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JOSUÉ JUNIOR ARAUJO PIEROTE

**Efeitos de dentifrícios dessensibilizantes na redução da
sensibilidade dolorosa causada por clareamento dental em
consultório: estudo clínico duplo cego controlado**

**Effects of desensitizing dentifrices on the reduction of pain
sensitivity caused by in-office dental whitening: double blind
controlled clinical study**

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Effects of desensitizing dentifrices on the reduction of pain sensitivity caused by in-office dental whitening: double blind controlled clinical study

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Orientador: Prof. Dr. Luis Alexandre Maffei Sartini Paulillo

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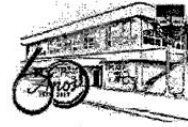
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A Ata da defesa com as respectivas assinaturas dos membros encontra-se no processo de vida acadêmica do aluno.

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RESUMO

Introdução: A sensibilidade dolorosa associada ao clareamento dental é o principal problema relatado pelos pacientes durante esse tratamento, sendo a utilização de dentifrícios dessensibilizantes uma alternativa para o tratamento da sensibilidade. **Objetivo:** Avaliar clinicamente os efeitos de dentifrícios dessensibilizantes, aplicados através de moldeira plástica, na redução da sensibilidade dolorosa e variação de cor causadas pela técnica de clareamento dental em consultório, por meio de estudo clínico duplo cego controlado. **Metodologia:** Realizou-se um estudo longitudinal prospectivo com 48 indivíduos, entre 18 e 30 anos de idade, sem distinção de gênero, os quais foram submetidos ao clareamento dental em consultório utilizando peróxido de hidrogênio a 35% em três sessões clínicas com intervalo de uma semana entre as mesmas. Os voluntários utilizaram na noite referente a cada sessão de clareamento uma moldeira plástica por 4 horas contendo um dos dentifrícios relativos aos grupos experimentais: Grupo 1 (Controle) – Sucralose (S); Grupo 2 (Controle ativo) – Fluoreto de Sódio (FS) com 1450ppm de Flúor; Grupo 3 – Arginina e Carbonato de Cálcio (ACC) e Monofluorofosfato de Sódio com 1450 ppm de Flúor; Grupo 4 – Nitrato de Potássio (NP) a 5% e Fluoreto de Sódio com 1450 ppm de Flúor. A avaliação da sensibilidade associada aos tempos de utilização da moldeira plástica na primeira sessão (S1: sensibilidade antes da moldeira; S2: sensibilidade depois da moldeira), na segunda sessão (S3: sensibilidade antes da moldeira; S4: sensibilidade depois da moldeira) e na terceira sessão (S5: sensibilidade antes da moldeira; S6: sensibilidade depois da moldeira) utilizou a escala numérica analógica com escores de 0 a 10. A variação de cor (ΔE) utilizou o espectrofotômetro para obtenção dos dados (L, a, b) que foram utilizados no sistema CIELab. Os dados de sensibilidade dolorosa foram submetidos ao teste de análise de variância multifatorial (MANOVA) com medidas repetidas e Teste de Lambda Wilks ($p < 0.05$). Para a análise da variação de cor o teste ANOVA em um critério foi aplicado ($p < 0.05$). **Resultados:** Os grupos ACC e NP 5% apresentaram redução da sensibilidade em relação aos demais grupos ($p < 0,05$). A relação da sensibilidade e tempo associados as três sessões de clareamento, mostrou que houve uma redução da sensibilidade após

a colocação da moldeira com dentifrício (S2; S4; S6). A avaliação de cor associada ao fator dentifrício mostrou que não houve diferença entre os grupos experimentais após o tratamento clareador ($p=0,9186$). **Conclusão:** A utilização de dentifrício dessensibilizante ACC ou NP a 5% em moldeira plástica foi eficiente para a redução da sensibilidade dolorosa causada por clareamento dental em consultório, e ainda, o uso de dentifrício dessensibilizante não diminuiu a eficiência do tratamento clareador.

Palavras-chave: Clareamento dental. Dentifrício. Sensibilidade.

ABSTRACT

Introduction: The pain sensitivity associated with tooth whitening is the main problem reported by patients during tooth whitening and the use of desensitizing dentifrices presents an alternative for the treatment of sensitivity. **Objective:** To clinically evaluate the influence of desensitizing dentifrices applied through a plastic tray, reducing the pain sensitivity and color variation caused by the technique of in-office dental whitening, through a controlled double-blind clinical study. **Methods:** A longitudinal prospective study was conducted with 48 individuals no gender distinction with ages ranging from 18 to 30 who underwent in-office dental whitening using 35% hydrogen peroxide in three clinical sessions with a one-week interval between them. In the night after each whitening session the volunteers have used for 4 hours a plastic tray containing one of the dentifrices related to the experimental groups: Group 1 (Control) - Sucralose (S) (B; Group 2 (Active Control) - Sodium Fluoride (SF) with 1450ppm of fluoride; Group 3 – Arginine and Calcium Carbonate (ACC) and Sodium Monofluorophosphate with 1450 ppm fluoride; Group 4 - 5% Potassium Nitrate (PN) and Sodium Fluoride with 1450 ppm fluoride. The evaluation of the sensitivity associated with the use of the plastic tray in the first session (S1: sensitivity before the tray, S2: sensitivity after the tray), in the second session (S3: sensitivity before the tray, S4: sensitivity after the tray) in the third session (S5: sensitivity before the tray, S6: sensitivity after the tray) has used the analog numerical scale with scores from 0 to 10. The color variation (ΔE) was performed with the spectrophotometer and the data (L, a, b) that were used in the CIE Lab system. The data to pain sensitivity were submitted to the multivariate analysis of variance (MANOVA) with repeated measurements and a Lambda Wilks test ($p < 0.05$). To analysed the color variation one-way ANOVA was applied ($p < 0.05$). **Results:** The ACC and 5% PN groups showed a reduction in sensitivity in relation to the other groups ($p < 0.05$). The relation of sensitivity and time associated with the three whitening sessions showed that there was a reduction in sensitivity after placement of the tray with dentifrice (S2, S4, S6). The color evaluation associated with the dentifrice factor showed that there was no difference between the experimental groups ($p = 0.9186$). **Conclusion:** The use of desensitizing

dentifrices based on ACC or 5% PN in a plastic tray was efficient for the reduction of the pain sensitivity caused by in-office dental whitening. In addition, the use of desensitizing dentifrice did not decrease the efficiency of whitening.

Keywords: Tooth whitening. Dentifrice. Sensitivity.

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INTRODUÇÃO

O sorriso é um dos importantes fatores de interação social. Por esse motivo há um aumento na demanda de pacientes em busca de tratamentos dentais estéticos (Abouassi *et al.*, 2011; Joiner, 2006), e uma grande preocupação dos pacientes está relacionada com a cor dos dentes (Abouassi *et al.*, 2011; He *et al.*, 2012).

Os dentes podem apresentar alteração de cor devido a causas intrínsecas ou extrínsecas (Goldberg *et al.*, 2010). O escurecimento intrínseco é causado por doenças genéticas, patologias fetais ou adquiridas pós-natal (Goldberg *et al.*, 2010). Já os pigmentos extrínsecos estão associados com o acúmulo de pigmentos sobre a superfície do esmalte causada pelo consumo de café, chá e vinho (Reis *et al.*, 2011). Assim, cabe ao cirurgião-dentista avaliar cada caso, para identificar a causa da alteração de cor e recomendar o melhor tipo de tratamento com prognóstico previsível (Reis *et al.*, 2011).

O clareamento dental é comprovadamente um tratamento conservador para remoção dos pigmentos dentais quando comparado às restaurações diretas ou indiretas (Abouassi *et al.*, 2011; Basting *et al.*, 2012; Tay *et al.*, 2009). Trata-se de um tratamento antigo que se iniciou com o clareamento de dentes não vitais, descrito na literatura em 1848 (Alqahtani, 2014). Em 1864 foi introduzido um método mais eficaz para esse tipo de tratamento, em que se usava uma solução de hipoclorito de cálcio e ácido acético, que futuramente foi denominada de solução de Labarraque (Alqahtani, 2014). O clareamento de dentes vitais iniciou-se logo depois, em 1868, com a utilização de diferentes tipos de ácidos, e, em 1911 foi introduzido o peróxido de hidrogênio como agente clareador, sendo utilizado até os dias de hoje (Alqahtani, 2014).

Para o clareamento de dentes vitais existem três abordagens. O clareamento em consultório, em que se utiliza altas concentrações do agente ativo entre, 30 a 40% de peróxido de hidrogênio ou 35 a 37% de peróxido de carbamida. Neste tipo de tratamento o cirurgião-dentista tem completo controle sobre a técnica clínica, podendo interrompe-la quando julgar necessário e o resultado é mais rápido, sendo perceptível após a primeira sessão de tratamento (Alqahtani, 2014; Armênio *et al.*, 2008; Basting *et al.*, 2012; He *et al.*, 2012).

