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Original Article

Dentistry Section

Comparison of Two Home-based Chemically-induced Teeth Whitening in Adults: A Randomised Clinical Trial

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ABSTRACT

Introduction: Whitening strips are one of the Over The Counter (OTC) bleaching products which performed tooth whitening through an easy-to-use, low-cost product with good esthetic results.

Aim: To compare the bleaching efficacy, tooth sensitivity and gingival irritation, of home-based chemically-induced teeth whitening treatment performed using either a conventional customised tray or strips as delivering systems for whitening agents.

Materials and Methods: This randomised clinical trial was conducted at Federal University of Pernambuco (UFPE), Brazil, from 15th May 2015 to 20th January 2018. Total 21 subjects, with maxillary incisor's shade A3 or darker were selected for this study. Patients were randomly assigned into two groups, according to the bleaching technique used i.e, G1 (n=10) was carbamide peroxide 10% (Whiteness Perfect/FGM) delivered in a customised tray, G2 (n=11) was hydrogen peroxide 10% delivered in strips (3D White Whitestrips/OralB). Colour changes were evaluated by an objective (Easyshade Spectrophotometer/VITA) method at baseline, middle of treatment period, end of treatment, 15 and 30 days after treatment end. Tooth sensitivity, gingival irritation and degree of satisfaction were also recorded. Fisher's-exact test was used for categorical variables i.e, Kolmogorov-Smirnov Normality Test for quantitative variables and Mann-Whitney's test for comparison between two groups.

Results: No significant difference was observed in occurrence of tooth sensitivity (p-value=0.635), gingival irritation (p-value=0.090) and treatment satisfaction (p-value=0.476) between groups. Increased whitening effectiveness was observed in both groups after 30 days of clinical evaluation, however with no significant difference between groups (p-value=0.139).

Conclusion: Both bleaching systems showed similar effectiveness and high degree of satisfaction. Low degree of tooth sensitivity and gingival irritation was observed with no difference between groups.

Keywords: Clinical trial, Dentine sensitivity, Peroxides, Tooth bleaching, Tooth bleaching agents

INTRODUCTION

In the past few decades, home-based bleaching products have been exponentially increasing [1]. In view of this market need, some products, such as bleaching strips or prefilled disposable trays products for at-home bleaching were introduced on market [2].

Supervised dental bleaching is one of the most commonly used techniques to change tooth colour alterations [3]. The main advantages of this modality are related to the reduced chair time and lower prevalence of tooth sensitivity in relation to in-office bleaching, which use high concentrations of peroxides [4]. This method is also safe, conservative, economical and effective alternative, as long as supervised by a qualified professional [5]. In relation to the concentration of peroxide used in this type of technique, usually, 10% Carbamide Peroxide (CP) is the most suitable bleaching agent recommended [6].

Whitening strips are one of the hydrogen peroxide-containing Over The Counter (OTC) bleaching products and were introduced in 2000 aiming to popularise tooth whitening through an easy-to-use, low-cost product with good esthetic results [7]. These whitening strips adhere to surface of anterior teeth and release 5-4% hydrogen peroxide during relatively short periods of time [5]. However, a previous study showed ocurrence of deleterious effect on enamel surface caused by whitening strips when compared to supervised whitening [8]. Strips adapts to the dental arches but they must be used under dentist's supervision. They can cause discomfort to the patient as they do not provide adequate sealing [9].

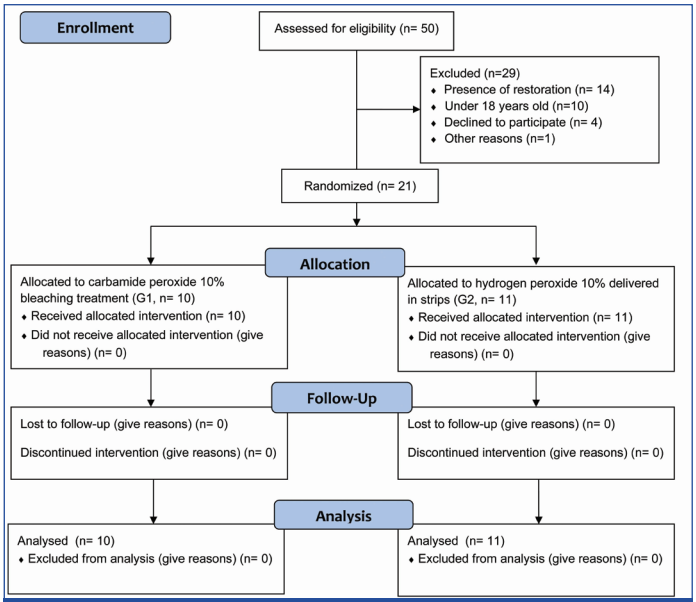
Even with the diversity of whitening techniques available, there is still a lack of clinical studies that provide scientific support for these OTC products [1,10]. Therefore, the aim of this clinical investigation was to compare the effects of whitening techniques using carbamide peroxide or hydrogen peroxide dispensed in customised trays or strips on colour change, tooth sensitivity, gingival irritation, and treatment acceptance. The null hypothesis tested was that there would be no difference in terms of tooth sensitivity, gingival irritation, and bleaching efficacy among the whitening strips in comparison to 10% carbamide peroxide in customised trays.

