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AVALIAÇÃO DE CLAREAMENTO DENTAL COMPARANDO TRÊS DIFERENTES PROTOCOLOS: ENSAIO CLÍNICO RANDOMIZADO COM 22 MESES DE ACOMPANHAMENTO

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Orientadora: Prof. Dra. Thaís Thomé Feldens
Coorientadora: Prof. Dra. Andréa de Azevedo Brito Conceição

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RESUMO

VILLARINHO, Lauren Neumann. **Avaliação de clareamento dental comparando três diferentes protocolos:** ensaio clínico randomizado com 22 meses de acompanhamento 2015. 36 f. Trabalho de Conclusão de Curso (Graduação em Odontologia) - Faculdade de Odontologia, Universidade Federal do Rio Grande do Sul, Porto Alegre, 2015

O presente estudo buscou realizar a avaliação clínica, por um período de 22 meses de acompanhamento, comparando clareamento dental utilizando tiras clareadoras a base de peróxido de hidrogênio a 10%, tiras clareadoras à base de peróxido de hidrogênio a 10% associadas ao clareamento dentário em consultório com peróxido de hidrogênio a 38%, e clareamento de consultório com peróxido de hidrogênio a 38%. Foram selecionados 36 pacientes que foram divididos em três grupos (n=12), randomicamente. Os participantes do grupo 1 receberam o tratamento pela técnica de tiras clareadoras profissionais Opalescence Go!/Ultradent durante 30 minutos, em ambas as arcadas dentárias, por 10 dias; os pacientes do grupo 2 utilizaram as tiras clareadoras Opalescence Go!/Ultradent conforme o grupo 1, porém associando-se duas aplicações de 40 minutos do peróxido de Hidrogênio a 38% (Opalescence Boost/Ultradent) através da técnica de clareamento em consultório, com intervalo de 6 dias entre as aplicações; para o grupo 3 os pacientes receberam duas aplicações de 40 minutos do peróxido de Hidrogênio a 38% (Opalescence Boost/Ultradent) através da técnica de clareamento em consultório, com intervalo de 6 dias entre as aplicações. Foram avaliados nesse estudo o grau de alteração de cor/ clareamento dentário, a estabilidade de cor, a sensibilidade dentária e o grau de satisfação dos pacientes após o tratamento. Os pacientes foram avaliados imediatamente após o clareamento, 14 dias, 3, 6 e 22 meses após o término do mesmo. Após análise estatística, através da Análise de Variância – ANOVA, teste de Scheffé e teste de Shapiro-Wilk ($p \leq 0,05$), concluiu-se que o uso das tiras clareadoras não aumentou o grau de clareamento dental quando associado à técnica de clareamento de consultório e que as três técnicas clareadoras utilizadas foram igualmente eficazes em relação à alteração de cor para todos os períodos avaliados. A estabilidade de cor foi determinada através do teste não paramétrico de Friedman, no qual observou-se que não houve diferença estatisticamente significativa entre os períodos de avaliação, ou seja, o grau de clareamento obtido nas três técnicas se manteve ao longo dos 22 meses. Nenhum paciente apresentou sensibilidade no período de 6 a 22 meses após o tratamento clareador. Em relação ao grau de satisfação, o grupo que apresentou resultados mais positivos foi o que associou as duas técnicas clareadoras, seguido do que utilizou a técnica em consultório, sendo o grupo das tiras o que obteve o menor grau de satisfação.

Palavras-chave: Clareamento dental. Odontologia estética. Peróxido de hidrogênio

ABSTRACT

VILLARINHO, Lauren Neumann. **Evaluation of tooth bleaching using three different protocols:** randomized clinical trial with longitudinal evaluation of 22 months. 2015 36 p. Final Paper (Graduation in Dentistry) - Faculdade de Odontologia, Universidade Federal do Rio Grande do Sul, Porto Alegre, 2015

The present study sought to clinically evaluate the bleaching potential of three different protocols: 10% hydrogen peroxide-based whitening strips, 10% hydrogen peroxide-based whitening strips associated with in-office tooth bleaching using 38% hydrogen peroxide gel, and in-office tooth bleaching using 38% hydrogen peroxide gel, within a period of 22 months follow-up. Thirty-six patients were selected and randomly divided into three groups (n=12). Group 1 was treated for a period of 10 days, with daily 30-minute applications of Opalescence Go!/Ultradent Professional Whitening Strips on both dental arches; Group 2 was also treated with Opalescence Go!/Ultradent Whitening Strips, although associated with two in-office bleaching sessions using hydrogen peroxide at 38% (Opalescence Boost/Ultradent) for 40 minutes, counting 6 days between each session; Group 3 was submitted to two in-office sessions of hydrogen peroxide at 38% (Opalescence Boost/Ultradent) for 40 minutes, 6 days apart from each other. The degrees of color change/tooth whitening, color stability, tooth sensitivity and patient satisfaction were evaluated in this study. The studied variables were assessed immediately after bleaching and on 14 days, 3 months, 6 months and 22 months after the end of the treatment. The statistical analysis was performed using analysis of variance – ANOVA, Scheffé test and Shapiro-Wilk test ($p \leq 0,05$). Through the results of this study, it was concluded that the use of bleaching strips did not increase the degree of tooth whitening technique when combined with in-office bleaching. The three techniques were equally effective regarding color change. Color stability after treatment was determined using the nonparametric Friedman test, which found no statistical differences between after treatment periods in all groups. In other words, the degree of tooth whitening was maintained during the 22 months assessed. Also, from 6 months to 22 months after the end of the treatment, no patient reported any tooth sensitivity. Regarding patient satisfaction after treatment, group 2, which combined the two bleaching systems studied, had a higher degree of satisfaction, followed by in-office and strips bleaching.