A segunda abordagem é denominada clareamento caseiro, a qual é supervisionada pelo cirurgião-dentista e foi relatada pela primeira vez no início da década de 1960, porém apenas em 1989 foram desenvolvidos produtos específicos (Alqahtani, 2014). Nesta técnica são utilizadas concentrações mais baixas do peróxido de hidrogênio, entre 3,6 e 10%, ou de seu precursor, o peróxido de carbamida, entre 10 e 22%, necessitando de períodos mais prolongados de aplicação, de 1 a 8 horas por dia, por no mínimo 2 semanas (Alqahtani, 2014; Armênio *et al.*, 2008; Haywood *et al.*, 1990).

A terceira abordagem de clareamento de dentes vitais é a denominada “over-the-counter”. Nos anos de 1990 houve o desenvolvimento de produtos de baixa concentração de peróxido de hidrogênio, 3 a 6%, para livre comercialização. São produtos aplicados pelo próprio paciente através de dentifrícios, tiras adesivas ou enxaguatórios bucais, sem acompanhamento profissional (Alqahtani, 2014).

Independente do tipo de tratamento clareador utilizado, o mecanismo de ação é o mesmo. O gel contém como componente ativo o peróxido de hidrogênio, ou seu precursor, o peróxido de carbamida, em diferentes concentrações (Abouassi *et al.*, 2011; Alqahtani, 2014). O peróxido de hidrogênio é um agente oxidante capaz de se difundir pelo esmalte dental e se dissociar em radicais livres instáveis, peridroxil, hidroxila e oxigênio que reagem com as moléculas dos pigmentos orgânicos. Essa reação leva à quebra das ligações duplas de carbono resultando em moléculas menores que promovem uma mudança no espectro de absorção da luz, não interferindo na sua reflexão, acontecendo assim o clareamento do dente (Alqahtani, 2014).

O efeito oxidante do peróxido de hidrogênio não é específico, pois além de reagir com os pigmentos, também pode reagir com a matriz orgânica do dente (Abouassi *et al.*, 2011; Browning *et al.*, 2012). Essa alteração morfológica da estrutura dental causada pelo agente clareador não está sedimentada na literatura. Acredita-se que o pH do gel clareador seja mais nocivo à estrutura dental do que o próprio peróxido de hidrogênio (Abouassi *et al.*, 2011), porque os radicais livres produzidos pelo peróxido de hidrogênio são os mesmos que o nosso organismo produz durante o metabolismo celular (Coldebella *et al.*, 2009). A principal sequela da ação do agente ativo do clareamento é o aumento da rugosidade de superfície do esmalte que ocorre durante a primeira hora de clareamento sendo que alguns

autores sugerem que esta rugosidade não pode ser percebida após 6 horas do término do tratamento (Abouassi *et al.*, 2011; Sulieman *et al.*, 2004). No entanto, Faraoni-Romano *et al.* (2009) encontraram alterações no esmalte em até 15 dias após o término do clareamento.

A alteração morfológica da estrutura dental, apesar de acontecer por um curto período de tempo, é considerada um dos efeitos adversos decorrentes do clareamento dental, porém não o único. Outro efeito adverso está relacionado com os tecidos moles, pois seu contato com o gel clareador promove queimaduras esbranquiçadas. Estas são transitórias, desde que o tempo de contato do gel com o tecido não seja prolongado, porém causam desconforto ao paciente (Alqahtani, 2014).

Entretanto, o principal efeito adverso da técnica de clareamento é a sensibilidade dental (Bonafe *et al.*, 2014; Haywood *et al.*, 1990; Kossatz *et al.*, 2011; Reis *et al.*, 2011), sendo relatada por pelo menos dois terços dos pacientes em algum momento do tratamento (Armênio *et al.*, 2008). A dor varia de leve a intolerável, podendo corresponder a 9,5% de abandono do tratamento no caso do clareamento caseiro e 4,3% em relação ao em consultório (Basting *et al.*, 2012). Esta sensibilidade dolorosa pode estar relacionada a técnica utilizada, ao tempo de aplicação e concentração do gel clareador, e ainda, a uma resposta individual de cada paciente (He *et al.*, 2012).

A etiologia dessa sensibilidade é complexa, porém acredita-se que esteja relacionada à quantidade de radicais livres do peróxido de hidrogênio que chegam à polpa (Armênio *et al.*, 2008; Basting *et al.*, 2012; Camargo *et al.*, 2007; Costa *et al.*, 2010). O peróxido de hidrogênio aumenta a permeabilidade do esmalte possibilitando a difusão dos íons oxigênio através da dentina, que podem atingir a polpa (Basting *et al.*, 2012; Cooper *et al.*, 1992; Thitinthapan *et al.*, 1999). A sensibilidade resulta da ação dos mediadores inflamatórios, tais como a substância-P que é o neuropeptídeo responsável pela vasodilatação e aumento do fluxo sanguíneo pulpar, que permite a chegada das células inflamatórias ao local (Caviedes-bucheli *et al.*, 2008), levando a uma reação inflamatória transitória que promove a dor (Bonafe *et al.*, 2014; Caviedes-bucheli *et al.*, 2008; Markowitz, 2010). Este processo ocorre quando há níveis insuficientes de antioxidantes (peroxidases,

oxigenases e catalases) ou então essas são incapazes de remover adequadamente os radicais livres (Bonafe *et al.*, 2014; Cercarini *et al.*, 2007; Costa *et al.*, 2010).

Algumas técnicas clínicas podem ser utilizadas visando a eliminação desses efeitos adversos, entre estas estão a diminuição da concentração de peróxido de hidrogênio, diminuição no tempo e frequência de aplicação do gel clareador (Armênio *et al.*, 2008; Basting *et al.*, 2012), administração de analgésicos/antiinflamatórios (Charakorn *et al.*, 2009) e a utilização de produtos dessensibilizantes (Bonafe *et al.*, 2014; Browning *et al.*, 2012; Cerqueira *et al.*, 2013; Tay *et al.*, 2009), como dentifrícios (Armênio *et al.*, 2008; Basting *et al.*, 2012; Haywood *et al.*, 2001).

Os dentifrícios dessensibilizantes utilizam dois mecanismos de ação. Podem agir obliterando os canalículos da dentina, e assim impedir a movimentação dos fluidos dentinários e, ainda auxiliar na remineralização da dentina (Basting *et al.*, 2012; Bonafe *et al.*, 2014), sendo os produtos à base de fluoreto, arginina e carbonato de cálcio exemplos desta classe de material.

O Fluoreto de sódio (FS) e a Arginina e Carbonato de Cálcio (ACC) atuam obliterando os canalículos da dentina e impedindo assim o movimento dos fluidos dentinários e, ainda, auxiliando na remineralização da dentina. (Basting *et al.*, 2012; Bonafe *et al.*, 2014). Além disso, a combinação de Arginina e Carbonato de cálcio é capaz de ser depositada sobre superfícies de dentina exposta para bloquear fisicamente e selar os túbulos dentinários expostos (Basting *et al.*, 2012; Bonafe *et al.*, 2014).

O segundo modo de ação é o bloqueio da atividade nervosa da polpa, através da diminuição da excitabilidade sensorial dos nociceptores. O nitrato de potássio atua diminuindo a capacidade de repolarização das fibras nervosas presentes na polpa dental, após sofrerem despolarização devido ao impulso de dor. (Basting *et al.*, 2012; Bonafe *et al.*, 2014).

O nitrato de potássio difunde através do esmalte e dentina até as terminações nervosas das fibras sensoriais, reduzindo a excitabilidade das fibras nervosas, inibindo o movimento dos íons sódio e potássio ao redor das fibras sensoriais, resultando na modulação ou supressão da sensação de dor (Basting *et al.*, 2012; Bonafe *et al.*, 2014).

No entanto, durante a higiene bucal os dentifrícios dessensibilizantes permanecem por pouco tempo em contato com os dentes, o que pode não ser suficiente para se eliminar ou reduzir a sensibilidade dolorosa causada pela técnica do clareamento dental em consultório, com isso torna-se necessário a utilização de métodos que complementem a escovação com dentifrícios dessensibilizantes. (Loguercio *et al*, 2013; Tay *et al*, 2009). Devido a isto, a utilização de dentifrícios dessensibilizantes em moldeira plástica pode ser uma alternativa viável para reduzir a sensibilidade dolorosa causada pelo clareamento dental.

Essa técnica apresenta como vantagens a simplicidade da confecção da moldeira pelo cirurgião-dentista, o baixo custo da moldeira e do dentifrício, a facilidade de utilização pelo paciente e a possibilidade de utilizar a mesma moldeira do tratamento clareador caseiro (Loguercio *et al*, 2013; Tay *et al*, 2009).

Dessa forma o objetivo deste estudo foi avaliar, clinicamente, os efeitos de dentifrícios dessensibilizantes aplicados através de moldeira plástica, na redução da sensibilidade dolorosa e variação de cor causadas pela técnica de clareamento dental em consultório, por meio de estudo clínico duplo cego controlado.

