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Clinical Research

Clinical Evaluation of Different Delivery Methods of At-Home Bleaching Gels Composed of 10% Hydrogen Peroxide

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Clinical Relevance

All 10% hydrogen peroxide systems showed similar whitening; however, bleaching strips and the prefilled disposable trays showed lower adverse effects.

SUMMARY

Objectives: This study aimed to compare the tooth sensitivity, gingival irritation, and bleaching efficacy of at-home whitening performed with 10% hydrogen peroxide (HP) using a conventional tray-delivered system or two different bleaching systems (strips or prefilled disposable trays).

Methods and Materials: Sixty patients, with maxillary incisors darker than A2 were selected for this single-blind, parallel randomized clinical trial. Teeth were bleached during 14 days with a 30-minute gel contact with teeth per day. The 10% HP was delivered in a bleaching tray (White Class, FGM) in strips (White Strips, Oral-B) or prefilled disposable trays (Opalescence Go, Ultradent). The color changes were evaluated by subjective (Vita Classical and Vita Bleachedguide) and objective (Easyshade Spectrophotometer) methods at baseline and 30 days after the second bleaching session. Tooth sensitivity was recorded during 14 days with a five-point numeric rating scale (NRS) and 0-10 visual analog scale (VAS). The risk of gingival irritation was also recorded during 14 days on a dichotomous scale. All data were submitted to appropriate statistical analysis (α=0.05).

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Results: No significant difference was observed in the risks of tooth sensitivity among groups ($p>0.09$). However, the conventional bleaching tray produced a higher intensity of tooth sensitivity when compared with the strips and prefilled disposable tray systems ($p<0.04$). Regarding gingival irritation, the prefilled disposable tray system showed a lower risk of gingival irritation when compared with the conventional bleaching tray ($p=0.003$). Significant whitening was observed in all groups after 30 days of clinical evaluation with no significant difference between them ($p>0.06$).

Conclusions: All 10% HP bleaching systems showed similar whitening after a 14-day use. However, the strips and prefilled disposable trays produced lower intensity of tooth sensitivity than the conventional bleaching tray system. The prefilled disposable tray produced lower risk of gingival irritation when compared to the conventional bleaching tray.

INTRODUCTION

Since the introduction of the at-home bleaching technique using 10% carbamide peroxide (CP) overnight,[1] long-term successful results have been reported.[2,3] Even though at-home bleaching is the most frequently recommended treatment, some patients do not adapt to the technique because they need to wear the bleaching tray for longer periods of time. More comfortable methods, with the same efficacy, are desired by these patients.

In view of this market need, some companies have introduced bleaching strips or prefilled disposable trays that deliver hydrogen peroxide (HP) products for at-home bleaching. The manufacturer claims that HP-based products could be used for shorter periods of time due to the fast HP delivery.[4-7] The amount of active HP after one hour for CP gels is around 60%,[4] but for HP products this amount is lower than 30%.[6]

This can be seen as advantageous for those patients who do not want to wear the bleaching tray for prolonged periods of time. Also, bleaching strips and prefilled disposable tray systems are comfortable, and they have a low cost, as the professional does not need to fabricate a bleaching custom tray (impression, model buildup, tray fabrication, and so on) and the procedure can be done at home.[8-10]

Several clinical studies that compared at-home bleaching with CP- and HP-based products showed that the different delivery systems do not impact effectiveness and do not increase side effects, such as tooth sensitivity (TS), with the advantage that HP-based products were used for shorter periods when compared with CP-based products in equivalent concentrations.[10-12]

However, only a few studies have compared HP-based products delivered through different methods.[8-10] These studies did not observe whitening, TS, and gingival irritation between different delivery methods of HP. Also, a closer view of these studies showed that the bleaching agents were usually applied in adults.[9,10,12-14] However, it is necessary to evaluate these different techniques in young patients, mainly because of the higher importance of smile esthetics in social perception during childhood and adolescence,[15] which is the reason for a significant increase over time of adolescent patients' desires for bleaching,[16,17] and also because of the scarce number of clinical studies applying at-home bleaching in this specific population.[9,18,19]

To our knowledge, no study so far has compared, in a single randomized clinical trial, at-home bleaching systems delivered in different ways to young patients. Only such a comparison will allow clinicians to decide which systems possess good whitening efficacy and fewer side effects, such as TS and gingival irritation.