Keywords: Tooth bleaching. Aesthetic dentistry. Hydrogen peroxide

SUMÁRIO

1 INTRODUÇÃO

O clareamento dental é conhecido desde meados do século XIX, embora tenha se tornado mais notório e utilizado a partir de 1989, quando Haywood & Heymann descreveram em detalhes a técnica de clareamento dental caseiro em moldeiras, utilizando peróxido de carbamida a 10%.[1]

Nas últimas décadas, com o avanço do poder da mídia, houve um grande crescimento na demanda por tratamentos estéticos. Na odontologia atual, a procura por um sorriso mais claro tem feito do clareamento dental um dos tratamentos mais requisitados em consultórios odontológicos.[2-6] Ao clarear os dentes, busca-se uma aparência de frescor, remetendo a uma imagem de saúde e jovialidade, o que promove o aumento da autoestima e satisfação estética.

A crescente demanda por estes procedimentos incentiva o desenvolvimento de novos produtos e técnicas clareadoras, que buscam oferecer resultados mais previsíveis e satisfatórios.[6,7] Com isso, novos produtos surgem no mercado, fazendo-se necessária a avaliação de sua real eficácia e segurança.[8]

O mecanismo de ação das substâncias clareadoras é originado da degradação do peróxido de hidrogênio (PH) que, por ter baixo peso molecular, penetra na estrutura dentária produzindo uma reação de oxidação-redução ou “redox” das moléculas complexas dos pigmentos orgânicos presentes. Estas moléculas complexas são clivadas em moléculas mais simples, que tornam-se mais claras e, parte delas, pode ser removida da estrutura dentária por um processo de contra-difusão, alterando a cor dos dentes e tornando-os mais claros.[3,9] Além disso, estudos mostram que há uma desidratação da matriz orgânica do esmalte, o que leva a sensação óptica de dentes mais brancos e opacos.[10]

O clareamento dental caseiro é normalmente realizado com o uso de moldeiras individuais, nas quais uma certa quantidade de gel clareador é aplicada e permanece em contato com os dentes diariamente por um período de tempo específico (de acordo com a concentração do gel e o perfil do paciente). Este procedimento é repetido por um período de ao menos uma semana, ou até que se atinja uma cor condizente com as expectativas do paciente.[3,11] Esta técnica se tornou especialmente popular devido à sua característica minimamente invasiva, simples, segura e de baixo custo.[12] Além de propiciar poucos

efeitos colaterais, estudos mostraram que este protocolo clareador produz resultados satisfatórios, incentivando através de seu sucesso o desenvolvimento de novos estudos e técnicas.[13]

As tiras de clareadoras à base de peróxido de hidrogênio chegaram ao mercado, oferecendo uma nova e simples forma de clareamento caseiro, com a conveniência de eliminar o processo de tomada de impressões para as moldeiras individuais. Ao invés disso, elas possuem forma adequada para se adaptar e aderir aos dentes de ambas as arcadas.[10,14] Inicialmente, estas tiras foram disponibilizadas apenas em versões de baixa concentração de peróxido de hidrogênio, em torno de 5,3%, sendo vendidas livremente e sem qualquer supervisão profissional. Devido à baixa incidência de sensibilidade dentinária observada associada a esta nova técnica, novos produtos vêm sendo desenvolvidos em concentrações mais elevadas, as quais necessitam monitoramento profissional.[15] O sistema Tres White/ Ultradent é uma destas novas alternativas, considerado seguro para o clareamento caseiro, e com a opção de ser associado à técnica de clareamento em consultório.[16] Um ensaio clínico mostrou resultados semelhantes desta técnica mista quando comparado com peróxido de carbamida a 10% durante um período de duas semanas.[17]

A técnica de clareamento vital de consultório oferece resultados mais rápidos, à medida que preconiza a utilização de elevadas concentrações de peróxido de hidrogênio, variando entre 20-38%.[13] Para o profissional, no entanto, este processo exige maior tempo clínico e, de acordo com estudos, proporciona um grau de clareamento mais baixo do que a técnica de clareamento caseiro com moldeiras individuais.[18] Inicialmente, a literatura recomendava o uso de fontes auxiliares de luz para acelerar a reação redox (e, portanto, o processo de branqueamento), tais como lâmpadas halógenas, LEDs e lasers. O uso destas, no entanto, foi posteriormente comprovado desnecessário, ao não demonstrar qualquer vantagem sobre as técnicas que não contam com tais fontes, e ser até mesmo prejudicial à estrutura dentária, já que o calor intenso sobre o substrato pode causar danos pulpares e sensibilidade dentinária.[12,16,19-21]

A sensibilidade dentária é um efeito colateral comum durante o clareamento dental, independentemente da técnica empregada. É geralmente reversível e resolve-se naturalmente. Em alguns casos, agentes dessensibilizantes contendo nitrato de potássio e fluoreto podem ser utilizados para acelerar este processo, proporcionando uma situação

mais confortável para o paciente.[22] Estes sintomas são atribuídos ao pH das substâncias clareadoras, juntamente ao baixo peso molecular e a livre passagem através de esmalte e dentina, possivelmente atingindo os tecidos pulpares.[21,23] A prevalência de sensibilidade dentária varia de 11% a 91%.[24] A grande variação é explicada pela natureza subjetiva da sensibilidade e da concentração de diferentes agentes clareadores disponíveis e utilizadas em estudos.[25]

Na tentativa de ajudar a compreensão das questões que envolvem as diferentes técnicas de clareamento dental disponíveis atualmente, o presente ensaio clínico procurou comparar o grau de clareamento obtido e a sensibilidade dentária utilizando tiras de clareamento de à base de peróxido de hidrogênio a 10%, tiras clareadoras a base de peróxido de hidrogênio a 10% associado a clareamento dental de consultório com peróxido de hidrogênio a 38%, e clareamento dental de consultório com peróxido de hidrogênio a 38%, dentro de um período de 22 meses de acompanhamento.

2 OBJETIVOS

O presente estudo teve o objetivo de avaliar o potencial clareador de três diferentes protocolos de clareamento dental, assim como o grau de sensibilidade dentária possivelmente associado a cada uma destas, durante um período de 3, 6 e 22 meses de acompanhamento.