Capítulo 1

Effects of desensitizing dentifrices on the reduction of pain sensitivity caused by in-office dental whitening: a double-blind controlled clinical study

Abstract: The purpose of this study was to evaluate clinically the influence of desensitizing dentifrices applied through a plastic tray, reducing the pain sensitivity and color variation caused by the technique of in-office dental whitening, through a controlled double-blind clinical study. A longitudinal prospective study was conducted with 48 individuals between 18 and 30 years and no gender who underwent whitening using 35% hydrogen peroxide in three clinical sessions. In the night after each whitening session the volunteers have used for 4 hours a plastic tray containing one of the dentifrices (Sucralose-S, Sodium Fluoride-SF, Arginine and Calcium Carbonate-ACC, and 5% Potassium Nitrate-PN). The evaluation of the sensitivity associated with the use of the plastic tray in each whitening session has used the analog numerical scale with scores from 0 to 10. The color variation (ΔE) was performed with the spectrophotometer. The data to pain sensitivity were submitted to the multivariate analysis of variance (MANOVA) with repeated measurements and a Lambda Wilks test ($p < 0.05$). To analysed the color variation one-way ANOVA was applied ($p < 0.05$). The ACC and 5% NP groups showed a reduction in sensitivity in relation to the other groups ($p < 0.05$). There was a reduction in sensitivity after placement of the tray with dentifrice. The color evaluation associated with the dentifrice showed no difference ($p = 0.9186$). The use of desensitizing dentifrices with ACC or 5% NP in a plastic tray was efficient for the reduction of the pain sensitivity and the use of desensitizing dentifrice did not decrease the efficiency of whitening.

Descriptors: Tooth whitening; Dentifrice; Sensitivity.

Introduction

The color of the teeth depends on their intrinsic and extrinsic coloration. Intrinsic staining is associated with light reflection and absorption by enamel and dentin. The main causes of intrinsic tooth darkening are aging, pulpal necrosis and use of drugs as tetracycline.¹ Furthermore, extrinsic darkening is associated with accumulation of stains on the enamel surface^{2,3} caused by consumption of coffee, tea, red wine, carrots, oranges and tobacco.^{3,4}

Vital whitening is a conservative and non-invasive alternative for aesthetic alteration of the smile when compared to other clinical techniques, e.g. enamel micro-abrasion, direct restorations, ceramic veneers and prosthetic crowns.^{1,5,6} Although dental whitening is a conservative technique, it has also shown a high success rate in the treatment of darkened tooth.^{7,8}

Gingival irritation and teeth sensitivity are the collateral effects most frequently reported during the whitening, although they are usually mild and transient.^{1,7-10} However, such collateral effects may be more intense and motivate the patients to give up the whitening.¹¹⁻¹³

Among the explanations for whitening related pain the Brännström's hydrodynamic theory is the most accepted. This theory suggests that dental sensitivity might be caused by fluid movement in the dentinal tubules.¹⁴ This movement would activate nociceptors and result in the perception of pain.¹ Moreover, the diffusion of hydrogen peroxide through the enamel and dentin reaching the pulp and the acidic pH of the whitening gel may cause transient painful sensitivity.^{5,12,15}

Some techniques can be used to eliminate such collateral effects. Among these there are the reduction of the concentration of hydrogen peroxide, administration of painkillers and anti-inflammatories, and use of desensitizers.^{7,11,17} However, such techniques are usually used in the dental office with no recommendations for the patient regarding what to do at home to minimize the effects of pain sensitivity during the posttreatment.^{7,11}

There are different dentifrices in the market for attenuating tooth sensitivity.¹⁸⁻²¹ In addition to this indication, such dentifrices may aid in reducing and / or eliminating the dental sensitivity caused by the whitening treatment. Thus, desensitizing dentifrices can be an option to reduce the adverse effects of whitening

agents¹⁷⁻¹⁹ because they decrease the excitability of nerve fibers present in the pulp and promote the obliteration of dentin tubules.²¹ The reduction of excitability in the nerve fibers occurs due to the diffusion of potassium salts through the enamel and dentin. The potassium salts reach the nerve endings and affect the transmission of the nerve impulse,^{11,18} reducing or eliminating the pain through the action of substances containing Potassium Nitrate (PN).²⁰ On the other hand, the occlusion of dentinal tubules reduces the permeability of the dentin and blocks the hydrodynamic mechanism by means of substances containing Sodium Fluoride (SF), Arginine and Calcium Carbonate (ACC).²⁰

However, during oral hygiene, the desensitizing dentifrices remain for a short time in contact with the tooth, which may not be enough to eliminate or reduce the pain sensitivity caused by the technique of in-office dental whitening. Thus, there is a need for methods that complement the toothbrushing with desensitizing dentifrices.^{7,11} Due to this, the use of desensitizing dentifrices in a plastic tray may be a new alternative to reduce the pain sensitivity caused by dental whitening.^{7,11}

The advantages of the technique of applying desensitizing dentifrices to a plastic tray are the ease of making the tray by the dentist, the low cost of both plastic tray and dentifrice, ease of use by the patient even at home, and the possibility of using the same plastic tray for at-home whitening and mixed technique.^{7,11}

The objective was to evaluate clinically the influence of desensitizing dentifrices applied through a plastic tray, reducing the pain sensitivity and color variation caused by the technique of in-office dental whitening, through a controlled double-blind clinical study. Our hypothesis was that the use of dentifrices associated with plastic tray due to the longer time of contact with the dental surface can reduce the dental sensitivity.

Methodology

This study was submitted and approved by the research ethics committee of the Piracicaba Dental School (FOP-UNICAMP) affiliated with the National Commission for Research Ethics of Brazil (CONEP) according to protocol number 104/2015. The Clinical Trials Register (ClinicalTrials) was obtained with the protocol number NCT03019224. All the volunteers signed a free informed consent form.

Clinical Trials was reported according to the CONSORT Statement standard protocol.

Tested materials

For the study of desensitizing dentifrices used in the plastic tray, four types of dentifrices were used (Table 1).

Table 1. Materials and composition used in study with desensitizing dentifrices applied in plastic tray.

Materials	Composition	Manufacturers
Control (C)	Sucralose (S)	Biotipo Pharmacy, Piracicaba, Brazil
Close Up Triple Action (CT)	Sodium Fluoride (SF) with 1450 ppm of Fluoride	Unilever, São Paulo, Brazil
Colgate Sensitive Pro-Relief (CS)	Arginine and Calcium Carbonate (ACC) associated with 1450 ppm of Sodium Monofluorophosphate	Colgate - Palmolive, São Paulo, Brazil
Sensodyne Pronamel (SP)	5% Potassium Nitrate (PN) associated with Sodium Fluoride with 1450 ppm of Fluoride	Glaxosmithkline Brasil Ltda., Rio de Janeiro, Brazil

Experimental design

This is a double-blind controlled study using volunteers (48) who were randomly divided into four groups. The dentifrice was studied at four levels that consisted of three experimental levels and one control level. The response variables were numerical analogue scale and color variation (ΔE).

Selection and preparation of the volunteers

Patients who sought the postgraduate dental clinic for whitening were invited to participate in the study. They were informed by the researcher (dentist) about all the aspects of the study, including that they might discontinue their participation at any moment of the treatment. In addition, it was clarified that their participation was voluntary and that refusal to participate would not result in any penalty or loss of benefits.

If they chose to participate in the study, they had to sign a free informed consent form before the clinical evaluation was started.

The criteria for selection and exclusion of the volunteers were as follows: (1) Inclusion criteria: age of 18 to 30 years, good oral and general health, hygid anterior tooth with color shade higher than A2 in the Vita Classic scale (VITA Zahnfabrink, Bad Säckingen, Germany). (2) Exclusion criteria: smoking, pregnancy or breastfeeding, previous dental whitening, parafunctional habits, dentin sensitivity, anterior tooth with restorations and carious lesions, non-vital discoloration and unsatisfactory restorations.

The general clinical evaluation of the volunteers was performed by asking them about their health conditions. Clinical mirror and probe were used for intraoral clinical examination and interproximal and periapical radiographs were taken for radiographic examination. From this evaluation, it was analysed whether the patients met the inclusion criteria set in the study, thus resulting in a sample of 48 volunteers.

The adequacy of the oral was performed by supra-gingival scaling of calculus with periodontal currettes and root planing with rubber cups at low rotation and water/pumice paste. Dental arches were molded with alginate (Hydrogum, Zhermack Clinical, Italy) to obtain a model (Herodent type III, Coltene, Rio de Janeiro, Brazil) for making the plastic tray, which was used in association with the dentifrices after the dental whitening sessions.

One week before starting the experiment, toothbrushes (Slim Soft, Colgate-Palmolive, São Paulo, Brazil) and standard dentifrice (Colgate Total 12, Colgate-Palmolive, São Paulo, Brazil) were given to each volunteer, which received guidelines on oral hygiene and recommendations to use only the dentifrice and toothbrush provided for oral hygiene until the start of the whitening sessions.

Clinical procedures

The evaluation of the tooth color was performed by using a spectrophotometer (Easyshade, Vident, Brea, CA, USA). The color was analysed with the tooth hydrated before of the start the first whitening session and one week after.

The spectrophotometer was always used in the same position by a silicon guide (Express XT, 3M ESPE, Sumaré, SP, Brazil) with opening was made in the guide to the buccal surface of the upper left central incisor, allowing the color of the tooth to be evaluated with the tip of the spectrophotometer at the height of the middle third.