Therefore, the aim of this single-blind, controlled, and parallel randomized clinical trial was to evaluate the absolute risk of TS (primary outcome) of at-home bleaching performed with 10% HP using a conventional tray-delivered system in comparison with bleaching strips or prefilled disposable trays in young patients. Also, the intensity of TS, risk and intensity of gingival irritation, and bleaching effectiveness were evaluated as secondary outcomes. The hypothesis was that bleaching strips or prefilled disposable trays would reduce the absolute risk of postoperative TS when compared to conventional tray-delivered systems. Also, the intensity of TS and absolute risk and intensity of gingival irritation would be lower in the bleaching strips or prefilled disposable trays when compared to conventional tray-delivered systems. Regarding bleaching effectiveness, no differences would be expected when the three systems were compared.

METHODS AND MATERIALS

This clinical investigation was approved by the Scientific Review Committee and by the Committee for the Protection of Human Subjects of the local university (#46945715.6.0000.5020), and it was also

registered in the REBEC (#RBR-8QDF7T). We prepared this article using the protocol established by the Consolidated Standards of Reporting Trials statement. This study was performed between June 2015 and July 2016 at the Federal University of Amazonas. Two weeks before the bleaching procedures, all the volunteers received dental prophylaxis with pumice and water in rubber cups and signed informed consent forms.

Parents and/or guardians gave the consent to patients under 18 years of age to take part in the study. Patients from ages 15 to 18 were also present during these explanations, but they were not the ones responsible for the decision to participate in the clinical trial.

Study Design

This was a single-blind, controlled, and parallel randomized clinical trial in which the evaluator was blinded to the group assignment.

Eligibility Criteria

Patients included in this clinical trial were between 15 and 20 years old and had good general and oral health. The participants had six caries-free maxillary anterior teeth without restorations and periodontal disease. The maxillary central incisors were shade A2 or darker as judged by comparison with a value-oriented shade guide (Vita Classical, Vita Zahnfabrik, Bad Säckingen, Germany). Two calibrated investigators performed this evaluation. They were required to have an agreement of at least 85% (kappa statistic) before beginning the study evaluation (data not shown).

Participants with anterior restorations, dental prosthesis, orthodontics apparatus, or severe internal tooth discoloration (tetracycline stains, fluorosis, and pulpless teeth) were not included in the study. Additionally, pregnant/lactating women, participants with any other pathology that could cause sensitivity (such as recession, dentin exposure, or the presence of visible cracks in teeth), smokers, bruxers, or participants who had previously undergone tooth-whitening procedures were also excluded.

Sample Size Calculation

The primary outcome of this study was the absolute risk of TS. A preliminary study with 20 patients using the tray-delivered 10% HP gel (White Class Calcium, FGM, Joinville, Brazil) showed an absolute risk of TS of 70%. Thus, a minimal sample size of 20 participants per group was required to have an 80% chance of detecting (as significant at the two-sided 5% level) a decrease in the primary outcome measure from 70% to 30% using a low concentration HP gel.

Randomization and Allocation Concealment

We used blocked randomization (block sizes of three and six) with an equal allocation ratio for the three groups. The randomization list was prepared using the software freely available online (http://www.sealedenvelope.com). Opaque, sealed, and consecutively numbered envelopes containing the identification of the groups were prepared by a third person not involved in the research protocol. These envelopes were opened immediately before the beginning of the bleaching procedure.

Study Intervention

In this study, we evaluated a conventional tray-delivered 10% HP bleaching system (White Class Calcium, FGM) in comparison with two different bleaching systems containing 10% HP gel: bleaching strips (White Strips, Oral-B, Procter & Gamble, Cincinnati, OH, USA) and prefilled disposable trays (Opalescence GO, Ultradent Products, Inc, South Jordan, UT, USA) applied to the maxillary anterior teeth.

