that is properly contoured to the gingival margin, however, allows for the profusion of excess gel upon placement. This excess gel can be efficiently removed, thus preventing direct contact with the gingival tissues.[18] Pinto et al[10] reported that approximately 25% to 30% of participants had to remove the excess gel during their at-home bleaching procedure. However, with this type of tray, saliva penetration is more likely, potentially reducing retention and causing mild trauma and soft tissue discomfort.[23]

Tooth sensitivity is a common side effect of bleaching procedures.[9] The overall risk of tooth sensitivity in this study (62.5%) was higher than the average reported previously during at-home bleaching procedures.[11,22] Despite this heightened risk, no statistically significant differences were observed between groups ($P>.05$), as has been reported.[12,22] However, of the participants who did experience tooth sensitivity, statistically significant differences were observed in the intensity of sensitivity ($P<.001$). Participants using the 3-mm trays demonstrated a significantly higher propensity for experiencing heightened sensitivity. This observation might be attributed to the fact that the 3-mm tray prevents bleaching gel leakage, ensuring its consistent presence in the cervical area.[17,23]

In the present study, the assessment of color changes was conducted using a spectrophotometer (Easyshade V; VITA Zahnfabrik) chosen for its ability to provide objective and precise measurements.[31] The CIEDE2000 formula (ΔE^{00}) was used for data analysis. This formula, which incorporates improvements and corrections over the previously used CIE L*a*b* formula, has been preferred for determining clinically relevant color differences.[32] The 2 tray designs used in this study did not influence the efficacy of the bleaching agents, as there were no significant statistical differences between groups ($P>.05$). These findings were consistent with those of Morgan et al,[22] but Carneiro et al,[12] using 10% HP, reported that the no scalloped group had a greater bleaching effect; however, these differences were not clinically noticeable.

Limitations of this study included that it was not possible to blind the participants in this trial. The knowledge of group assignment may have influenced their behavior during the trial and their responses to subjective outcome measures. The findings were based on a specific bleaching agent, and different brands or concentrations may have distinct effects on the gingiva, tooth sensitivity, and color change. The comparison was exclusively between 2 tray designs, 3-mm and 1-mm. Exploring intermediate sizes could reveal a balance between the advantages of each tray type. Therefore, future studies incorporating various bleaching agents and tray designs are essential to understand broader effects.

CONCLUSIONS

Based on the findings of this clinical trial, the following conclusions were drawn:

1. The use of a 3-mm extended tray during an NGVB with 16% CP increased the risk of objective gingival irritation.
2. The risk of tooth sensitivity was not influenced by the cutout of the tray; however, among those participants experiencing tooth sensitivity, there was a notable tendency toward heightened sensitivity when using an extended bleaching tray.
3. No differences were found between the 2 cutouts in terms of the effectiveness of bleaching.

PATIENT CONSENT

A written informed consent was obtained from each participant. This clinical trial received approval from the Galician Drug Research Ethics Committee.

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