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In-Office Tooth Bleaching for Adolescents Using Hydrogen Peroxide-Based Gels: Clinical Trial

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The aim of the present study was to evaluate colorimetric changes and tooth sensitivity in adolescents and young patients submitted to tooth bleaching with 20% and 35% hydrogen peroxide. A randomized, controlled, clinical trial was conducted with 53 patients aged 11 to 24 years who were allocated to groups based on the use of the following commercial products: Whiteness HP – FGM® (35% hydrogen peroxide); Whiteness HP Blue Calcium – FGM® (35% hydrogen peroxide); and Whiteness HP Blue Calcium - FGM® (20% hydrogen peroxide). After the bleaching procedure, the visual analog scale was used to measure tooth sensitivity and the Vita Classical Shade guide was used to determine changes in tooth color. Statistical analysis involved the Friedman, Kruskal-Wallis and Student-Newman-Keuls tests, with $p \leq 0.05$ considered indicative of statistical significance. The addition of calcium contributed to a reduction in tooth sensitivity, especially when the lower concentration of hydrogen peroxide (20%) was used. Tooth sensitivity occurred in a transitory way and did not influence the tooth bleaching process. Significant differences in color were found after each of the two bleaching sessions. In-office tooth bleaching was considered an effective method for adolescents and young adults. Further studies in this population are necessary in order to fully evaluate the effects of bleaching in young teeth.

Key Words: adolescents, clinical trial, tooth bleaching.

Introduction

In dentistry, esthetics has become increasingly important in recent decades due to the fact that the media and advertising companies tend to emphasize the effect of a pleasing appearance in everyday situations. Thus, a large portion of individuals are unsatisfied with their smile and wish to improve their dental esthetics. Tooth color is one of the major concerns of such individuals, which has led to a greater demand for bleaching processes (1-4).

The American Academy of Pediatric Dentistry recognizes the growing interest in tooth bleaching among children and adolescents. Such interest likely stems from the increase in the variety, availability and popularity of bleaching products. Moreover, the change in color between the primary and permanent teeth may alarm young people and their caregivers (5,6). While the literature indicates that tooth bleaching can be performed on young people, the majority of studies have involved adults and few controlled trials involving the younger population have been conducted. Although more common among adults, tooth darkening is a possible indication for bleaching procedures in children and adolescents. Other indications include white spots and stains on the anterior teeth due to fluorosis, which can be quite evident and undesirable (7).

Bleaching is the most conservative treatment for darkened teeth, as it does not involve the loss of tissue (8-11). At-home bleaching with a gel and mouth guard supervised by a dentist is the most widely used modalty (12). A protocol for the use of this technique in young people was published in 1994 (13). However, in-office bleaching with high concentrations of hydrogen peroxide seems to be an appropriate alternative to at-home bleaching, especially in cases of severe discoloration, the discoloration of individual teeth, a lack of patient adherence and if the desire is to achieve an immediate result with a short application time (14-16).

Tooth sensitivity is the most undesirable side effect of tooth bleaching and affects 8 to 66% of patients, normally with a moderate degree of pain in the early stages of treatment (10,17,18). Researchers have suggested that the oxygen bubbles that form in dentinal tubules during the application of hydrogen peroxide cause movements in the dentinal fluids, which activate nerve endings (19,20). Another theory suggests that hypersensitivity is caused by oxygen released from the bleaching agents that passes through the permeable enamel and dentin, causing harm to the pulp tissue. Kossatz et al. (20) found that the addition of calcium compounds to bleaching gels can help prevent mineral loss and the reduction in microhardness of the enamel caused by the bleaching process, thereby reducing sensitivity. Moreover, calcium compounds maintain a stable,

high pH of 8 to 9 throughout the process (20).