MATERIALS AND METHODS

This randomised clinical trial was conducted at Federal University of Pernambuco (UFPE), Brazil, from 15th May 2015 to 20th January 2018. The study was in full accordance with ethical principles, including the Declaration of Helsinki, as revised in 2002, and was approved by the Research Ethical Committee of Universidade Federal de Pernambuco, School of Dentistry, Recife, Pernambuco, Brazil (No. 29049814.5), prior to the start of the study. This article was also prepared using the protocol established by the Consolidated Standards of Reporting Trials statement [Table/Fig-1].

This study was a single-blind, parallel randomised clinical open trial in which the evaluator was blinded to the group assignment.

Inclusion criteria: Patients with minimum age of 18 years, presence of all permanent anterior teeth, vitalised, without restorations involving the vestibular faces, and with maxillary incisor's shade A3 or darker on the VITA scale (VITA shade, VITA Zahnfabrik, Bad Säckingen, Germany) and with good oral health were included in the study.



[Table/Fig-1]: Flow diagram of study design phases including enrollment and allocation criteria.

Exclusion criteria: Patients with tooth sensitivity, cervical injuries or fractures, smokers, pregnant women and lactating women, children and adolescents (upto 18 years), previous history of cancerous lesions, caries and periodontal disease, prostheses and/or previous restorations were excluded from the study.

Based on pre-established criteria described above, a total of 21 patients (convenience sample), of both sexes, were selected for the study.

Procedure

The patients fit to participate were assigned by simple randomisation into two groups according to the bleaching treatment. For this step, 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.

- Group G1 (n=10)- Patient underwent tooth whitening treatment with 10% Carbamide Peroxide (CP) (Whiteness Perfect 10-FGM, Joinvile, SC, Brasil) delivered in a customised tray.
- Group G2 (n=11)- Patient underwent tooth whitening treatment with 10% hydrogen peroxide delivered in strips (White Strips, Oral-B, São Paulo, SP, Brazil).

Group 1: For G1, custom-fitted trays were fabricated. Alginate impressions (Jeltrate/Dentsply, São Paulo, SP, Brasil) were made of both dental arches. After this step, disinfection was perfomed and these impressions were filled with dental stone (Diamante/IGE, Araripina, PE, Brazil). To fabricate the customised trays, a soft vinyl material (Whiteness Placas para Moldeiras/FGM) was submitted in a vacuum forming machine (Plastivasc P7/Bioartl, São Carlos, SP, Brazil) [2].

Instructions were given to the participants regarding placement of the gel in the disposable tray. All participants checked the adaptation of the bleaching tray before starting the clinical study, and It was also instructed to follow the recommendations to use the bleaching agent for 8 hours, during sleep, once a day for 15 days [2].

Group 2: The G2 members were given instructions on how to apply the bleaching strips and how to use them, according to the guidelines described by the manufacturer. The usage time was 30 minutes, twice a day for 7 days. All patients received verbal instructions about oral hygiene, encouraging participants to brush their teeth regularly with fluoridated toothpastes without whitening components.

For the colour evaluation with the Vita Easyshade Spectrophotometer (Vita Zahnfabrik), an impression of the maxillary arch was taken with Alginate (Jeltrate/Dentsply). The impression served as a standard colour measurement guide for the spectrophotometer. For each tooth to be evaluated, a window whose diameter corresponds to the diameter of the Spectrophotometer tip was created on the buccal surface of the moulded silicone guide [Table/Fig-2]. This way, the measurement was always taken at the same location, after tooth prophylaxis with pumice and water. The shade of the middle third of the upper anterior elements (11 and 21) was taken as reference, according to the CIELab space of the Commission Internationale de l'Eclairage. The colour variation was expressed as a continuous variable (ΔE). The arithmetic mean between the values of L* (black-white), a* (red-green) and b* (yellow-blue) of these two teeth was considered [1,11].