Foram avaliados os seguintes protocolos: clareamento dental com tiras clareadoras a base de peróxido de hidrogênio a 10%; clareamento dental com tiras clareadoras a base de peróxido de hidrogênio a 10% quando associadas ao clareamento dentário em consultório com peróxido de hidrogênio a 38%; e clareamento dentário em consultório com peróxido de hidrogênio a 38%. As três técnicas foram comparadas entre si para a avaliação de uma possível supremacia de alguma sobre as outras, e separadamente para avaliar estabilidade de cor e/ou sensibilidade ao longo do tempo.

A hipótese levantada foi de que todos os protocolos teriam igual potencial clareador, embora o clareamento com tiras apresentasse uma menor estabilidade de cor ao longo do tempo. Quanto à sensibilidade, a hipótese foi de que os grupos tratados em consultório apresentariam maior sensibilidade dentinária durante o período de tratamento, estabilizando não muito após o fim do mesmo.

3 ARTIGO CIENTÍFICO*

Evaluation of tooth bleaching using three different protocols: Randomized clinical trial with longitudinal evaluation of 22 months.

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Running title: Clinical evaluation of dental bleaching, 22 months follow-up

Clinical Relevance: The three protocols did not show statistical difference in whitening efficiency, color stability or sensitivity in a period of 22 months follow-up.

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Evaluation of tooth bleaching using three different protocols: Randomized clinical trial with longitudinal evaluation of 22 months.

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Running title: Clinical evaluation of dental bleaching, 22 months follow-up

Clinical Relevance: The three techniques did not show statistical difference in whitening efficiency, color stability or sensitivity in a period of 22 months follow-up.

SUMMARY

Objectives: The present study sought to clinically evaluate the bleaching potential of three different techniques: 10% hydrogen peroxide-based whitening strips, 10% hydrogen peroxide-based whitening strips associated with in-office tooth bleaching using 38% hydrogen peroxide gel, and in-office tooth bleaching using 38% hydrogen peroxide gel, within a period of 22 months follow-up.

Methods: Thirty-six patients were selected and randomly divided into three groups (n=12). Group 1 was treated for a period of 10 days, with daily 30-minute applications of Opalescence Go!/Ultradent Professional Whitening Strips on both dental arches; Group 2 was also treated with Opalescence Go!/Ultradent Whitening Strips, although associated with two in-office bleaching sessions using hydrogen peroxide at 38% (Opalescence Boost/Ultradent) for 40 minutes, counting 6 days between each session; Group 3 was submitted to two in-office sessions of Hydrogen Peroxide at 38% (Opalescence Boost/Ultradent) for 40 minutes, 6 days apart from each other. The degrees of color change/tooth whitening, color stability, and tooth sensitivity were evaluated in this study. The studied variables were assessed immediately after bleaching and on 14 days, 3 months, 6 months and 22 months after the end of the treatment. The statistical analysis was performed using analysis of variance – ANOVA, Scheffé, and Shapiro-Wilk test ($p \leq 0,05$).

Results: Through the results of this study, it was concluded that the use of bleaching strips did not increase the degree of tooth whitening technique when combined with in-office bleaching. The three techniques were equally effective in relation to color change. Color stability after treatment was determined using the nonparametric Friedman test, which found no statistical differences between after treatment periods. In other words, the degree of tooth whitening was maintained during the 22 months assessed. Also, from 6 months to 22 months after the end of the treatment, no patient reported any tooth sensitivity. Regarding patient satisfaction after treatment, group 2, which combined the two bleaching systems studied, had a higher degree of satisfaction, followed by in office and strips bleaching.

Keywords: Tooth bleaching. Hydrogen peroxide. Aesthetic dentistry. Whitening strips.

INTRODUCTION

Dental bleaching has been known since the mid-nineteenth century, although it has become more notorious in 1989 when Haywood & Heymann first described nightguard tooth bleaching with 10% carbamide peroxide (CP) in detail.[1]

In the past decades, the advance of media power has brought a growing demand for aesthetic treatments. In current dentistry, the search for a brighter smile has made dental bleaching one of the most requested treatments in dental offices.[2-6] By whitening the smile, patients seek an appearance of freshness associated with health and youth,[3] increasing self-esteem and aesthetic satisfaction.

The growing demand for these procedures boosts the development of new products and bleaching techniques sought to provide more predictable and satisfactory results.[6,7] With that, new products arise in the market, making it necessary to evaluate their actual efficacy and safety.[8]

The action mechanism of whitening substances is originated through the breakdown of hydrogen peroxide (HP) which, for having low molecular weight, penetrates the tooth structure producing an oxidation-reduction (or "redox") reaction on the complex molecules of organic pigments. These complex molecules are cleaved into simpler ones that become clearer, and part of them may be removed from the tooth structure through a process called counter-diffusion, altering tooth color and making teeth brighter.[3,9] Besides that, studies have shown that there is a dehydration of the organic enamel matrix, which leads to the optic sensation of whiter and more opaque teeth.[10]

Nightguard dental bleaching is usually carried out with the use of individualized trays, on which a certain amount of whitening gel is placed and remains in contact with the teeth for a specific daily amount of time (according to gel concentration and patient profile). This procedure is repeated for a period of at least one week, or until the teeth reach a brighter color that satisfies the patient's expectations.[3,11] This technique has become especially popular due to its minimally invasive, safe, simple and low-cost character.[12] Besides the few side effects, it has been shown to provide satisfactory results in short and long-term follow-ups,[13] propelling the development of new studies and techniques from its success.