The hypotheses tested in the present study are that in-office tooth bleaching can be performed on adolescents and young adults and the addition of calcium gluconate in bleaching gels leads to a reduction in post-procedure sensitivity. Thus, the aim of this study was to evaluate colorimetric changes and tooth sensitivity in young patients submitted to tooth bleaching with 20% and 35% hydrogen peroxide with and without the addition of calcium compounds.

Material and Methods

Patients and Randomization

A randomized, controlled, clinical trial was conducted with 53 young patients recruited from the dental clinic of Universidade Metropolitana de Santos (Santos, SP, Brazil). In total, 70 patients were initially evaluated in order to participate in the research, but, out of these, 17 did not complete the treatment or did not come back for the controls, so they were not considered in the statistical analysis. This study received approval from the Human Research Ethics Committee of the university under process number 167.886 and the patients or their caregivers were asked to sign an informed consent form. The CONSORT (21) recommendations for controlled clinical trials were followed and the study is registered in Clinical Trials under process number NCT02414464.

Volunteer individuals aged 11 to 24 years, who thought their teeth were too yellowish and desired whiter teeth, signed a statement of informed consent and were included in the study. Individuals with dentofacial anomalies, those without the complete eruption of the permanent canines, those in orthodontic or orthopedic treatment of the jaws, those who took medications that could alter tooth color and those who had previously been submitted to tooth bleaching were excluded (Fig. 1).

The 53 patients were randomly allocated to different groups using numbers on cards in opaque envelopes. Each group used a different type of bleaching gel: Whiteness HP 35% (Group 1; n=17), Whiteness HP Blue Calcium 35% (Group 2; n=17) and Whiteness HP Blue Calcium 20% (Group 3; n=19). All products were manufactured by FGM® (Joinville, SC, Brazil).

Bleaching Process

After the selection of the patients, a clinical exam was performed and the initial tooth color was determined with the aid of the Vita Classical Shade guide. The researchers carried out the evaluations and also provided the treatment. The upper left canine was chosen as the reference because it is the most saturated teeth in the arch (greatest dentinal mass and greatest amount of intrinsic pigments). We