The color was determined by an EasyShade spectrophotometer and the data (L, a, b) were used in the CIELab system for indicating the following value: (E). Color comparison was made before the first and after the last treatment sessions, resulting in a difference between both colors (ΔE)³.

The clinical procedures were performed under relative isolation using lip retractor (Arcflex, FGM, Joinville, SC, Brazil) and dental cotton rollers to apply a gingival protection barrier (Top Dam, FGM, Joinville, SC, Brazil) extending from right first molar to left first molar in both arches.

The gingival protection barrier was placed over the margins and gingival papilla corresponding to the areas receiving the whitening gel with approximately 3 mm in height and photopolymerized for 20 seconds in each group of three teeth. Photoactivation was performed with high power LEDs (light intensity = 600mw / cm²) (RadiiCal, São Paulo, SP, Brazil).

The desensitizing gel containing 5% Potassium Nitrate associated with 2% Sodium Fluoride (Desensibilize KF 2%, FGM, Joinville, SC, Brazil) was applied with a microbrush (Brush KG, KG Sorensen, Cotia, SP) on the buccal surface from right first molar to left first molar in both arches and remaining for 10 minutes.⁷ Then, the desensitizer was then removed with water jet and disposable plastic suction cannula.

The handling of 35% hydrogen peroxide (Whiteness HP, FGM, Joinville, SC, Brazil) followed the manufacturer's recommendations. The gel remained in contact with the buccal surface of the teeth for 15 minutes and was removed with disposable plastic suction cannula and water wash. This procedure was performed three times per clinical session. The volunteers underwent three whitening clinical sessions with a one-week interval between them.

During the clinical whitening sessions, each volunteer used an unidentified dentifrice corresponding to their experimental group, which was previously defined by means of a draw made by a dentist who did not participate in the study. Thus,

the researcher (dentist) who provided the dentifrice and the volunteer were not aware of which experimental group the latter belonged to (i.e. double blind).

After the first session, each volunteer received a plastic tray and instructions for using the dentifrice as described below: it should be placed in small quantities on the buccal side of the plastic tray at the region corresponding to right first molar to left first molar in both arches. So, the set was taken to the buccal cavity and pressed onto the buccal surface of the tooth until the contact of the dentifrice was established with the tooth structure. Excessive dentifrice should be removed with dental cotton rolls and the volunteers used the plastic tray with dentifrices during sleep (for 4 hours) in the same night that the whitening session was performed. In the next morning the patient washed and dried the plastic tray before storing it in the case. The volunteers received the guidelines for using the tray containing the specific dentifrice according to their experimental group only at the night of the whitening session. In addition, the volunteers should use the same dentifrice throughout the experiment.

For sensitivity analysis we have used the numerical analogue scale ⁷ with scores ranging from 0 to 10 in six moments: before the placement of the tray in the first whitening session (S1), after placement of the tray in the first whitening session (S2), before the placement of the tray in the second whitening session (S3), after placement of the tray in the second whitening session (S4), before the placement of the tray in the third whitening session (S5), after placement of the tray in the third whitening session (S6) in relation to the dentifrices Control (C), Close Up Triple Action (CT), Colgate Sensitive Pro-Relief (CS), Sensodyne Pronamel (SP) used in the plastic tray.

Statistical analysis

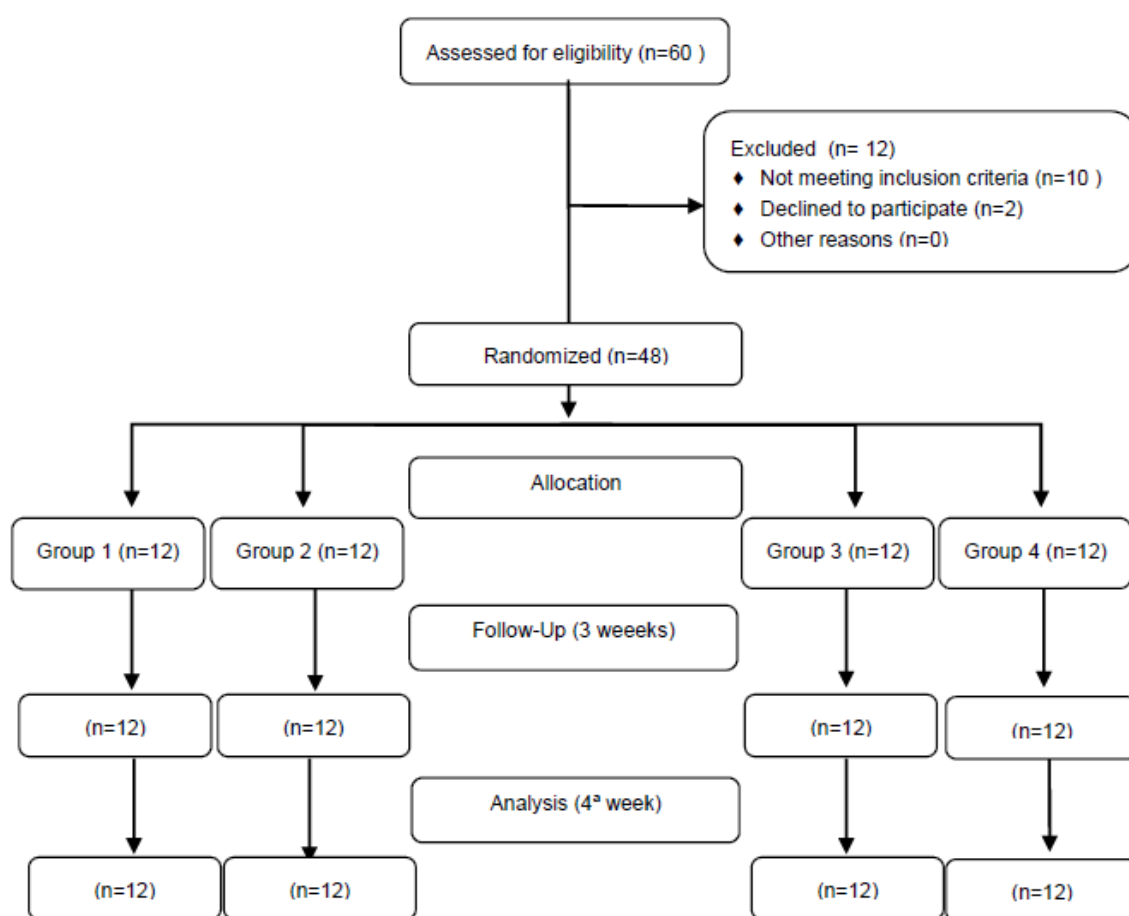
To sensitivity analysis the multivariate analysis of variance (MANOVA) test for repeated measurements and the Lambda Wilks test in a 5% probability level were used to evidence the differences between the studied groups (C, CT, CS and SP) in evaluation times (S1, S2, S3, S4, S5 and S6).

One-way ANOVA was applied for color variation (ΔE) in relation to the dentifrices C, CT, CS, SP used in the plastic tray.

Results

At the end of 4 weeks, 48 participants have completed the study and no participant interrupted participation (Figure 1).

Figure 1. The consort flow chart.

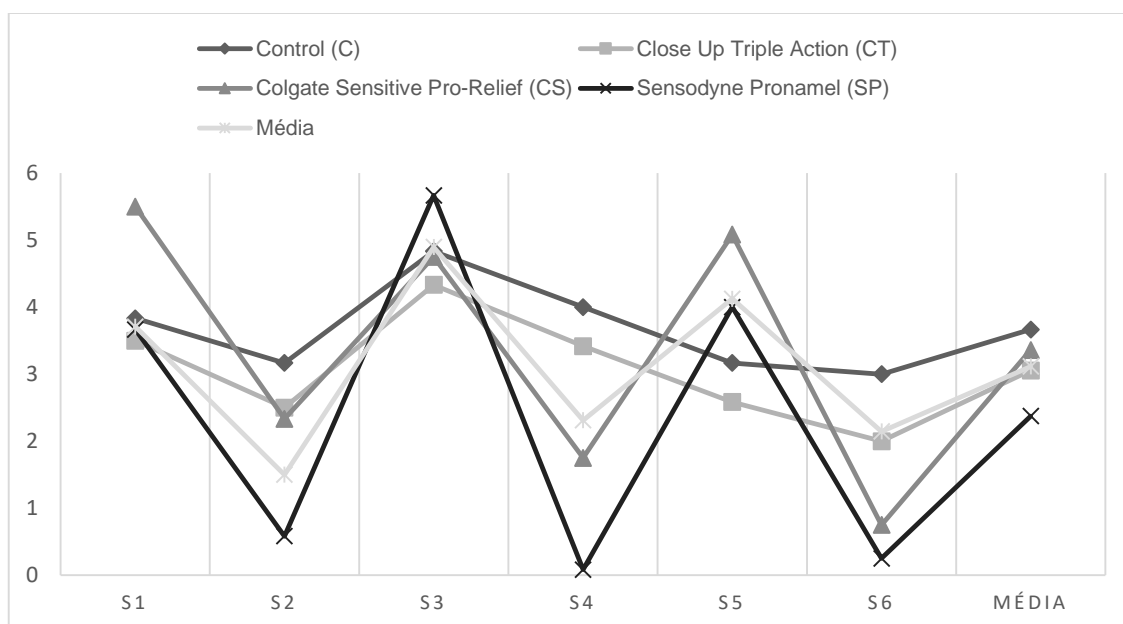


The groups were compared two by two and the result showed that there was a statistically significant difference between C and SP ($p=0.0001$); CT and SP ($p=0.0003$); CS and C ($p=0.0022$); CS and CT ($p=0.0062$); CS and SP ($p=0.0488$). However, when comparing CT and C, there was no statistical difference between them ($p=0.9681$).