The HP-based whitening strips have recently made their way into the market, offering a new and simple form of at-home bleaching, with the convenience of eliminating the process of taking impressions for the individual trays. Instead, they have the appropriate shape to adapt and adhere to the teeth on both arches.[10,14] Initially, these strips were available only in low-HP concentration forms, around 5,3%, being sold over the counter without any professional supervision. As a low incidence of dental sensitivity was observed, new products have been developed in higher concentrations, which require professional monitoring.[15] The Tres White/Ultradent system (available in HP at 10 and 15%, being 10% the concentration used in this study) is one of these new alternatives, considered safe for at-home whitening, and with the option of the associated in-office technique.[16] A clinical trial showed similar results of this mixed technique when compared to 10% CP for a two-week period.[17]

The in-office vital bleaching technique offers faster results, as it is performed using high concentrations of HP, varying from 20-38%.[13] For dentists, however, this process demands greater clinical time and, according to studies, provides a lower degree of whitening than at-home bleaching with individual trays.[18] In the beginning, literature

recommended the use of auxiliary light sources to accelerate the redox reaction (and, therefore, the whitening process), such as halogen lamps, LEDs, and lasers. The use of these, however, was later proven to show no benefit over techniques with no auxiliary light sources, and even be detrimental to the tooth structure, as the intense heat over the substrate can cause pulp damage and tooth sensitivity.[12,16,19-21]

Tooth sensitivity is a common side effect during dental bleaching, regardless the technique. It is generally reversible and resolves itself naturally. Sometimes, desensitizing agents containing potassium nitrate and fluoride may be used to accelerate this process and provide a more comfortable situation for the patient.[22] These symptoms have been attributed to the pH of the bleaching substances, alongside low molecular weight and the free passage through enamel and dentin, possibly reaching pulp tissues.[21,23] The prevalence of tooth sensitivity varies from 11% to 91%.[24] The great variation is explained by the subjective nature of sensitivity and the different concentration of bleaching agents available and used in studies.[25]

In an attempt to help the understanding of matters involving the different techniques of dental bleaching available today, the present clinical trial sought to compare the degree of whitening obtained and the tooth sensitivity using 10% hydrogen peroxide-based whitening strips, associated or not with in-office tooth bleaching using 38%, within a period of 22 months follow-up. The evaluations were made 14 days and 3, 6, and 22 months after treatment, under the null hypothesis that the use of whitening strips will not intensify the effects of regular in-office bleaching.

MATERIALS AND METHODS

The scientific review committee and ethics committee of the Federal University of Rio Grande do Sul (protocol No. 26557/19631) approved this clinical trial.

Study Design

For this study, thirty-six volunteer students, ages 18-28, were selected from various courses within the university, and signed a term of free and informed consent to participate. They were randomly divided into three different groups (n=12).

The outcomes analyzed were degree of color change and tooth sensitivity after treatment, comparing the three following techniques: 1) Daily 30-minute applications of Opalescence Go!/Ultradent Professional Whitening Strips on both dental arches; 2) Opalescence Go!/Ultradent Whitening Strips, associated with two in-office bleaching sessions using hydrogen peroxide at 38% (Opalescence Boost/Ultradent) for 40 minutes, counting 6 days between each session; 3) Two in-office bleaching sessions using Hydrogen Peroxide at 38% (Opalescence Boost/Ultradent) for 40 minutes, 6 days apart from each other. The patients were evaluated at baseline, immediately after treatment, 14 days, 3 months, 6 months and 22 months after finishing treatment.

Sample Size Calculation

The sample calculation was based on previous studies with similar methodology, such as the ones from Marson et al. (2008) and Matis et al. (2009), where it has been shown

that the use of 10 patients per group allows a normal distribution of data and proper application of statistical tests.[7,26]

Participant Inclusion & Exclusion Criteria

To participate in the study, patients should: be unsatisfied with the dim color of their teeth and wish to whiten them; be 18 years of age or older; have higid labial surface of the anterior teeth; have good periodontal conditions; not smoke; not present with cervical lesions or any kind of tooth hypersensitivity; agree on not participating on other clinical studies during the course of this project.

Patients would be excluded from the study if: informed to have undergone tooth bleaching treatment in the past; had any dental work planned involving the anterior teeth or that could impact general health conditions of the individual for the period of the study; possessed teeth with complex intrinsic staining due to: tetracycline, fluorosis, or hypocalcification; possessed A1 and B1 teeth or lighter, according to the evaluation of the examiner, according to Vitta scale; was pregnant or breastfeeding.

Clinical Protocol

All patients were initially submitted to anamnesis, clinical examination and photographic records. Impressions were taken of both arches on alginate (Hydrogum/Zhermack). Plaster models were created and, from that, heavy-duty condensation silicone (Zetalabor/Zhermack) guides, with buccal perforations of anterosuperior teeth (13 to 23) and inferior canines. The guides were used for color measurements with Vita EasyShade/Vita spectrophotometer, to allow measurements to be made on the same area of the tooth, avoiding interferences from environmental lighting.

Baseline data for initial tooth color were collected and registered previous to any whitening protocol application. Two evaluators were responsible for color measurements with the spectrophotometer and were calibrated by an experienced researcher on the use of the equipment. For calibration purposes, they performed color measurement on three different people in three different times, in order to get the same mean results in all measurements. The VITA EasyShade spectrophotometer tip was positioned on the buccal surface of each tooth through the perforations made on the silicone guides. Three measurements were made on each tooth to obtain a final average value.

Group 1 was treated with 10% hydrogen peroxide Opalescence Go!/Ultradent Professional Whitening Strips on both dental arches. All patients went through previous orientation at a single moment, with live and video demonstrations, and received printed instructions with a form for daily self-assessment of tooth sensitivity. The following treatment protocol was performed for 10 consecutive days, at the same time: a) patient-held oral hygiene; b) whitening product should be at ambient temperature, withdrawn from the refrigerator 30 minutes prior to application. Refrigeration was needed for better conservation of the product; c) position whitening strip on each arch, according to the previous demonstration; d) remove whitening strips after 30 minutes of utilization and wipe off excess gel with absorbent paper tissue; e) perform regular oral hygiene.