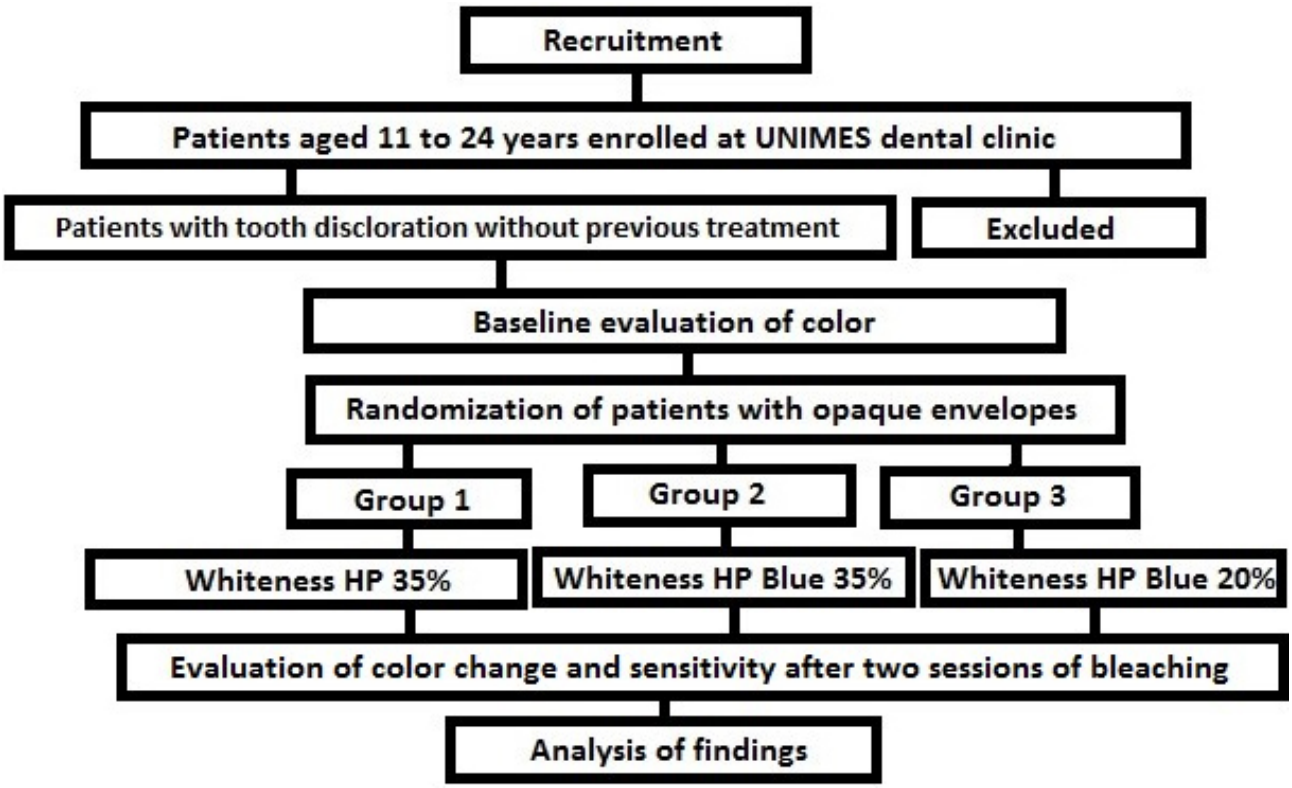

Figure 1. Flowchart of study based on CONSORT (21) recommendations.

compared the colors of the different thirds of these teeth and chose the color of the scale which was more similar to teeth color as a whole. In the second session, prophylaxis was performed with a jet of sodium bicarbonate to remove extrinsic pigments and plaque.

Each patient underwent two bleaching sessions. A lip retractor (Arc Flex, FGM®) was placed. Cotton roles or gauze compresses were used to achieve relative isolation. A dental dam (Top Dam, FGM®) was placed over the free marginal gingival tissue and the inter-tooth papillae from the upper right to the upper left first pre-molars in each session. The gels were applied to the vestibular faces of these teeth. There were neither missing nor extra teeth in the arches of the patients, nor did the teeth have cavities, restorations or cracks. Tooth color was recorded before the prophylaxis and 48 h after each session to determine the difference in tone before and after the procedures. The evaluations were made under natural light, in the morning or early afternoon and in the same office every time. The visual analog scale was used for the subjective measure of sensitivity during and after the procedures. This scale consists of a 10-cm line on which 0 corresponds to the absence of pain and 10 corresponds to unbearable pain (22). All clinical procedures and evaluations were performed by an examiner who had undergone training and calibration exercises before the beginning of the research.

The gel used in Group 1 (Whiteness HP 35%) can be used with or without a light accelerator. In the present study, the gel was applied without an external auxiliary source. As this is not a self-catalyzed system, the gel was removed after each 15-minute application and reapplied two more times, totaling 45 min of contact with the teeth. Whiteness HP Blue Calcium 35% (Group 2) and Whiteness HP Blue Calcium 20% (Group 3) are self-catalyzed systems and there is no need to remove and reapply the gel during the procedure (single application). Moreover, no auxiliary light source is used. It is necessary to move the gel every ten min with a micro-applicator to release oxygen bubbles. The calcium gluconate in the composition of these gels contributes to maintaining the integrity of the enamel during the bleaching process with the aim of reducing sensitivity. Whiteness HP Blue Calcium 20% is recommended for young people due to the lower concentration of hydrogen peroxide. Whiteness HP Blue Calcium 35% was applied for 40 min and Whiteness HP Blue Calcium 20% was applied for 50 min in each of the two sessions. The directions for use (DFU) are specified in Table 1.