[Table/Fig-2]: Silicon guide for colour mesurement with easy shade.

The readings were taken 5 times for each patient in both groups:

- At baseline (before the beginning of the study),
- After 1 week for G1 and after 4 days for G2 (middle of treatment of each group),
- After 15 days of the beginning of treatment for G1 and 7 days after the beginning of treatment for G2 (end of treatment of each group), and
- 15 days and 30 days after the end of treatment for both groups.

To determine colour differences at different times of treatment, ΔE was calculated using the formula: $\Delta E^* = [\Delta L^{*2} + \Delta a^{*2} + \Delta b^{*2}]$ 1/2, where $\Delta L^* = L0 - L1$; $\Delta a = a0 - a1$; $\Delta b = b0 - b1$. ΔE were checked at four different times: ΔE1=shade registered in the middle of the treatment compared to the initial shade; ΔE2: shade at the end of the treatment compared to the initial shade; ΔE3: shade after 15 days compared to the shade at the end of the treatment; ΔE4: shade after 30 days compared to the shade at the end of the treatment [1].

Gingival irritation: The gingival irritation was also recorded during the period of bleaching treatments by filling out a form with a dichotomous scale in which patients recorded whether they experienced gingival alterations due to peroxide contact. The patients have answered the form any time during treatment, and the data were collected at evaluation appointments. In this same form, patients were also asked about the occurrence of tooth sensitivity during and immediately after the use of whitening products.

Sensitivity: This sensitivity was measured using a Visual Analogue Scale (VAS). This scale is a 10 cm horizontal line with scores of 0 and 10 at their ends, in which 0 means no sensitivity and 10 means severe tooth sensitivity. If the participant scored 0 (no sensitivity) after the bleaching session, this participant was considered to be insensitive to the bleaching protocol. In all other circumstances, scored >0 in VAS, the participants were considered to have bleaching-induced tooth sensitivity [12].

Degree of satisfaction: At the end of the treatment, the patients were evaluated for their degree of satisfaction with the technique and with the results obtained, by filling in a specific form [1].

STATISTICAL ANALYSIS

Data were submitted to statistical analysis, all tests were applied considering an error of 5% and the confidence interval of 95% and the analyses were carried out using Statistical Package for the Social Sciences (SPSS) software version 23.0 (SPSS Inc. Chicago, IL, USA). Numerical variables were represented by measures of central tendency and measures of dispersion; to verify the existence of an association, Fisher's-exact test was used for categorical variables; the Kolmogorov-Smirnov normality test was used for all quantitative variables and Mann-Whitney's test for comparison between 2 groups. The p-value <0.05 was considered as statistically significant.

RESULTS

The sample was composed by 61.9% (n=13) male with an average age of 24.22 years, ranging from 19-37 years old.

The colour change at ΔE1 was grater for G1 (p-value <0.05). However, the comparison between the mean values of ΔE2 obtained between the initial and final evaluations of treatment (11.06 for G1 and 8.47 for G2), using the Mann-Whitney's test showed no statistically significant difference (p-value=0.139) [Table/Fig-3].

ΔE	Group		p-value* (Mann-Whitney test)
	G1 Means±SD	G2 Means±SD	
Δ E1	9.32±4.13	7.31±4.27	0.035
Δ E2	11.06±4.66	8.47±2.96	0.139
Δ E3	3.27±3.03	4.68±9.15	0.438
Δ E4	4.13±2.08	3.44±2.14	0.406

[Table/Fig-3]: Spectrophotometric evaluation values.
*A p-value <0.05 was considered as statistically significant

Only 28.6% (n=6) of the sample showed sensitivity during treatment, gingival reaction was observed in 19.0% (n=4) of the patients and satisfaction with the treatment result obtained was 90.5% (n=19). No statistical significance was obtained for comparisons among groups for these variables [Table/Fig-4].