In patients using the conventional bleaching tray, custom-fitted trays were fabricated. Alginate impressions (Avagel, Dentsply, Petrópolis, RJ, Brazil) were made of each subject's maxillary and mandibular arches, and after disinfection these were filled with dental stone (Asfer, Asfer Indústria Química Ltda, São Caetano do Sul, SP, Brazil). After 24 hours, a 0.9-mm soft vinyl material (Whiteness Placas para Moldeiras, FGM) was used to fabricate in a Plastivac P7 (BioArt, São Carlos, SP, Brazil) the custom-fitted trays that would hold the whitening gel.

Instructions were given to the participants regarding placement of the gel in the tray and the tray over the teeth. The excess material from the labial and lingual surfaces was trimmed to 1 mm from the gingival junction. We instructed all participants to test the fit of the bleaching tray with regard to adaptation before starting the clinical study, followed by wearing the tray with the bleaching agent for 30 minutes once a day for 14 days. We instructed the participants to remove the trays after each bleaching period, wash them with water, and brush their teeth as usual.

The patients from the bleaching strips or tray-delivered groups received instructions on how to

apply the bleaching strips and how to use them. The usage time was the same for the conventional tray-delivered system: 30 minutes once a day. All patients received verbal instructions about oral hygiene, encouraging participants to brush their teeth regularly with fluoridated toothpastes without whitening components.

Color Evaluation

Two calibrated evaluators recorded the shade of each subject's teeth at baseline, during treatment (after the first and second week of bleaching treatment), and one month postbleaching. In the event of disagreements between the examiners during shade evaluation, a consensus was reached through discussion.

The color evaluation was performed with the use of two value-oriented shade guide units—Vita Classical (Vita Zahnfabrik) and Vita Bleachedguide 3D-MASTER (Vita Zahnfabrik)—and with the aid of a spectrophotometer (Easyshade, Vita Zahnfabrik).

For color evaluation with the Vita Classical scale, the 16 tabs of the shade guide were arranged from the highest (B1) to the lowest (C4) value. Although this scale is not linear in the truest sense, for the purpose of analysis the changes were treated as though they represented a continuous and approximately linear ranking. The Vita Bleachedguide 3D-MASTER contains lighter shade tabs and is already organized from the highest (0M1) to the lowest (5M3) value. The measurement area of interest for shade matching was the middle one-third of the facial surface of the maxillary central incisor, according to American Dental Association guidelines.[20]

The two examiners, blinded to the allocation assignment, scheduled these patients for bleaching and evaluated their teeth against the shade guide at the different time assessments. Color changes were calculated from the beginning of the active phase through to the individual recall times (one month after treatment) by calculating the change in the number of shade guide units (ΔSGU) that occurred toward the lighter end of the value-oriented list of shade tabs.

For the color evaluation with the Vita Easyshade Spectrophotometer (Vita Zahnfabrik), an impression of the maxillary arch was taken with dense silicone paste (Speedex Putty, Coltene, Rio de Janeiro, Brazil). The impression was extended to the maxillary canine and served as a standard color measurement guide for the spectrophotometer. For each tooth to be evaluated, a window was created on the labial surface of the molded silicone guide using a metal device with a radius of 6 mm and well-formed borders. The shade was determined using the parameters of the Easyshade device where it indicated the following values: L*, a*, and b*, in which L* represented the value from 0 (black) to 100 (white) and a* and b* represented the shade, where a* was the measurement along the red-green axis and b* was the measurement along the yellow-blue axis. The color comparison before and one month after treatment was given by differences between the two colors (ΔE), which was calculated using the formula $\Delta E = [(\Delta L^*)^2+(\Delta a^*)^2+(\Delta b^*)^2]^{1/2}$ (Commission Internationale de l'Eclairage).

Evaluation of TS and Gingival Irritation

The subjects and parents were instructed to fill out a form to record daily whether they experienced TS and gingival irritation. We explained in detail for the patients how to fill out the form, with special attention given to describing the differences regarding TS symptoms (pain evoked by cold or other stimuli associated with some complaints, such as tingling or shooting pain [zingers] of very short duration but variable frequency) and gingival irritation (very localized aggression caused by mechanical trauma or chemical burning).[11,21,22] The patients were to fill out the form any time they felt pain. We also explained to them that if they did not feel any TS, the intensity in the pain scales would be zero. The patients returned forms to the researcher on the next appointment (one week later).