Group 2 was also treated with 10% hydrogen peroxide Opalescence Go!/Ultradent Professional Whitening Strips, only associated with two sessions of in-office bleaching with 38% hydrogen peroxide Opalescence Boost/Ultradent gel. Treatment protocol for the

strips was the same as the one used for Group 1. For in-office bleaching, following whitening protocol was held in two clinical sessions, 6 days apart from each other: a) individual protection for professional and patient; b) prophylaxis using pumice powder and water; c) placement of lip and tongue retractor (ArcFlex/FGM); d) light-cured gingival barrier (Opal Dam/Ultradent) installation, from 15 to 25 and 35 to 45; e) preparation of 38% hydrogen peroxide whitening gel (Opalescence Boost/Ultradent), with the mixture of the two phases (thickener + HP), according to manufacturer instructions (the syringes are connected by pushing the plungers alternately 25 times, to mix all of the contents, that are then pushed to one of the syringes to be ready to use; f) application of a layer approximately 1 mm thick of bleaching gel on the labial surface of the teeth, from 15 and 25 and 45 to the 35, including interproximal sites, and extending slightly to the incisal or occlusal surfaces g) remove the gel after 40 minutes with disposable surgical suction, followed by abundant air-water spray over the teeth. Self-assessment forms for tooth sensitivity were provided after each session.

Group 3 was treated in-office alone, in two sessions, with 38% hydrogen peroxide Opalescence Boost/Ultradent gel. Treatment protocol was the exact same as Group 2 for in-office bleaching. Tooth sensitivity was assessed after each session.

All patients responded a quick survey after finalizing treatment, with a simple yes or no question regarding patient satisfaction.

Treatment outcome of sensitivity / Exclusion of participants

In case of severe and intolerable sensitivity (numbers 4 and 5 in the visual scale of sensitivity), the participant would be treated for it. Protocol was as follows: a) combined relative isolation (cotton rolls, lip retractor, sucking); b) prophylaxis with pumice powder; c) application of desensitizing gel (UltraEz / Ultradent, based on potassium nitrate and sodium fluoride) evenly over the teeth with a microbrush; d) after 15 minutes the gel was removed from the teeth with cotton and plenty of water; e) In addition, each patient was given an individualized tray and a syringe of UltraEZ gel, to be used at home daily for 1 hour to terminate the sensitivity.

If there were no continuity conditions, the patient would be excluded from the study.

Clinical evaluation plan

Two calibrated operators for the use of Vita Easyshade spectrophotometer/Vita carried out clinical evaluations. For group 1 these evaluations were performed from the first consultation for baseline measure, after 5 days of using the test strips, and after 10 days of use. For group 2 evaluations began from the first consultation, before the 2nd application of in-office whitening (6 days after the use of bleaching strips), and after the 10th day of using bleaching strips**.** For group 3 evaluations were performed from the first consultation and after the 1st and 2nd applications**.** All groups were evaluated 14 days, 3 months, 6 months and 22 months after completion of treatment.

Criteria and procedures for indirect evaluation

Comparisons were performed using standardized reading measurements of tooth color using the spectrophotometer VITA Easyshade/Vita, on the labial surface of the anterior maxillary teeth 23 to 13, and to the lower teeth (33 and 43), individually measured as previously described. The reading with a spectrophotometer provides a quantitative analysis, unlike with Vita assessment scale, which may lead to a subjective response.

For this study, three measurements were made for each tooth, and arithmetic average was obtained from the results. Three measured values were considered: L*, a*, and b* according to the CIELAB system. In this system, L* indicates the brightness ranging from 0 (black) to 100 (white) and the a* and b* hue, where a* represents a hue and saturation in the red-green axis and b* hue and saturation in the blue-yellow axis. The color comparison before and after bleaching was obtained by ΔE, or color difference, which is represented by the equations: $\Delta E = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{0.5}$ (International Commission of Leclairage, 1978); $\Delta L^* = L^*1 - L^*0$ (final reading, minus baseline reading); $\Delta a^* = a^*1 - a^*0$ (final reading, minus baseline reading); $\Delta b^* = b^*1 - b^*0$ (final reading, minus baseline reading).

To evaluate the sensitivity during and after the whitening treatment, patients responded to a visual scale ranging from 0 to 5 (where 0 = no sensitivity, 1 = mild, 2 = moderate, 3 = substantial, 4 = severe and 5 = intolerable sensitivity).

Statistical analysis of the results

To confirm the normal distribution of data and proper application of the statistical tests, the Shapiro-Wilk test was performed. The results of color change were analyzed by analysis of variance (ANOVA) using the design in repeated measurements (performed by the *Statistical Package for Social Sciences* - SPSS version 23.0 software), complemented by Multiple Comparisons Test of Scheffé ($p \leq 0.05$). For intra-group analysis of color stability throughout time, we used the nonparametric Friedman test ($p \leq 0.05$). To statistically evaluate sensitivity between groups, we used the nonparametric Kruskal-Wallis ($p \leq 0.05$).

RESULTS

Sample size alterations

In the course of 22 months, the study gradually suffered sample losses. Group 1 was the most affected, with final n = 5. Of the 7 losses, 3 were excluded of the final count for going through different bleaching treatments after the 6-month period, 3 gave up on the study and 1 could not be reached for the last evaluation. Group 2 finished with n = 10, accounting 1 exclusion for new bleaching treatment after 6 months and 1 patient who moved away after the 6-month evaluation. Group 3 suffered 4 losses, finishing with n = 8. Of the 4 losses, 1 patient moved away after the 14-day evaluation, 2 patients gave up after the 3-month period, and 1 patient gave up after the 6-month period.

Table 1 illustrates the sample losses through time for each group.

Group	14 days	3 months	6 months	22 months
G1	n=12	n=12	n=9	n=5
G2	n=12	n=12	n=11	n=10
G3	n=12	n=11	n=9	n=8

The normal distribution of groups was verified by the Shapiro-Wilk test, which was not significant (p> 0.05), indicating that sample data does not differ significantly from the normal distribution, i.e. they may be normal. A confidence interval of 94,7% was found, which confirms the power of statistical tests for the samples considering the losses, and justifies the use of data collected in the 22-month evaluation.

Numbers analyzed

All sample losses were taken out of the calculation for all periods on the Friedman test (G1 n = 5; G2 n = 10; G3 n = 8). The ANOVA test, however, allowed inclusion of data collected for every patient present in each period.

Quantitative color evaluation with spectrophotometer

Color change (ΔE) between initial measurement (baseline) and the different time periods (14 days, 3 months, 6 months and 22 months) was examined for each of the groups (G1, G2, and G3) and compared. Comparison between groups was performed through ANOVA test using the design in repeated measurements, and between evaluation periods (intra-groups) through non-parametric Friedman test.