Figure 2 illustrates the behavior of each dentifrice as a function of time. In this graph it may be observed that after the application in the tray and a brushing with the active principles 5% PN (SP) and ACC (CS) there was a significant reduction of the pain sensitivity. On the other hand, the same did not occur with S (C) and the group with SF (CT). The dentifrice with 5% PN (SP) presented the greatest reduction in sensitivity after its application in the tray.

It is still observed in Figure 2 that for analyses of the sensitivity in relation to application time, it was found a significant reduction of the sensitivity after placement of the plastic tray with dentifrice in each whitening session: the first - S2, the second - S4, and the third - S6 when it compared to the application times before: the first - S1, the second - S3 and the third session - S5.

Figure 2. Means, standard deviations for interaction dentifrice and time.



One-way ANOVA was applied for color evaluation in relation to each dentifrice and showed that there was no significant color difference after the whitening ($p=0.9186$) (Table 2).

Table 2. Means, standard deviations and One-Way ANOVA for color variation (ΔE).

Dentifrice	Color Variation (ΔE)*
Control (C)	3.47 (2.06) ^a
Colgate Sensitive Pro-Relief (CS)	4.09 (1.92) ^a
Sensodyne Pronamel (SP)	4.70 (2.83) ^a
Close Up Triple (CT)	4.97 (1.79) ^a

* Equal letters show that there is no significant difference between the means of color variation.

Discussion

In relation to the dentifrice and time, it was observed that S (C) had results similar to those of group SF (CT). Sucralose is made from sugar and tastes like sugar, however it is not recognized by the body as carbohydrate and therefore has zero calories. In addition, it is not used as food by oral bacteria that cause dental caries and has no action on sensitivity.²²

One of the hypotheses that may explain the absence of desensitizing effect of SF in the present study is that in three weeks the deposition of fluoride compounds in the dentin may not have been enough to obliterate tubules and to smooth the movement of fluids inside.²² The SF in small and constant concentrations only becomes able to reduce dentin sensitivity in the fourth week of use.²² This fact may be even more complicated when only the enamel is exposed, i.e., in this study there was no exposed dentin and direct contact occurred between the toothpaste and the enamel surface.

The S (C) present a significant difference in relation to dentifrices containing ACC (CS), which act by obliterating the canaliculus of the dentin, and thus prevent the movement of the dentin fluids and still assist in the remineralization of the dentin.^{16,22} The combination of ACC (CS) is capable of being deposited on surfaces of exposed dentin to physically block and seal the open dentinal tubules.^{24,25,26} This technology (CS) has shown that it physically promotes the obliteration and formation of a plug in the exposed dentinal tubules and is able to alleviate dentin hypersensitivity^{24,25,26}.

This new technology provides clinically proven benefits over rapid and long-lasting relief from dentin hypersensitivity and demonstrates that ACC work together to accelerate the natural mechanisms of tubule occlusion and form a protective layer

on the dentin surface ²⁷. Clinical findings show that toothpastes containing ACC provide a significant relief of dentin sensitivity ^{24,25}.

Sucralose (C) presents a significant difference in relation to dentifrices containing 5% PN (SP), which act by blocking the nerve activity of the nerve fibers of the pulp, through the decrease of the sensory excitability of the nociceptors.^{4,6,18}

Potassium Nitrate diffuses through the enamel and dentin to the nerve endings of the sensory fibers, reducing the excitability of the nerve fibers by inhibiting the movement of the sodium and potassium ions around the sensory fibers. Thus, this results in modulation or suppression of pain sensation.^{16,20,21} Due to such mechanism, potassium salts have been suggested as an effective treatment of sensitivity caused by tooth whitening.^{16,18} The study demonstrates that the use of PN can be more effective than fluoride in reducing sensitivity after dental whitening, as in other studies.^{21,28}

Reducing sensitivity during the period of tooth whitening is beneficial because it improves the patient's comfort and commitment to treatment.^{18,28} The use of a plastic tray with dentifrice has become an efficient procedure in reducing the sensitivity caused by in-office dental whitening. Our evaluation of sensitivity in relation to the application time has shown that sensitivity values after placement of the tray (S2, S4, 66) were different and lower significantly in all application times. This happened because the use of the plastic tray allowed for a longer contact time between dentifrice and dental surface inhibiting the pain.^{16,21,28}

Therefore, dentifrices did not influence the results of whitening since no significant difference in color shades was observed between the groups evaluated. It was expected that the dentifrice containing ACC (CS) could influence the diffusion of the whitening gel due to its mechanism of action, which is similar to that of fluoride, because both promote the obliteration of dentinal tubules and modification of enamel permeability.²⁹ However, the hydrogen peroxide molecule is very small and can penetrate the interstitial spaces between the enamel prisms. This probably explains the similar results of color variation after whitening obtained for the different groups.^{7,30-32}

This study has shown an efficient alternative for reducing the pain sensitivity associated with tooth whitening in the technique of using dentifrice in a plastic tray.

The limitations associated with the present study are related to the need for observing the volunteers for a longer period of time in order to evaluate the sensitivity and color stability after the whitening. This will require further studies with longer follow-up periods.

Conclusions

The use of desensitizing dentifrice containing 5% PN or ACC in a plastic tray were efficient in reducing the pain sensitivity caused by in-office dental whitening.

The dentifrices used in this study did not affect the efficacy of the hydrogen peroxide used in the in-office whitening.

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CONCLUSÕES

A utilização de dentifrícios dessensibilizantes contendo 5% de nitrato de potássio (NP) ou Arginina e Carbonato de cálcio (ACC) em moldeira plástica foram eficientes na redução da sensibilidade dolorosa causada por clareamento dental em consultório.

Os dentifrícios utilizados neste estudo não afetaram a eficácia do peróxido de hidrogênio usado no clareamento em consultório.

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APÊNDICE

APÊNDICE 1 - MATERIAIS E MÉTODOS

MATERIAIS

Para a técnica do dentífrico dessensibilizante em moldeira plástica foram utilizados quatro tipos de dentífricos: Dentífrico controle; Close Up Triple; Colgate Sensitive Pró-alívio; Sensodyne Pró-Esmalte (Tabela 1).

Tabela 1: Dentífricos, composição e fabricantes utilizados no experimento do dentífrico em moldeira plástica.

Materiais	Composição	Fabricantes
Controle	Sucralose (S)	Farmácia de Manipulação (Piracicaba, São Paulo)
Close Up triple	Fluoreto de sódio (FS) com 1450ppm de flúor	Unilever (São Paulo, Brasil)
Colgate Sensitive Pró-Alívio	Arginina e carbonato de cálcio (ACC) associado a monofluorfosfato de sódio com 1450ppm de flúor	Colgate-Palmolive (São Paulo, Brasil)
Sensodyne Pró-Esmalte	Nitrato de Potássio (NP) 5% associado a Fluoreto de sódio com 1450ppm de flúor	Glaxosmithkline Brasil (Rio de Janeiro, Brasil)

DELINEAMENTO EXPERIMENTAL

Estudo duplo cego controlado com a unidade experimental voluntário (48 voluntários). As unidades foram distribuídas por sorteio nos grupos experimentais. O fator em estudo foi o dentífrico em 4 níveis, sendo 2 níveis de tratamento e 2 níveis de controle. As variáveis de resposta foram escala analógica de dor e variação de cor (ΔE).

GRUPOS EXPERIMENTAIS

O fator em estudo, dentífrico, originou quatro grupos experimentais:

- Grupo 1 (Controle) – Sucralose (S) (Biotipo - farmácia de manipulação);
- Grupo 2 (Controle ativo) – Fluoreto de sódio (FS) com 1450ppm de flúor (Close Up Triple, Unilever);
- Grupo 3 – Arginina, Carbonato de Cálcio (ACC) e monofluorofosfato de sódio com 1450 ppm de flúor (Colgate Sensitive Pró-Alívio, Colgate – Palmolive);
- Grupo 4 – Nitrato de Potássio (NP) a 5% e Fluoreto de sódio com 1450 ppm de flúor (Sensodyne Pró-Esmalte, GlaxoSmithKline).

SELEÇÃO E PREPARAÇÃO DOS VOLUNTÁRIOS

Os pacientes que procuraram a clínica de pós-graduação da FOP/UNICAMP para realizarem tratamento clareador foram convidados a participar do estudo foram informados pelo pesquisador sobre todos os aspectos do estudo e que seriam livres para recusar-se a participar, retirar seu consentimento ou interromper a participação a qualquer momento do tratamento. Além disso, foram esclarecidos que sua participação era voluntária e a recusa em participar não iria acarretar qualquer penalidade ou perda de benefícios.