Each patient was asked to indicate the numerical value of the degree of sensitivity using a five-point numeric rating scale (NRS) where 0 = none, 1 = mild, 2 = moderate, 3 = considerable, and 4 = severe. Patients were also asked to express their pain intensity using the visual analog scale (VAS). This scale is a 10-cm horizontal line with scores of 0 and 10 at each end, respectively, where 0 = no sensitivity and 10 = severe sensitivity. A patient was to mark with a vertical line across the horizontal line of the scale the intensity of the TS. Then the distance in millimeters from the zero end was measured with the aid of a millimeter ruler.

We merged the data from both bleaching sessions. The worst score (NRS) or the highest numeric value (VAS) obtained from both bleaching sessions at each assessment point was taken for statistical purposes and for the determination of the overall risk and intensity of bleaching-induced TS. If the participant scored 0 (no sensitivity) in all time assessments from the 14-day bleaching period, this participant was

Table 1: *Baseline Characteristics of the Participants Included in This Clinical Trial*

Characteristics	Conventional Tray Delivered	Bleaching Strips	Prefilled Disposable Tray Delivered	*p*-Value[a]
Age (mean±SD, years)	17.8 ± 1.4	17.7 ± 1.6	17.9 ± 1.4	0.62
Baseline color (mean±SD, SGU)[b]	7.4 ± 2.4	7.2 ± 2.1	6.8 ± 2.3	0.54

[a] *One-way ANOVA.*
[b] *Shade guide units (SGU) obtained with Vita Classical.*

considered to be insensitive to the bleaching protocol. In all other circumstances, the participants were considered to have bleaching-induced TS. This dichotomization allowed us to calculate the absolute risk of TS, which represented the percentage of patients who reported TS at least once during treatment. We also calculated the overall intensity of TS during the 14-day period based on the worst score (NRS) or numerical VAS unit.

Statistical Analysis

The analysis followed the intention-to-treat protocol and involved all participants who were randomly assigned. The statistician was also blinded to the study groups.

The mean age (years) of the participants and the baseline SGU were compared using one-way analysis of variance (ANOVA) and the Tukey test. The absolute risks of TS and gingival irritation were compared using the Fisher exact test. The intensity of TS from the VAS was compared using one-way ANOVA and the Tukey test, and the data obtained from the NRS were compared using the Kruskal-Wallis and Mann-Whitney tests. The color change data in ΔSGU (two scales) and ΔE of different groups were compared with one-way ANOVA, and the Tukey test was used for pairwise comparisons. In all statistical tests, the significance level was set at 5%.

RESULTS

The mean age (years) of the participants and the baseline SGU are described in Table 1. One can observe equivalent data among treatment groups, which ensures that the data were comparable in terms of baseline features ($p>0.54$; Table 1). None of the patients discontinued the intervention or presented adverse effects during the intervention (Figure 1). No medication and/or desensitizer needed to be prescribed/applied to the participants from this study to relieve bleaching-induced TS. Only after finishing the whitening in the maxillary anterior teeth was the same bleaching procedure used in the mandibular anterior teeth (data not shown).

TS

The risks of TS of the different groups ranged from 70% (95% confidence interval [CI] 48-85) to 75% (95% CI 53-89) for bleaching strips and predisposable trays, respectively. The conventional tray-delivered system showed a 95% (95% CI 76-99) risk of TS and was statistically similar ($p>0.09$; Table 2). Regarding TS intensity, bleaching strips and predisposable trays showed lower scores in the VAS (1.4±1.7 and 1.6±2.3, respectively) and NRS (median 1 for both bleaching methods) compared to the conventional tray-delivered system (3.2±3.2 for VAS and median 2 for NRS). For both scales, significant differences were observed in the TS intensity ($p=0.04$ and $p=0.03$ for the VAS and the NRS, respectively; Table 3). The use of the conventional bleaching tray generated a higher level of TS intensity than bleaching strips and prefilled disposable trays.