Variables	Groups		Total	p-value (Mann-Whitney test)
	G1 n (%)	G2 n (%)		
Treatment satisfaction				
Satisfied	10 (100%)	9 (81.8)	19	0.476
Unsatisfied	0	2 (18.2)	2	
Tooth sensitivity				
Present	2 (20%)	4 (36.4)	6	0.635
Absent	8 (80)	7 (63.6)	15	
Gingival irritation				
Present	0	4 (36.4)	4	0.090
Absent	10 (100%)	7 (63.6)	17	

[Table/Fig-4]: Comparison between groups for treatment satisfaction, tooth sensibility and gingival irritation.
The p-value <0.05 was considered as statistically significant

DISCUSSION

Tooth whitening is an esthetic procedure widely performed in dental clinic, this technique is able to reverse the darkened colour of tooth and enhance patient's self-esteem [13]. There are several modalities of tooth whitening: in-office technique which use high concentrate gels of hydrogen peroxide associated or without LED [14], supervised whitening that use gel with low concentrations of hydrogen peroxide or domestic whitening strategies, called Over The Counter (OTC) products, which are available to public without dental supervison [5].

In this present study, bleaching strips (OCT) were evaluated in comparision to a supervisioned dental bleaching (10% carbamide peroxide). Although the use of bleaching strips offers advantages, such as shorter application time and ease of use compared to other systems, there is still a lack of clinical evidence regarding the safety of these products [1,9]. Thus, the safety of these whitening agents remains controversial, and may have potentially deleterious effects on health [8].

The difference in treatment duration between the tested groups in this study (15 days for G1 and 7 days for G2) is justified by the need to conduct the protocol as recommended by the manufacturers.

In the present study, the strips showed a satisfactory bleaching effect. This finding can be explained due to the concentration of HP present in the product (10%), which is associated with good whitening results [2,8,15]. Few studies in the literature have evaluated the real efficacy of these products and their main effects on dental structure and tissues of the oral cavity [1,2,9,10,15-19]. The results of the present clinical investigation point to a whitening effect in both groups with no difference significance. This finding does not corroborate with a previous clinical study which patients submited to different tooth whitening strategies obtained difference significance on whitening efficacy using the whitening strips and 10% of carbamide peroxide [1]. However, a systematic review where the effectiveness and safety of the bleaching treatment with 10% CP and whitening strips were evaluated revealed same whitening efficacy between these groups through analysis of eight previous studies [20]. Data from previously published studies have been compared with the present study in [Table/Fig-5] [1,2,8,9,15,18].

The evaluation of the durability of the whitening effect, revealed similar results for both techniques, with slight colour reversal in the first 15 days. This data may correlate to the presence of dyes on patient's diets, however, previous findings suggest that there is no influence of diet on the whitening effect [13]. This finding is more probably correlated to tooth dehydration immediately after whitening, which can influence tooth colour due to demineralisation caused by the low pH of some whitening products [21]. Although it is considered a conservative treatment, tooth whitening may cause adverse effects after the procedure, such as transient dental sensitivity, which can be uncomfortable or imperceptible depending on the individual [22]. This consequence can be associated with toxic components released by bleaching agents

Author and year of publication	Sample size	Bleaching agents	Parameters compared	Conclusion
Auschill TM et al., (2005) [9]	N=39	Group A: Whitestrips (over-the-counter technique), Group B: Opalescence PF 10% (at-home bleaching technique), and Group C: Opalescence Xtra Boost (in-office bleaching technique)	Bleaching efficacy (ΔE), side effects, patients' acceptance, SEM.	Side effects noted within the three groups were minimal. Tooth hypersensitivity ranged from 2.62 (Whitestrips) to 3.38 (Opalescence PF), and gingival irritation ranged between 0.23 (Opalescence Xtra Boost) and 0.85 (Whitestrips). The most accepted method was the at-home bleaching technique. None of the teeth studied showed detectable enamel surface changes in the subsequent SEM analysis.
Donly KJ et al., (2006) [15]	N=48	10% hydrogen peroxide whitening strip, 6.5% hydrogen peroxide strip with a thicker gel layer.	Bleaching efficacy (ΔE), clinical response.	Groups did not differ significantly (p>0.33) with respect to combined deltab* or deltaL* at end-of-treatment. Tooth sensitivity and oral irritation represented the most common adverse events. Teenagers who used either 10% hydrogen peroxide gel or 6.5% hydrogen peroxide gel whitening strips twice a day for 44 days saw significant tooth whitening without serious adverse events.