Os voluntários que optaram por participar do estudo, assinaram o termo de consentimento livre e esclarecido (TCLE) (Anexo 1) após a leitura detalhada do mesmo e foi dado início a avaliação clínica.

Os critérios de seleção e exclusão dos voluntários foram os seguintes:

(1) Critérios de inclusão: ter idade igual entre 18 e 30 anos, possuir boa saúde bucal e geral, dentes anteriores hígidos e com cromia superior a A2 na escala de cor Vita Classical (VITA Zahnfabrik, Bad Säckingen, Germany). (Figura 1).

(2) Critérios de exclusão: voluntários fumantes, grávidas ou lactantes, que já realizaram clareamento dental prévio, portadores de hábitos parafuncionais, sensibilidade dentinária, dentes anteriores com restaurações e lesões cariosas, escurecimento em dente não vital e restaurações posteriores insatisfatórias.

A avaliação clínica dos voluntários foi realizada através de anamnese, na qual se realizou perguntas sobre condições de saúde (Anexo 2); para o exame clínico foram usados espelho clínico e sonda exploradora e para o exame radiográfico foram realizadas as radiografias interproximais e periapicais. A partir dessa avaliação, foi analisado se os pacientes preenchiam os requisitos de inclusão na pesquisa, formando uma amostra de 48 voluntários.

Após a seleção dos voluntários, foi realizada nestes pacientes a adequação do meio bucal através de raspagem supra-gengival de cálculos com curetas periodontais e alisamento radicular com taças de borracha em baixa rotação e pasta de água/pedra pomes. Após este procedimento foi realizada moldagem dos arcos dentários com alginato (Hydrogum, Zhermack clinical, Italy) para obtenção de modelo em gesso pedra (Herodent tipo III, Coltene, Rio de Janeiro, Brasil) (Figura 2) que foi utilizado para a confecção da moldeira plástica (Figura 3 - a,b,c,d), a qual foi utilizada em associação aos dentifrícios após as sessões de clareamento dental.

Uma semana antes do início do experimento, foram fornecidos a cada voluntário escova dental (Slim Soft, Colgate-Palmolive, São Paulo, Brasil) e dentifrício padrão (Colgate Total 12, Colgate-Palmolive, São Paulo, Brasil), além disso foram dadas orientações sobre a higiene bucal e feitas recomendações para que os voluntários utilizassem apenas este dentifrício e escova para a higiene bucal até o início das sessões de clareamento.

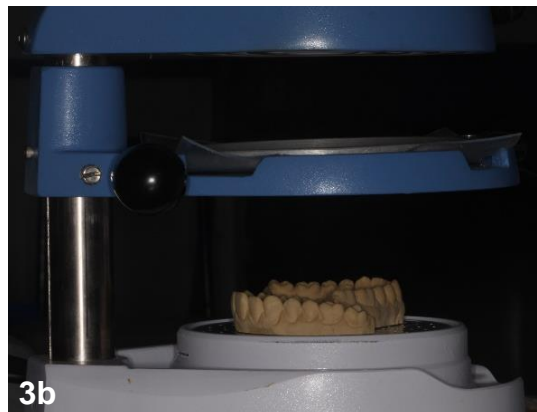
Figura 1: Seleção da cor inicial utilizando escala Vita



Figura 2: Modelo em gesso utilizado para confecção de moldeira plástica.



Figura 3: Confeção de moldeira plástica. **3a:** Modelo de gesso na base da plastificadora a vácuo. **3b:** Placa de acetato em plastificadora. **3c:** Moldeira plástica confeccionada sobre o modelo em gesso. **3d:** Moldeiras plásticas



PROCEDIMENTOS CLÍNICOS

Avaliação de cor

Foi feita a avaliação objetiva utilizando espectrofotômetro (Easysshade, Vident, Brea, CA, EUA) (Figura 4 – a,b). A cor foi analisada com os dentes

hidratados antes do início da primeira sessão de clareamento e uma semana após o término do clareamento.

A avaliação de cor com o espectrofotômetro foi feita sempre na mesma posição, através de um guia em silicone. Para a confecção do guia foi realizada a moldagem das arcadas dentais utilizando-se a pasta densa de silicone por adição (Express XT Pasta Densa Soft, 3M ESPE, Sumaré, SP, Brasil) (Figura 5 - a,b), no molde foi confeccionada uma abertura na face vestibular do incisivo central superior esquerdo no qual a cor dos dentes foi avaliada na altura do terço médio por meio da ponta do espectrofotômetro colocada nessa abertura. (Figura 6 - a,b)

A cor foi determinada utilizando os parâmetros do dispositivo do aparelho EasyShade, que indicam os seguintes valores: L^* , (a^*) e (b^*) , em que L^* representa o valor do dente em uma escala de 0 (preto) a 100 (branco) e a^* b^* representam a sombra, onde (a^*) é a medida ao longo do eixo vermelho (a^* positivo) - verde (a^* negativo), e (b^*) é a medida ao longo do eixo amarelo (b^* positivo) – azul (b^* negativo). A comparação de cor antes da primeira sessão e depois da última sessão de tratamento foi determinada pela diferença entre as duas cores (ΔE), que foi calculada usando-se a fórmula: $\Delta E = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}$. Essa avaliação foi realizada para se constatar a efetividade do tratamento clareador e se os dentifrícios usados não influenciavam na qualidade do clareamento.

Figura 4: 4a: Aparelho espectrofotômetro (Easysshade, Vident, Brea, CA, EUA). 4b: Dados objetivos obtidos a partir do espectrofotômetro.



Figura 5: Confeção do guia em silicone. **5a:** Moldagem da arcada superior para confecção da guia em silicone. **5b:** Guia de Silicone.

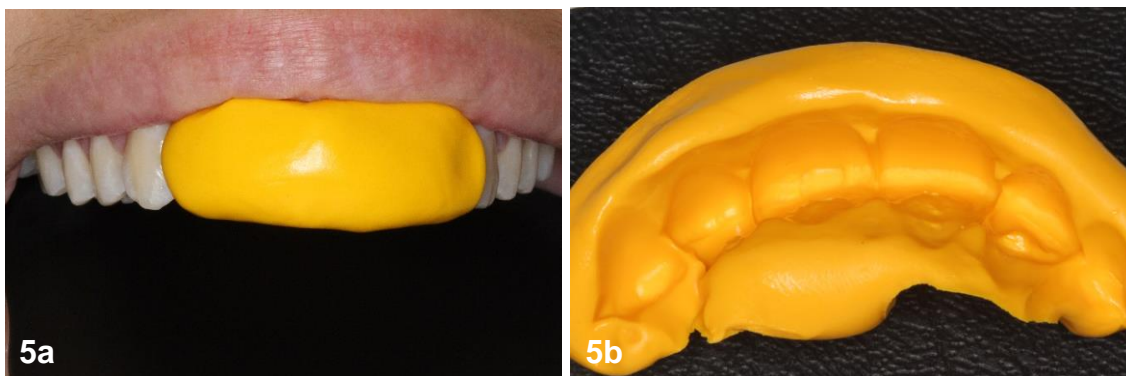
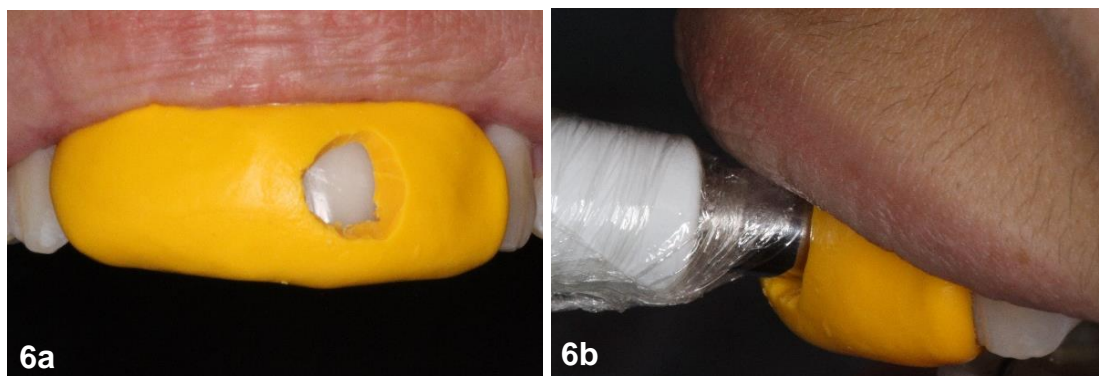


Figura 6: Utilização do guia em silicone em associação ao espectrofotômetro para avaliação da cor dos dentes. **6a:** Confeção de orifício em guia de silicone. **6b:** Posicionamento do espectrofotômetro na região do orifício do guia de silicone.