Statistical Analysis

The colorimetric data were ranked using the Vita Classical Shade guide, in which the brightest teeth (B1 scale) receive a ranking of 1 and darkest teeth (C4 scale) receive a ranking of 16 (Table 2). The data were submitted to descriptive analysis. The Friedman test (comparison

Table 1. Directions for Use (DFU) according to FGM®

Bleaching gel	Preparation of the gel	Applying the gel
Whitening HP 35%	Using the mixing board that comes with the kit, mix the peroxide phase (phase 1) with the thickener (phase 2) in the proportion of 3 drops of peroxide for 1 drop of thickener.	Let the gel remain on the tooth surface for 15 min from the start of the application. With the aid of a brush or gel microapplicator move the gel three to four times to release any oxygen bubbles generated and renew the best possible contact with the teeth. At the end of the recommended time, remove the gel on the teeth with a suction tube and clean them with a gauze to let them ready to receive new gel portion. Repeat twice more (maximum) in the same session if necessary according to the evolution of the results and monitoring the sensitivity of the patient.
Whitening HP Blue 35%	Mix the two phases with syringes connected by pushing the plungers alternately up to 8 times, then push the entire content mixed to one of the syringes and the gel is ready for use.	Let the gel remain on the tooth surface for 40 min with a single application of the gel during the session. With the aid of a Cavibrush microapplicator move the gel on the teeth often (every 5 or 10 min) to release any generated oxygen bubbles and renew the gel contact with the teeth.
Whitening HP Blue 20%	Mix the two phases with syringes connected by pushing the plungers alternately up to 8 times, then push the entire content mixed to one of the syringes and the gel is ready for use.	Let the gel remain on the tooth surface 50 min for the HP Blue 20 %, with a single application of the gel during the session. With the aid of a Cavibrush microapplicator move the gel on the teeth often (every 5 or 10 min) to release any generated oxygen bubbles and renew the gel contact with the teeth.

Table 2. Ranking of colors on Vita Classical Shade guide.

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

of dependent groups – Groups 1, 2 and 3 between the sessions), Kruskal-Wallis test (comparison of independent groups – Groups 1, 2 and 3 compared to one another) and Student-Newman-Keuls test were employed. A p ≤0.05 was considered indicative of statistical significance.

Results

Tooth sensitivity was compared between the two sessions in all groups using the Friedman test. In Groups 1 (Whiteness HP 35%) and 3 (Whiteness HP Blue 20%), the changes in the degree of sensitivity were not statistically significant. In Group 2 (Whiteness HP Blue 35%), however, a significant increase in sensitivity was found from the initial reading to the first session (p=0.036), whereas no difference was found between the first (p=0.594) and second sessions (p=0.092). To compare the independent groups, the Kruskal-Wallis and Student-Newmann-Kleus tests were used. No significant differences among groups were found with regard to initial sensitivity (p=0.0944). After the first session, Group 1 reported greater sensitivity in comparison to Groups 2 (p=0.042) and 3 (p=0.007). In the second session, no differences were found between Groups 1 and 2 (p=0.320), whereas Group 3 reported less sensitivity in comparison to Groups 1 (p=0.0006) and 2 (p=0.015). Thus, the greatest sensitivity was found in Group 1 and the least was found in Group 3 (Fig. 2).

Statistically significant differences in color were found after each of the two sessions in all groups, which confirms the need for two bleaching sessions and demonstrates that all bleaching gels were effective. No significant differences were found among the three groups with regard to the initial color (p=0.811) and the color achieved after the first session (p=0.156). After the second session, however, greater bleaching occurred in Group 1 in comparison to Groups 2 (p=0.042) and 3 (p=0.046), whereas no significant difference was found between Groups 2 and 3 (p=0.924) (Fig. 3).

Discussion

The present study is relevant due to the scarcity of investigations on in-office tooth bleaching for adolescents and young patients. A number of studies have evaluated the increase in sensitivity that can occur in patients submitted to this process (17,18,20,15). In the present investigation, some of the young patients reported post-procedure sensitivity in the early stages of treatment (up to approximately 48 h after the procedure). This sensitivity, however, exerted no influence on the bleaching process.