Comparison between groups

The mean values of Δ E for the different bleaching techniques at the different periods are shown in Table 2.

	Comparison (Δ E)	**Mean**	***P***
14 days	G1	7,48	0,240
	G2	8,88	
	G3	8,83	
3 months	G1	7,72	0,469
	G2	9,00	
	G3	8,40	
6 months	G1	9,53	0,760
	G2	9,19	
	G3	8,52	
22 months	G1	9,60	0,441
	G2	10,53	
	G3	8,58	

Table 2 - Comparison of the groups regarding color change / Δ E (14 days, 3 months, 6 months and 22 months after the end of treatment).

Through the results of the ANOVA test, it was found that there is no significant statistical difference among the three techniques in terms of color change (ΔE), for all periods analyzed (p <0.05).

Comparison between evaluation periods (Intra-groups)

The results of color change after treatment with three different techniques were also assessed intra-groups, to evaluate color stability throughout time for all periods analyzed, as shown in Table 3.

Comparison (Δ E)	Mean	Std. Deviation	*P*
G1			
14 days	7,43	3,82	0,656
3 months	6,80	3,52	
6 months	7,95	3,30	
22 months	8,95	5,72	
G2			
14 days	8,82	1,93	0,352
3 months	9,20	2,44	
6 months	9,23	2,43	
22 months	10,25	2,82	
G3			
14 days	8,64	1,86	0,319
3 months	8,02	2,03	
6 months	8,97	1,64	
22 months	8,94	1,47	

Table 3 – Intra-group comparison of color change throughout time, from immediately after finishing treatment (supposed to be brightest tooth color) to 22 months after treatment. Evaluation of color stability after treatment.

Through the results of Friedman's non-parametric test, there is no significant statistical difference between the times of evaluation for each whitening technique studied. It appears, therefore, that the degree of whitening obtained in the three bleaching techniques was maintained over the 22-month evaluation.

Tooth sensitivity analysis

Tooth sensitivity was assessed by asking the patients to respond to a visual scale ranging from 0 to 5, in which 0 was related to no sensitivity at all and 5 to intolerable tooth sensitivity. In the period of 22 months after treatment, all patients reported 0 sensitivity on the scale.

Regarding gingival sensitivity, 95,8% of patients who participated in Group 1 (strips) and Group 2 (strips and in-office) felt necessary to report gum irritation during treatment, which was resolved on its own before treatment completion.

Patient satisfaction analysis

Table 4 presents the percentage of satisfied and unsatisfied patients.

Were you pleased with the results of color change from your treatment?		
Group	YES	NO
G1	10%	90%

G2	100%	0%
G3	90%	10%

Table 4 – Percentage of answers to Yes or No survey regarding patient satisfaction after treatment.

As shown in Table 4, the highest satisfaction rate was found in Group 2, in which the two bleaching techniques (strips and in-office) were associated, followed by Group 3, in which in-office technique was used on its own. Group 1, which corresponded to whitening strips technique, achieved a very low degree of satisfaction, of only 10% of treated patients.

DISCUSSION

The scientific literature in recent years has been trying to understand the effectiveness of bleaching treatments, by testing and evaluating different products and techniques according to a previously defined clinical protocol.[27] Several whitening products reach the market every year, so it's up to our professional skills to offer patients the techniques and knowledge to achieve their aesthetic goals in a safe, healthy way. This responsibility makes scientific research of these products increasingly important.[28]

Hydrogen peroxide at 38% has been widely used in dentistry for many years, mainly because it produces visible results after a single application. However, to obtain better results with this technique, multiple sessions are necessary to increase the amount of time that tooth structure is in contact with the gel.[18]

This study did not use any auxiliary light source, as several recent studies have shown, through clinical evaluations, that the use of such sources does not promote better results for enhanced whitening.[26,29] Studies also point out that the heat and activation by light sources can cause increased intrapulpal temperature, with consequent inflammation of the pulp tissue, therefore generating greater dental hypersensitivity than found in bleaching protocols without the use of these light sources.[30]

Also in reference to pulp damage, studies have found that 35% hydrogen peroxide as a bleaching agent can cause a discrete pulp inflammation, however, perfectly reversible.[31] This inflammation may be responsible for dental hypersensitivity, the most common side effect found during bleaching, which in most cases is temporary and disappears after one or two days of starting treatment.[32]

From the past decades, a new home whitening technique based on low concentrations of hydrogen peroxide has come to the market. This technique uses flexible polyethylene strips loaded with hydrogen peroxide gel and aimed at improving the ease of use and access to dental whitening. This whitening technique eliminates molding needs, laboratory steps, and tray settings for maintenance during the bleaching process.[32-34]

Several studies have been conducted since the emergence of bleaching strips to assess their effectiveness, however, due to the variety of hydrogen peroxide concentrations[20] and the different durations of utilization, it is difficult to compare these different studies.[17]

Gingival irritation appears as the most common adverse effect related to the use of whitening strips, according to recent studies. In the present study, this was proved true since almost every patient presented with symptoms during treatment, which disappeared on their own before the end of treatment on every case.

Tooth sensitivity, on the other hand, is considered low, probably due to the short duration of contact with the teeth, which was also found in the present study, in which the patients reported little or no sensitivity. The treatment is usually well tolerated, with side

effects confined to symptoms of mild and transient nature, and which disappear after the completion of treatment. [17,33,35] This was also found in this study since no participants had to be removed from the study for hypersensitivity. All cases of reported sensitivity regressed to close to zero on the visual scale 14 days after completion of treatment, and continued regressing within 3 months. By 6 months, no patient had gingival irritation or tooth hypersensitivity, results that persisted through 22 months after whitening treatment.