Isolamento do campo operatório

Os procedimentos clínicos foram realizados sob isolamento relativo com auxílio de afastador labial (Arcflex, FGM, Joinville, SC, Brasil) (Figura 7) e roletes de algodão para a aplicação de barreira de proteção gengival, agente dessensibilizante e agente clareador de 1º molar direito à 1º molar esquerdo das arcadas superior e inferior.

Figura 7: Isolamento relativo com auxílio de afastador labial (Arcflex, FGM, Joinville, Brasil).



Aplicação de barreira de proteção:

A barreira para a proteção gengival (Top Dam, FGM, Joinville, SC, Brasil) foi inserida sobre as margens e papilas gengivais correspondentes às áreas que receberam o gel clareador com aproximadamente 3 mm em altura e fotopolimerizou-se por 20 segundos cada grupo de três dentes. A fotoativação foi feita por LED de alta potência (intensidade de luz = 600mw/cm²) (RadiiCal, São Paulo, SP, Brasil). (Figura 8 - a,b,c).

Figura 8: **8a:** Inserção da barreira sobre as margens e papilas gengivais (3mm). **8b:** Fotopolimerização da barreira gengival por 20 segundos utilizando LED de alta potência (intensidade de luz = 600mw/cm²) (RadiiCal, São Paulo, SP, Brasil). **8c:** Barreira de proteção gengival finalizada.





Aplicação de agente dessensibilizante:

A aplicação do gel dessensibilizante a base de nitrato de potássio 5% associado a 2% de fluoreto de sódio (Desensibilize KF 2%, FGM, Joinville, SC, Brasil) foi realizada com o auxílio de um pincel tipo micro-brush. O produto permaneceu por 10 minutos sobre a face vestibular de 1º molar direito à 1º molar esquerdo das arcadas superior e inferior (Figura 9). Em seguida, o dessensibilizante foi removido com jato de água e cânula de sucção plástica e descartável.

Figura 9: Aplicação do dessensibilizante sobre a superfície vestibular dos dentes.

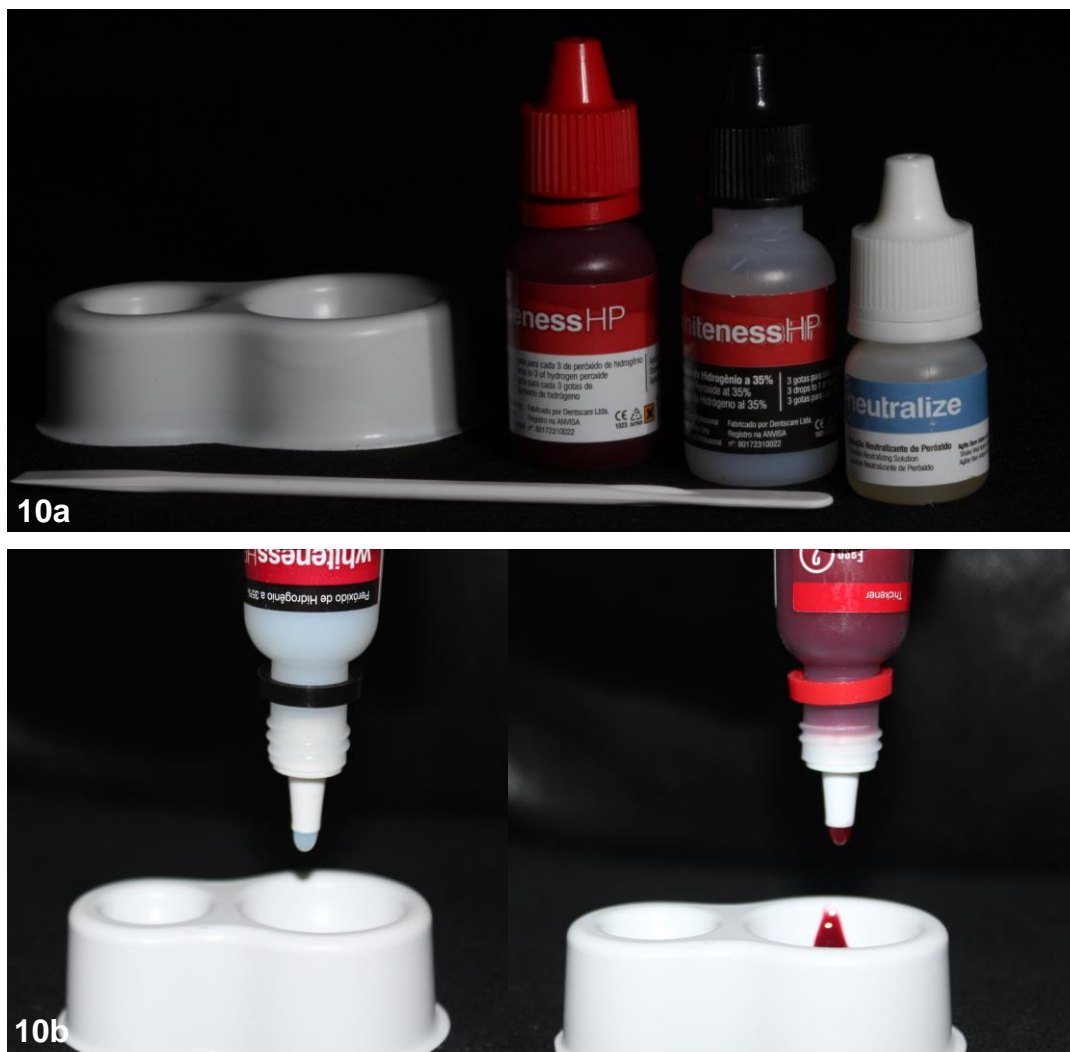


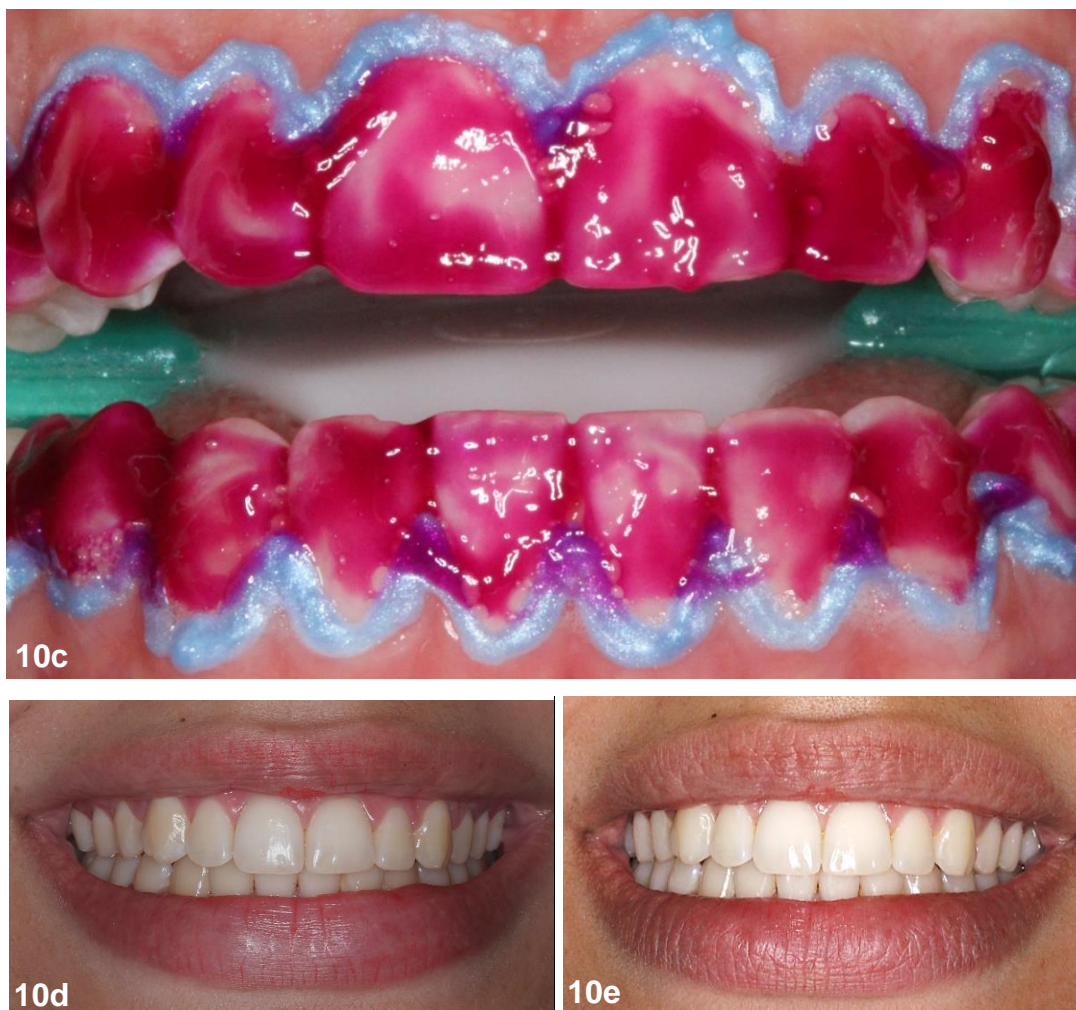
Aplicação de agente clareador:

A manipulação do peróxido de hidrogênio 35% (Whiteness HP, FGM, Joinville, SC, Brasil) seguiu as recomendações do fabricante que consistiu na mistura de 3 gotas de peróxido de hidrogênio à 35% para 1 gota de espessante, essa mistura foi suficiente para aplicação em pelo menos três dentes (Figura 10 - a,b). O gel permaneceu em contato com a face vestibular dos dentes por 15 minutos (Figura 10 - c), sendo removido com ajuda de uma cânula de sucção e lavagem

com água. Esse procedimento foi realizado três vezes por sessão clínica. Os voluntários foram submetidos a três sessões clínicas de clareamento, com intervalo de uma semana entre as sessões (Figura 10 – d,e).