Table 2: *Comparison of the Number of Patients Who Experienced Tooth Sensitivity (TS) at Least Once During the Three Different Bleaching Regimens Along With Absolute Risk*[a]

Treatments	Number of Participants With TS		Absolute Risk[b] (95% CI)	Relative Risk[c] (95% CI)
	Yes	No		
Conventional tray delivered	19	01	95 (76-99) A	
Bleaching strips	15	05	75 (53-89) A	1.26 (96-1.66)
Prefilled disposable tray delivered	14	06	70 (48-85) A	1.35 (1.00-1.84)

[a] *Risks identified with same letters are statistically similar.*
[b] *Fisher exact test (p>0.09).*
[c] *Compared with tray-delivered 10% HP.*

Table 3: *Tooth Sensitivity Intensity at the Different Assessment Points for the Study Groups and the Statistical Comparison*[a]

Time Assessments	VAS (Mean±SD)[b]			NRS (Median and IR)[c]		
	Conventional Tray Delivered	Bleaching Strips	Prefilled Disposable Tray Delivered	Conventional Tray Delivered	Bleaching Strips	Prefilled Disposable Tray Delivered
First week	2.3 ± 2.8	1.3 ± 1.7	0.9 ± 1.3	1 (1/2)	1 (0.5/1)	1 (0/1)
Second week	1.9 ± 2.8	1.0 ± 1.7	0.9 ± 2.3	1 (0.25/1.75)	0 (0/1)	0 (0/1)
Overall	3.2 ± 3.2 B	1.4 ± 1.7 A	1.6 ± 2.3 A	2 (1/2.25) b	1 (0.75/1) a	1 (0/2) a

[a] *Values identified with the same uppercase (VAS) or lowercase (NRS) letters are statistically similar.*
[b] *Mean ± SD: one-way ANOVA and Tukey test (p=0.04).*
[c] *Median (interquartile range): Kruskal-Wallis and Mann-Whitney tests (p=0.03).*

Gingival Irritation

The risks of gingival irritation in the different groups ranged from 15% (95% CI 5-36 for the prefilled disposable tray) to 75% (95% CI 53-89 for the conventional bleaching tray). Bleaching with the prefilled disposable tray showed the lowest risk of gingival irritation, which was statistically different from the conventional bleaching tray ($p=0.003$); (Table 4). The bleaching strips showed an intermediate result (Table 4). Usually, the gingival irritation was mild and transient, and no significant difference was observed between groups (data not shown).

Color Change

A whitening of approximately 3 to 5 shade guide units (Vita Classical) and 6 to 7 shade guide units (Vita Bleached) and approximately 7 to 10 units in ΔE were detected for the different groups after 30 days of bleaching (Table 5). No statistically significant difference was observed ($p>0.06$).

DISCUSSION

The results of the present study showed no significant difference in the absolute risk of TS for the different bleaching delivery systems, probably because they all contain the same percentage of active HP and were applied for the same period. However, the absolute risk of TS was high for all groups, in agreement with other studies that used similar HP concentration.[7,8,10,13,14]

As mentioned in the introduction, only young patients were included in this study. It is believed that the amount of HP that reaches the pulp chamber is the main cause of TS.[22] Therefore, as the teeth of young patients are more permeable and have a wider pulp chamber, there is less dentin substrate for oxidization in comparison with the teeth of older patients;[23,24] it would be expected that in the former, higher absolute risk of TS would be reported. With advancing age, there is the formation of secondary dentin associated with a continuous deposition of secondary dentin and reduction of the diameters of dentinal tubules, which in turn increase the thickness of dentin.[25,26] Therefore, a reduction of dentin permeability with age may reduce the amount of HP that reaches the pulp tissue.[27-29] Although no individual clinical studies have compared the effect of age on bleaching-caused TS,[16] in some recent clinical trials, authors have reported that the occurrence of TS in incisors was higher than in premolars.[30,31] Other indirect evidence is the fact that the absolute risk of TS shown in the present study is higher (70%-95%) compared to bleaching studies when similar percentages of HP were used to whiten the teeth of older patients.[9,32,33]

On the other hand, the intensity of TS in the present study was similar to bleaching studies that evaluated older patients.[9,32,33] There is no clear explanation for these results, but we hypothesize that as the pulp chambers of young patients are