It is important to highlight that studies demonstrate the use of whitening strips should always occur under professional supervision and orientation, as any other whitening technique. According to Goldstein, the increase of whitening techniques designed to be used with little or no professional supervision should be further discussed. Dentistry should maintain control of research and treatments, for there to be maximum patient protection and success rates.[36]

Tooth color evaluation in this study was performed with the spectrophotometer. This equipment has been widely used to evaluate post-bleaching tooth color. It consists on a more practical and objective method, that is quantitative and statistically more reliable than visual evaluation being, therefore, the instrument of choice for several professionals.[37] Studies show that examiners often have difficulty identifying exact colors or colors that are immediately adjacent to others in the Vita Classic shade guide.[38] Therefore, based on the literature, it is clear that evaluation of color with the spectrophotometer is more accurate and reproducible than plain visual evaluation.[39] This method has been used in numerous studies for quantitative longitudinal assessment of color variation after bleaching treatment.[38,40,41]

The present study, by analyzing the values obtained with the spectrophotometer, shows no significant statistical difference between the three techniques for all periods. The results suggest that tooth whitening will be presented in a statistically equal form, regardless of which technique is chosen.

Although color differences were not observed from the color assessment with the spectrophotometer in the groups of this study, they were perceived by the patients. The group that showed the highest satisfaction with treatment was the one on which the hybrid technique was performed, blending the use of whitening strips with in-office bleaching technique, followed by the group that only received the in-office bleaching technique. The group that only received the whitening strips achieved the lowest degree of satisfaction, of only 10%. These degrees of satisfaction, interestingly, correspond to the sample losses that occurred in this study. It is possible to observe that patients who received the hybrid technique, the most satisfied, were also the most motivated to carry on with the study through the period of 22 months. On the other hand, the least satisfied patients had the highest level of desistance, three of them excluded from the study for undergoing new bleaching treatments during the evaluation period.

A few studies were compared regarding the outcomes of bleaching strips and, despite having different concentrations, number of sessions, and time intervals of application, a comparison with the results of the present study was possible since ΔE is proportional to these variables. It can be observed, therefore, that color change is related to the longer period of contact with the tooth surface. The results were lower in studies where the overall and/or daily application duration of treatment were lower, reinforcing the idea that longer treatment may indicate a better clinical response. However, the concentration of the whitening gel also played a role in color change, as the results of this study were higher than when compared to studies that used bleaching strips based on hydrogen peroxide at 6 and 9.5 % .[33-35]

Regarding in-office whitening, this study used hydrogen peroxide at a concentration of 38% for 40 uninterrupted minutes. Recent studies show that when two hydrogen peroxide concentrations are compared (35% and 38%), the results obtained are similar. This suggests that the duration of contact between whitening gel and tooth surface has more effect on tooth whitening than gel concentration.[42] With respect to the duration of contact of the bleaching gel with the tooth, the default is around 45 minutes per consultation, having the gel replaced completely every 15 minutes, and performing two to three bleaching sessions. However, no data in the literature consolidates this protocol. The decomposition of the bleaching agent over time is minimal and presents no statistical difference, which suggests that bleaching agents continue to be active after 15 minutes and allows the indication of maintaining the gel for longer periods during in-office bleaching sessions.[43]

Regarding longevity of the whitening treatment, color stability was observed in the present study after 22 months for all three groups. In another clinical study that evaluated bleaching effect over time, a discreet relapse to the original tooth color was observed after two years.[44] A recent study evaluating color change has shown that there is an after-treatment color recurrence of 45-52% regarding ΔE, for in-office bleaching. However, for the home whitening technique using bleaching strips, the study has shown a relapse of only 1-4% over time.[45]

A study has found an average color maintenance of 43%, 10 years after the end of treatment when at-home bleaching was used. This supports the idea that satisfactory results can be obtained when associating in-office bleaching with at-home whitening techniques.[46] Studies have shown that a significant increase in whitening effect can be achieved with the combination of in-office bleaching and the conventional at-home technique.[47] In the present study this advantage was not statistically proven, which could be due to the fact that home bleaching was carried out with bleaching strips.

Based on the results of this study, it was concluded that: a) the bleaching techniques were equally effective regarding color change; b) no significant color regression was observed for the studied groups within 22 months after treatment, which suggests there was color stability after treatment for this period; c) in the period of 6 months after treatment no patient reported lasting tooth sensitivity, which was maintained on the 22-month evaluation; d) the participants who received the in-office technique reported higher levels of satisfaction when compared to those who did not.

Further longitudinal studies are needed to evaluate the potential and limitations of bleaching strips. Moreover, it can be suggested that tooth bleaching, despite being a widely studied and consolidated technique, is still the subject of many questions as there are various techniques and products currently available. The individual characteristics of each patient should always be taken into consideration in order to better define the clinical protocol and bleaching agent and obtain the best results.

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4 CONSIDERAÇÕES FINAIS

Com base no presente estudo, foi possível concluir que:

a) As técnicas clareadoras foram igualmente eficazes em relação à alteração de cor;

b) Não houve recidiva da cor estatisticamente significativa para os grupos estudados ao longo dos 22 meses de avaliação, o que sugere que houve estabilidade de cor após o tratamento para este período;

c) No período de 6 meses após o tratamento clareador não ocorreu sensibilidade dental, o que se manteve até a avaliação de 22 meses;

d) Os pacientes que receberam o clareamento dental através da técnica de Clareamento de consultório relataram alto grau de satisfação quando comparados aos que não receberam.

Conclui-se, a partir destes resultados, que são necessários mais estudos longitudinais que avaliem o potencial e as limitações das tiras clareadoras. Além disso, pode-se sugerir que o clareamento dental, apesar de ser uma técnica bastante estudada e consolidada, ainda é alvo de muitas dúvidas visto que existem diversas técnicas e produtos disponíveis atualmente. As características individuais de cada paciente, para que se defina o melhor protocolo clínico e agente clareador, devem sempre ser levadas em consideração para que se obtenham os melhores resultados com maior segurança.