Bizhang M et al., (2009) [18]	N=75	Group A: home-bleaching (illumine Home, 10% carbamide peroxide, trays, overnight, for two weeks), Group B: in-office bleaching (Illumine Office, 15% hydrogen peroxide, trays for 45 minutes, three times over three weeks), Group C: Whitestrips (strips, twice a day, 30 minutes each for two weeks).	Bleaching efficacy (ΔE)	Group A and B were found to be superior to Whitestrips. Home bleaching and in-office bleaching were equally efficient for bleaching teeth and maintaining the results for up to three months.
Omar F et al., (2019) [8]	N=65	Opalescence PF 15%, VOCO Perfect Bleach 10%, OTC Crest 3D Whitestrips, Whitelight Teeth Whitening System	Colour change (ΔE), enamel microhardness, surface roughness	Opalescence PF 15% is effective in whitening the teeth, while the other bleaching products may be effective but also have deleterious effects on the enamel.
Silva JVBS et al., (2021) [1]	N=32	G1:10% carbamide peroxide (Whiteness Perfect/ FGM) G2: teeth whitening pen containing hydrogen peroxide (Walgreens), G3: night-time whitening gel (CVS), G4: whitening strips (3D White Oral B)	Chromatic changes (ΔE), Tooth sensitivity, gingival irritation, and degree of satisfaction.	The comparison between the average ΔE means, revealed a statistically significant difference between G1 and the other groups. No significant difference was observed in the occurrence of tooth sensitivity and gingival irritation. The patients from G1 and G4 were more satisfied with the treatment outcome.
Cordeiro D et al., (2019) [2]	N=60	10% HP delivered in a bleaching tray (White Class, FGM), in strips (White Strips, Oral-B) or prefilled disposable trays (Opalescence Go, Ultradent).	Tooth sensitivity, gingival irritation, and bleaching efficacy (ΔE).	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.
Present study, 2022	N=21	Patients were randomly assigned into two groups, according to the bleaching technique used: G1 (n=10) - carbamide peroxide 10% (Whiteness Perfect/FGM) delivered in a customized tray, G2(n=11) - hydrogen peroxide 10% delivered in strips (3D White Whitestrips/OralB).	Chromatic changes (ΔE), Tooth sensitivity, gingival irritation, and degree of satisfaction.	No significant difference (p-value >0.05) was observed in occurrence of tooth sensitivity, gingival irritation and treatment satisfaction between groups. Increased Whitening effectiveness was observed in both groups after 30 days of clinical evaluation, however with no significant difference between groups (p-value >0.05).

[Table/Fig-5]: Characteristics of similar studies [1,2,8,9,15,18].

which are able to diffuse in the enamel and dentin causing damage to the dental pulp [23].

Among the 21 participants, six had transient dental sensitivity, four of them in the whitening strips group (G2). However, there was no significant difference between the groups, corroborating the results of a previous investigation where no significant difference was found regarding dental sensitivity between participants who used 10% hydrogen peroxide gel and whitening strips [9].

Considering the occurrence of gingival irritation, there was no significant difference between the groups analysed in the present study. Among the patients evaluated during treatment, only 19% (n=4) had gingival irritation, annd all belonged to strips group (G2). However, similar studies [7,20], demonstrated a higher frequency of gingival irritation in supervised whitening using trays, proposing as a cause the lower amount of gel in the whitening strips, since in the trays the excess of whitening gel can overflow and increase the contact with gingival tissue, causing gum damage.

The use of bleaching strips with 10% hydrogen peroxide cause a discrete cell viability reduction and slight alterations in odontoblast-like cells morphology [17]. However, in addition to negative consequences documented in the present study due to exposure to bleaching agents, some researchers [16,24] reported genotoxic effects of the whitening gel on the gingival epithelial, which is directed related to deoxyribonucleic acid damage [16]. This reaffirms the need for qualified professional supervision, regardless of the chosen bleaching agent or delivery system.

Despite the existence of some transient side effects such as dental sensitivity and gingival irritation observed in the present study, the bleaching products used were equally effective in obtaining a satisfactory esthetic result. However, it is necessary to perform tooth whitening safely, employing scientific based evidence practices in order to obtain satisfactory and long-lasting whitening results, avoiding potential side effects.

Limitation(s)

Inspite of the interesting results found in the present study, the sample size was a limitation given the exclusion of a large number of patients due to the inclusion criteria necessary to carry out the research. Thus, future studies with a larger sample size are necessary in order to discuss the risks of uncontrolled use of over the counter bleaching agents without professional supervision.

CONCLUSION(S)

Both bleaching systems showed similar effectiveness and high degree of satisfaction. Low degree of tooth sensitivity and gingival irritation was observed with no difference between groups. However, further studies are necessary in order to follow-up the durability of the whitening result achieved by OTC products and its safety due to the use of these products does not require a professional monitoring.

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