Table 4: *Comparison of the Number of Patients Who Experienced Gingival Irritation (GI) at Least Once During the Three Different Bleaching Regimens Along With Absolute Risk*[a]

Treatments	Number of Participants With GI		Absolute Risk[b] (95% CI)	Relative Risk[c] (95% CI)
	Yes	No		
Conventional tray delivered	15	05	75 (53-89) B	
Bleaching strips	09	11	45 (26-66) AB	1.66 (0.96-2.88)
Prefilled disposable tray delivered	03	17	15 (05-36) A	5.00 (1.71-14.6)

[a] *Risks identified with same letters are statistically similar.*
[b] *Fisher exact test (α=0.05).*
[c] *Compared with tray-delivered 10% HP.*

Table 5: *Color Change in Shade Guide Units (SGU; Vita Classical and Vita Bleachedguide) and ΔE (Means ± SD) Between Baseline vs 30 Days After Bleaching for the Three Different Bleaching Regimens*

Color Evaluation Tools	Conventional Tray Delivered	Bleaching Strips	Prefilled Disposable Tray Delivered	*p*-Value[a]
ΔSGU (Vita Classical)	5.6 ± 2.0	5.5 ± 2.0	4.6 ± 1.7	0.18
ΔSGU (Vita Bleached)	8.2 ± 2.8	6.6 ± 4.1	7.0 ± 3.8	0.46
ΔE	10.4 ± 2.4	9.2 ± 3.6	7.9 ± 3.6	0.06

[a] *One-way ANOVA and Tukey test.*

wider than those of older patients, it is possible that HP could be metabolized more rapidly, and this helps explain the lower intensity of TS levels in the young patients. The same rationale could be applied for older patients and justify the lower TS intensity seen in previously published clinical studies.[9,32,33] However, future studies need to be done to evaluate the effect of age on bleaching-caused TS.

Although no significant difference was seen in the absolute risk of TS, the results of the present study showed a higher intensity of TS for the conventional bleaching tray compared with the strips and the prefilled disposable tray. Apart from the concentration of HP, which was equal among all three systems, other characteristics could be responsible for the different levels of TS intensity, such as the viscosity of the bleaching gel[34] and the amount of gel in contact with the dental structure. Although bleaching strips and prefilled disposable trays contain a standardized amount of HP, this does not occur for custom-bleaching trays, as it depends on the subjective interpretation of the dentists' prescription about the dose of gel to be applied daily, and therefore variations are expected to occur.[1,35,36]

Nevertheless, Haywood and Heymann[1] estimated that a dose of approximate 90 mg was used in custom-bleaching trays for the daily bleaching application. But there are other *in vitro* and *in vivo* studies that report that this amount may vary between 500 and 900 mg per application.[35,36] Regardless of this variation, the amount of bleaching gel contained in bleaching strips is around 12 mg and in prefilled disposable trays around 60 mg as per manufacturer descriptions. In light of that, we believe that the more plausible hypothesis to explain the higher level of TS intensity of patients who wear custom-bleaching trays is due to the higher amount of product used in such a delivery method.

However, when the findings of the TS are compared with some previously published studies in the same age-group, the results are controversial. Two clinical studies published by Donly and others[18,19] showed that TS varied between 23% and 49% when using bleaching strips and around 40% when using conventional tray-delivered systems in childhood and adolescents (ages 12-17 years) with no difference between groups. In a more recently published clinical trial, Pinto and others[8] showed that more TS was observed in bleaching strips (70%) than conventional disposable-tray systems (20%-40%) when patients 12 to 20 years old underwent bleaching. Also, these differences were observed when HP in at-home bleaching systems was applied in adult patients.[7,8,10,13,14] However, these controversial results can be attributed mostly to the different methodologies used between these studies. For instance, the evaluation of sensitivity is reported by patients on a scale that is different in each study: "Yes" or "No"[18] and the VAS (0 to 10).[8]