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APÊNDICE A – TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO PARA PARTICIPAÇÃO EM PESQUISA CIENTÍFICA (TCLE)

O projeto **ENSAIO CLÍNICO RANDOMIZADO COMPARANDO TRÊS DIFERENTES TÉCNICAS DE CLAREAMENTO DE DENTES VITAIS,** será um estudo realizado na Faculdade de Odontologia da UFRGS, sendo uma pesquisa sem fins lucrativos para os profissionais e que não oferecerá bonificação e/ou remuneração aos indivíduos que concordarem em participar do estudo.

OBJETIVOS DA PESQUISA :

1. Comparar o clareamento dental realizado com 3 diferentes técinicas: caseiro com tiras clareadoras, caseiro noturno com moldeira individual e clareamento de consultório.
2. Avaliar o grau de sensibilidade dental ocasionado ou não pelas técnicas de clareamento realizadas neste estudo.

Você está sendo selecionado (a) para essa pesquisa por apresentar dentes anteriores e superiores com coloração amarelada e por ter o desejo de obter dentes mais claros através do clareamento dental supervisionado.

Será realizada uma consulta clínica onde serão realizadas avaliação da cor dos seus dentes, fotografias, instruções para a utilização do clareador. Após essa consulta os participantes do estudo serão divididos em 3 grupos: O grupo 1 fará uso das tiras clareadoras durante 30 minutos, por 10 dias nos dentes superiores e inferiores; O grupo 2 realizará 2 consultas de 40 minutos cada de clareamento de consultório nos dentes superiores e inferiores; o Grupo 3 fará clareamento caseiro noturno com uso de moldeiras individuais nos dentes superiores e inferiores durante 2 semanas. Dessa forma, será permitida a comparação entre as 3 técnicas de clareamento dental, levando em consideração as características pessoais de cada paciente.

Após o término do tratamento, serão realizadas consultas de controle após 14 dias, 3 meses, 6 meses e 22 meses. Nas avaliações serão medidas, além da cor dental, a sensibilidade dentária .

Os riscos e características desse procedimento são os mesmos de qualquer tratamento de clareamento dental convencional, ou seja, não há nenhum risco adicional ou diferente das técnicas tradicionais. Em contrapartida, como benefício, você estará recebendo o clareamento

dos seus dentes realizado sob cuidadoso protocolo técnico, o qual será observado ao longo do tempo.

Efeitos Adversos: A sensibilidade nos dentes é um efeito colateral possível de acontecer neste tipo de tratamento, que normalmente desaparece em poucos dias. Caso você tenha sensibilidade nos dentes após ou durante o clareamento será disponibilizado o devido tratamento para alívio do desconforto durante todo o acompanhamento de 1 ano (período de acompanhamento da pesquisa) independente do grau de intensidade.

Pelo presente consentimento informado, declaro que fui esclarecido de forma clara e detalhada, livre de qualquer forma de constrangimento, dos objetivos dos procedimentos a que serei submetido pelo presente projeto de pesquisa.

Fui igualmente informado:

- Da garantia de receber resposta a qualquer pergunta ou esclarecimento, a qualquer dúvida a respeito dos procedimentos, riscos e benefícios relacionados com a pesquisa;

- Da segurança de que não serei identificado e que se manterá o caráter confidencial das informações relacionadas com a minha privacidade;

- Da possibilidade de abandonar o estudo a qualquer momento, sem que isso traga prejuízo aos meus dentes.

A Pesquisadora Responsável por este Projeto de Pesquisa é a Profa. Dra. Andréa Brito Conceição, que encontra-se disponível para contato e qualquer esclarecimento pelo telefone: (51) 3308.5202/ 9175.9133. O Comitê de Ética e Pesquisa da UFRGS se disponibiliza no telefone: (51) 3308 3629.

Data____/_____/_____Nome_____

Assinatura do voluntário:_____

Assinatura do Pesquisador Responsável:_____

Observação: O presente documento, baseado no item IV das Diretrizes e Normas Regulamentadoras para Pesquisa em Saúde, do Conselho Nacional de Saúde (Resolução 466/12), será assinado em duas vias, de igual teor, ficando uma em poder do paciente e outra do pesquisador responsável.

APÊNDICE B – FICHA DE AVALIAÇÃO CLÍNICA DE COR

FICHA DE AVALIAÇÃO DE COR SUPERIOR

C		Avaliação Indireta (Espectrofotometro)			
AVALIAÇÃO Nº __ Data:		Medição 1	Medição 2	Medição 3	**Média**
13	L				
	a				
	b				
12	L				
	a				
	b				
11	L				
	a				
	b				
21	L				
	a				
	b				
22	L				
	a				
	b				
23	L				
	a				
	b				

FICHA DE AVALIAÇÃO DE COR INFERIOR

Paciente:		Avaliação Indireta (Espectrofotômetro)			
AVALIAÇÃO Nº __ Data:		Medição 1	Medição 2	Medição 3	Média
33	L				
	a				
	b				
43	L				
	a				
	b				

APÊNCIDE C – ESCALA DE AVALIAÇÃO VISUAL DA SENSIBILIDADE – GRUPO CONSULTÓRIO

ESCALA VISUAL

0----------1----------2----------3----------4----------5

Onde:

0: nenhuma sensibilidade
1: leve sensibilidade
2: moderada sensibilidade
3: considerável sensibilidade
4: severa sensibilidade
5: sensibilidade intolerável

* Colocar o número correspondente ao grau de sensibilidade referida pelo paciente em determinado arco.

APÊNDICE D – ESCALA DE AVALIAÇÃO VISUAL DA SENSIBILIDADE – GRUPO CASEIRO/TIRAS

PESQUISA CLAREAMENTO CASEIRO - TIRAS

MARCAR com um X referente ao grau de sensibilidade após a utilização do clareador, sendo 0 sem sensibilidade, 1 Muito leve, 2 Leve, 3 Moderada, 4 Forte e 5 Intolerável, diariamente. S = dentes superiores e I = dentes inferiores.

NOME:_____

GRUPO:_____

Dor / Dia		0	1	2	3	4	5
1	S						
	I						
2	S						
	I						
3	S						
	I						
4	S						
	I						
5	S						
	I						
6	S						
	I						
7	S						
	I						
8	S						
	I						
9	S						
	I						
10	S						
	I						