A reduction in sensitivity was found when calcium gluconate was added to the bleaching gel with 35% hydrogen peroxide in comparison to this same concentration without calcium compounds. This finding is in agreement with a study conducted in 2012, in which the authors state that the difference in post-procedure sensitivity between gels with the same concentration with and without calcium may be explained by the fact that calcium reduces the porosity of enamel and the permeability of both enamel and dentin caused by the bleaching agent (20). The authors of a study conducted in 2011 found that the use of a casein phosphopeptide-amorphous calcium phosphate paste increased the microhardness of enamel and exerted no influence on the bleaching effect (3). Abreu et al. (23) report that the benefits of the addition of amorphous calcium phosphate may be restricted to low concentrations of hydrogen peroxide and emphasize the important re-mineralizing role of saliva. In the present investigation, although sensitivity was lower in the groups in which the bleaching gel contained calcium gluconate (Whiteness HP Blue 35 and 20%®), the bleaching effect of these gels was less than that achieved using the gel without calcium compounds (Whiteness HP 35%®). This may have been due to the fact that the consistency of the gels containing calcium gluconate seems to favor the slippage of the gel, which may translate to less contact with the tooth structure. Moreover, Whiteness HP 35%

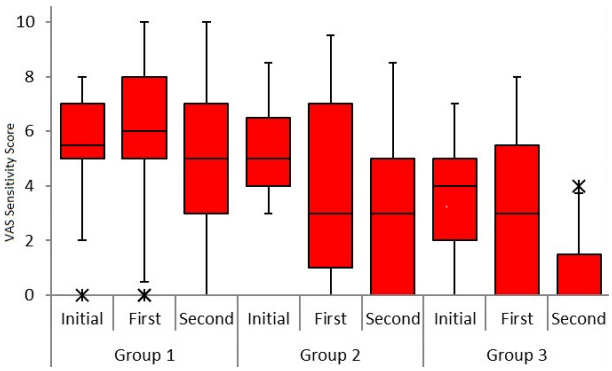

Figure 2. Sensitivity in the different groups at each evaluation time.

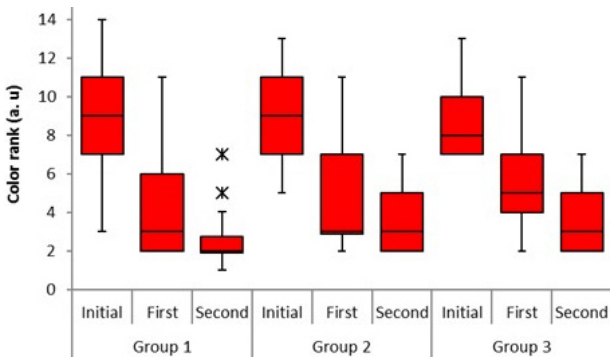

Figure 3. Color ranking in the different groups at each evaluation time.

was in contact with the teeth for a total of 45 min in each session, which is five min more than the contact time used with Whiteness HP Blue 35% and may have contributed to this difference in bleaching.

Significant differences in color were found after both the first and second sessions. Although the results differed, all gels demonstrated effective bleaching. This may have occurred due to the fact that the proper thickness of the gels (2 mm) was respected at the time of application and the contact times were rigorous, thereby providing a satisfactory outcome after each session.

The bleaching effect was proportional to the concentration of hydrogen peroxide, which is in agreement with data reported in previous studies (8,12,14,24). Gels with a lower concentration of hydrogen peroxide require a longer contact time with the teeth to whiten as well as gels with a higher concentration. In contrast, gels with a higher concentration whiten the teeth at a faster rate, but are more likely to cause sensitivity (15). Studies have shown that 35% hydrogen peroxide diffuses more quickly through the tissues than a concentration of 20% and can alter the structural and biochemical properties of both hard and soft dental tissues (25). This may explain why the 20% gel caused the least sensitivity in the present study, despite its longer contact time (50 min) in comparison to the other gels analyzed.