In terms of gingival irritation, the results of the present study showed a higher intensity of gingival irritation for the conventional bleaching tray compared with the strips and prefilled disposable tray, and we hypothesize that the lower amount of gel in the bleaching strips and prefilled disposable trays is responsible for lower gingival irritation than the conventional tray-delivered systems. In the case of gingival irritation, this excess of gel may flow out of the tray and increase the contact with gingival tissue. It is estimated that between 25% and 30% of all subjects needed to remove excess gel every time they performed the procedure.[8] Matis[37] and Christensen[38] indicate that at least 25% to 50% of the bleaching agent administered in conventional tray-delivered system is ingested at the beginning of the bleaching. Unfortunately, to the extent of our knowledge, no previous studies have measured the amount of bleaching agent ingested by patients during the use of bleaching strips or prefilled disposable trays, and this was not measured by the authors of the present study as well. Future studies need to be done to evaluate this hypothesis.

Also, the presence of bleaching gel inside the tray can play an important role in the retention of the device to the teeth; therefore, according to Carlos and others,[9] detachment of the tray and solubility of the bleaching agent in the saliva may have reduced

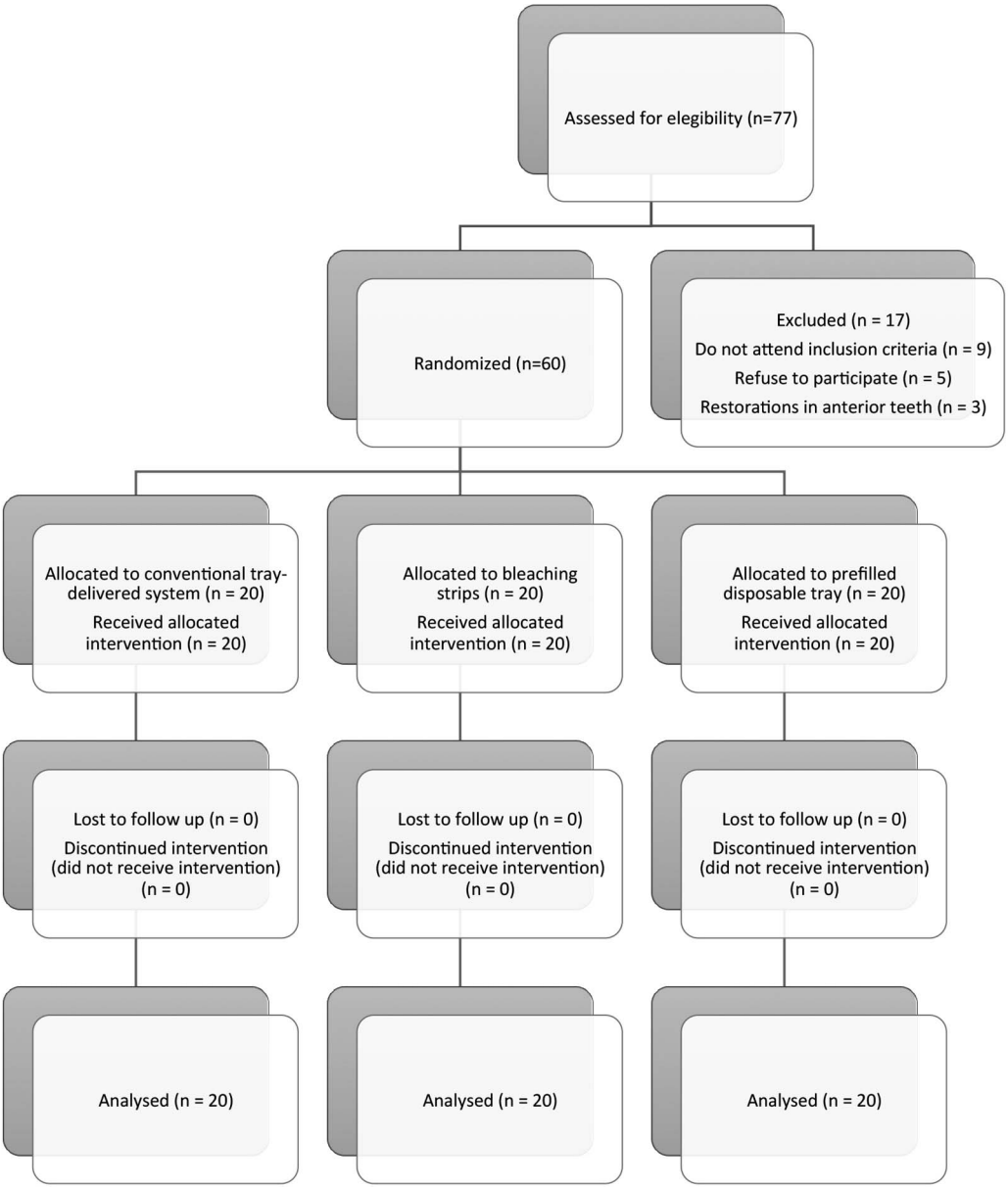

Figure 1. *Flowchart of participants.*

tray retention, causing patients some discomfort even for a short period of use (30 minutes).

It is worth mentioning that the best result in terms of gingival irritation was shown when prefilled disposable trays were used in comparison with the conventional tray-delivered system. The prefilled disposable trays showed a good tray adaptation to the patient arcade compared to bleaching strips, mainly because the trays were thin and fitted well around the teeth[9] and used a lower amount of HP in comparison with the conventional tray-delivered system. The clinical studies that evaluated gingival irritation of different groups showed controversial results,[8,9,13,39,40] and the different methodologies, as previously mentioned, can explain the variability in the results.

However, the manufacturer of the bleaching strips has launched high-adhesion bleaching strips,[18,41] probably to work around the problem of displacement of the bleaching strips. In the specific case of bleaching strips, some studies showed that patients found it hard to apply them, whereas patients found the trays very easy to slightly difficult to use,[8,13] and

this leads patients to prefer a conventional tray-delivered system rather than bleaching strips.[39]

Finally, regarding the color evaluation, no significant differences were observed between the groups, even when compared with three different instruments to evaluate color change. We used a spectrophotometer because it is a systematic and objective color assessment. On the other hand, Vita Classical is the most commonly used method among clinicians.[2,7,9,20,30,39,44,46] We also decided to add a second shade guide scale that was specifically designed to evaluate color changes in bleached teeth.[42,43] Despite these advantages, this scale is still not routinely used to evaluate color in dentistry; unfortunately, the sole use of this scale would preclude comparisons with previous studies in the literature.[44]

All bleaching systems applied showed a significant whitening effect, as previously shown by different clinical studies, since 10% HP is considered a higher concentration to be applied in at-home bleaching.[9,40,41] At the end of the bleaching protocol, a whitening of approximately 3 to 8 shade guide units was detected for all groups, and the ΔE varied by approximately 7 to 10 units, meaning a clinically important whitening, as previously observed in several clinical studies.[7-9,45] These results are much closer to those of a comprehensive systematic review published by Matis and others[46] for at-home bleaching gels.

The results of the present study showed that bleaching strips and prefilled disposable trays under dentist supervision seem to be good options to reduce the intensity of bleaching-induced TS and gingival irritation, two common side effects of at-home bleaching therapies. Also, the use of bleaching strips and prefilled disposable trays can make application of the whitening treatment faster because it is not necessary to make impressions, plaster casts, and tray customization; thus, the bleaching treatment could be easier.

Although all the adverse effects, such as TS and gingival irritation, reported in the present study related mainly to the conventional tray-delivered system, these events are expected and are typically transient and can be easily solved with the transient discontinuation of the bleaching process until the symptoms are relieved, as previously shown in studies of adolescents[8,18,19] and adults.[7-9,13,14] More clinical studies should focus on evaluating different whitening delivery systems to help clinicians have stronger recommendations regarding this topic.

CONCLUSIONS

All 10% HP systems showed detectable whitening after a 14-day bleaching with a 30-minute daily usage. However, the use of bleaching strips and prefilled disposable trays showed reduced intensity of TS. Regarding gingival irritation, prefilled disposable trays showed a significantly lower risk of gingival irritation when compared to the tray-delivered system.

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Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of approval of the Federal University of Amazonas. The approval code for this study is 46945715.6.0000.5020.

Conflict of Interest

The authors of this article certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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