Since the inception of the in-office bleaching technique, the use of light (halogen, plasma arc, LED and laser) has been recommended to accelerate the action of the gel. However, the effectiveness of such activating sources has not yet been clinically confirmed. Moreover, the heat released from these sources can cause an increase in pulp temperature and the diffusion of toxic components through hard tissues, which contributes to an increase in tooth sensitivity following the bleaching procedure (8,26,27).

Despite the existence of more technical, objective color measurement methods, such as colorimeters, spectrophotometers and computer imaging analysis (28), a number of studies indicate that a visual evaluation using a color scale is a valid reliable method for differentiating dark and light colors on teeth (29). Indeed, previous clinical trials have employed this method (5) and the Vita Classical Shade guide scale facilitates the dentist's understanding of the change in tone following the bleaching procedure, as this method is commonly used to evaluate color following in-office tooth bleaching (3).

Donly et al. (7) demonstrated that tooth bleaching can be safely performed in adolescents with short-duration hydrogen peroxide strips or carbamide peroxide-mouth guard systems for nighttime use. Croll and Donly (6) performed a review of the literature on this topic and state that bleaching for children and adolescents is safe, beneficial and can be performed in a manner similar to the procedure used for adults provided that the youth is supervised by an adult throughout the process. In addition, a randomized clinical trial in adolescents conducted in 2016 came to the conclusion that in-office bleaching systems could be used on young permanent teeth (30). The present findings are in agreement with these observations, as satisfactory results were achieved using the in-office method with 20 and 35% hydrogen peroxide in individuals aged 11 to 24 years.

The main limitations of this study were the difficulties encountered regarding the return of the patients for the follow-up evaluations and the selection of individuals with a statement of informed consent signed by a parent or guardian.

Significant differences in color were found after each of the two bleaching sessions, what proved that the procedure was efficient and that the two bleaching sessions were important to achieve a satisfactory result. Tooth sensitivity occurred in a transitory way and did not influence the tooth bleaching process. The addition of calcium in the bleaching gels seems to aid in the reduction of sensitivity (20). In-office tooth bleaching with 20 or 35% hydrogen peroxide was considered an effective method for adolescents and young adults, but further studies are necessary to determine the effect of bleaching in this population.

Resumo

O objetivo do presente estudo foi avaliar alterações colorimétricas e sensibilidade dentária em adolescentes e jovens submetidos ao clareamento dental com peróxido de hidrogênio a 20% e 35%. Foi realizado um ensaio clínico controlado e randomizado com 53 pacientes, com idade entre 11 e 24 anos, que foram alocados em grupos com base nos seguintes produtos comerciais: Whiteness HP - FGM® (35% peróxido de hidrogênio); Whiteness HP Blue Calcium - FGM® (peróxido de hidrogénio a 35%); e Whiteness HP Blue Calcium - FGM® (20% de peróxido de hidrogênio). Após o procedimento de clareamento, a escala analógica visual foi utilizada para medir a sensibilidade dentária e a escala clássica Vita® foi utilizada para determinar as alterações de coloração. A análise estatística envolveu os testes de Friedman, Kruskal-Wallis e Student-Newman-Keuls, com valor de $p \leq 0,05$ considerado indicativo de significância estatística. A adição de cálcio contribuiu para uma redução da sensibilidade dentária, especialmente quando se utilizou a menor concentração de peróxido de hidrogénio (20%). A sensibilidade dentária ocorreu de forma transitória e não influenciou o processo de clareamento dos dentes. Foram encontradas diferenças significativas na cor após cada uma das duas sessões de clareamento. O clareamento dental de consultório foi considerado um método eficaz para adolescentes e adultos jovens. Estudos adicionais nesta população são necessários para avaliar completamente os efeitos do clareamento em dentes jovens.

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