Figura 10: **10a:** Produto utilizado para a aplicação do peróxido de hidrogênio 35% (Whiteness HP, FGM, Joinville, SC, Brasil). **10b:** Manipulação do peróxido de hidrogênio 35 (Whiteness HP, FGM, Joinville, SC, Brasil). **10c:** Peróxido de hidrogênio 35% sobre a superfície dentária. **10d:** Aspecto inicial (antes do clareamento). **10e:** Aspecto final (após o clareamento).





Utilização de dentifício dessensibilizante:

Entre as sessões clínicas de clareamento, cada voluntário utilizou dentifício, não identificado, correspondente ao seu grupo experimental, o qual foi previamente definido por meio de sorteio realizado por profissional que não participou da pesquisa. Assim, o pesquisador (cirurgião-dentista) que forneceu o dentifício e o paciente não estavam cientes de qual grupo experimental pertencia o paciente (duplo cego).

Após a primeira sessão de clareamento em consultório, cada voluntário recebeu uma moldeira plástica e instruções para o uso do dentifício, como descrito a seguir. (Figura 11) O voluntário recebeu instruções para colocar o dentifício em pequenas quantidades na face vestibular da moldeira plástica na região correspondente ao 1° molar direito ao 1° molar esquerdo das arcadas superior e inferior, em seguida, levar o conjunto à cavidade bucal e pressionar sobre a face

vestibular dos dentes, até que se estabelecesse o contato do dentífrico contido na moldeira com a estrutura dental. Os excessos de dentífricos que extravasassem deveriam ser removidos e utilizar a moldeira com dentífrico (por 4 horas) na mesma noite referente a cada sessão do tratamento clareador. Na manhã seguinte, o paciente deveria realizar a higiene da moldeira, seca-la e acondiciona-la no estojo fornecido (Figura 12 - a,b,c,d,e). Foram dadas orientações para que utilizassem a moldeira contendo o dentífrico específico para o seu grupo experimental apenas na primeira noite após cada sessão de clareamento. Somado a isso, o voluntário deveria usar o mesmo dentífrico para a higiene bucal 3 vezes por dia (após o café da manhã, após o almoço e antes do jantar). Foi enfatizado ao voluntário que usasse apenas o dentífrico fornecido em todas as escovações realizadas ao longo da pesquisa (Figura 13 – a,b,c).

Figura 11: Caixa fornecida para acondicionar a moldeira quando não estivesse em uso e exemplo de tubo contendo o dentífrico fornecido aos voluntários.

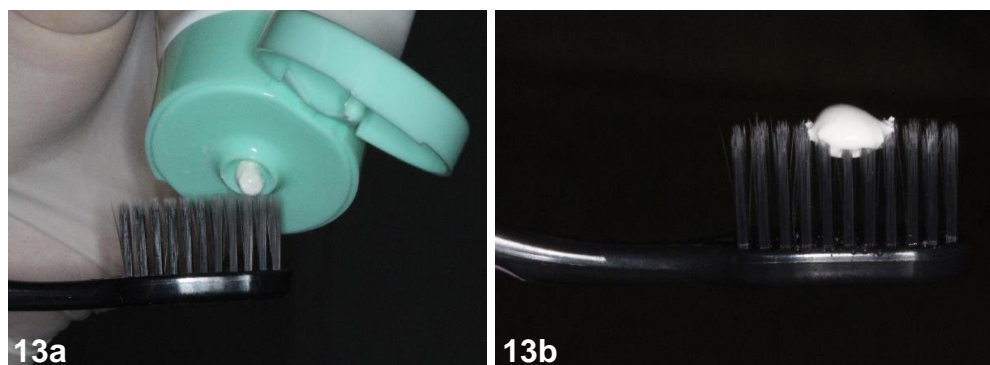


Figura 12: Utilização de dentífrico associado a moldeira. **12a:** Inserção do dentífrico com espátula. **12b:** Espátula contendo dentífrico. **12c:** Inserção do dentífrico na moldeira plástica. **12d:** Moldeira plástica contendo dentífrico. **12e:** Moldeira plástica na cavidade bucal do voluntário.





Figura 13: Utilização do dentífrico associado a escovação. **13a:** Inserção do dentífrico em escova dental. **13b:** Escova dental contendo dentífrico. **13c:** Voluntário utilizando o dentífrico na escovação.





Avaliação da sensibilidade:

A avaliação da sensibilidade foi realizada em seis tempos: na primeira sessão (S1: sensibilidade antes da moldeira; S2: sensibilidade depois da moldeira), na segunda sessão (S3: sensibilidade antes da moldeira; S4: sensibilidade depois da moldeira) e na terceira sessão (S5: sensibilidade antes da moldeira; S6: sensibilidade depois da moldeira), na qual utilizou-se a escala numérica analógica com escores de 0 a 10. (Figura 14)

Figura 14: Escala analógica de dor (0-10) utilizada como parâmetro de avaliação da sensibilidade.

Escala de dor (0-10)										
0	1	2	3	4	5	6	7	8	9	10
14										

Aspectos éticos

O projeto foi submetido a previa aprovação do Comitê de Ética em Pesquisa da FOP-UNICAMP afiliado a Comissão Nacional de Ética em Pesquisa – CONEP obtendo o número de protocolo 104/2015 (Anexo 3) e do Banco de Dados de Registros e Resultados de Estudos Clínicos (ClinicalTrials) obtendo o número de protocolo NCT03019224 (Anexo 4). Todos os voluntários assinaram o Termo de Consentimento Livre e Esclarecido. O Ensaio clínico foi relatado de acordo com o protocolo padrão da Declaração CONSORT (Anexo 5).

ANEXOS

ANEXO 1 – Termo de consentimento livre e esclarecido



UNIVERSIDADE ESTADUAL DE CAMPINAS
FACULDADE DE ODONTOLOGIA DE PIRACICABA
Programa de Pós-Graduação em Clínica Odontológica
Mestrado - Área de Dentística



TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Você está sendo convidado (a) como voluntário (a) a participar da pesquisa **“Influência de dentifrícios dessensibilizantes na redução da sensibilidade causada por clareamento dental de consultório”**, sendo o responsável pela pesquisa o professor Luís Alexandre Maffei Sartini Paulillo. A apresentação e obtenção desse consentimento serão de responsabilidade do aluno Josué Junior Araújo Pierote, se responsabilizando por esclarecer qualquer dúvida com relação ao desenvolvimento da pesquisa.

O motivo que nos leva estudar a sensibilidade decorrente do clareamento dental é por se tratar da principal queixa dos pacientes que realizam esse procedimento estético, correspondendo ao principal critério de desistência do tratamento por parte do paciente. A pesquisa se justifica, pois, busca minimizar ou até mesmo evitar esse desconforto através da utilização de agentes e dentifrícios dessensibilizantes, ou seja, agentes responsáveis por diminuir a sensibilidade gerada pelo tratamento clareador.

Na primeira consulta você será submetido a um questionário contendo perguntas sobre sua saúde geral e bucal, em seguida será feita uma avaliação minuciosa de todos os seus dentes e a realização de radiografias para conclusão de diagnóstico, sendo esses procedimentos padrões para qualquer atendimento odontológico. Para que o seu tratamento clareador seja efetivo é necessário a realização de adequação do meio bucal, que consiste em raspagem supra-gengival de tártaros e profilaxia (limpeza). Após essa consulta você receberá uma escova dental, dentifrício padrão (Colgate Total 12, Colgate-Palmolive, São Paulo, Brasil), orientações de higiene bucal e recomendações para que se utilize apenas este

dentifrício e escova durante a higiene bucal realizada ao longo de todo o tratamento clareador.

Serão agendadas as suas próximas consultas conforme sua disponibilidade de horário. Essas sessões serão realizadas uma (01) vez por semana, num total de quatro (04) semanas, com duração de aproximadamente uma hora e meia cada uma, esse intervalo de tempo deve ser respeitado para um melhor resultado do clareamento.

Para analisar a cor do seu dente utilizaremos um aparelho chamado espectrofotômetro e para isso iremos realizar um molde de suas arcadas superior e inferior, para que todas as medições sejam feitas na mesma posição. A obtenção da cor de seu dente será obtida antes do início da 1ª sessão de clareamento e uma semana após o término do clareamento. Para isso, necessitamos isolar os seus dentes, portanto iremos utilizar um afastado labial, roletes de algodão e o sugador.

Após a primeira sessão de clareamento em consultório, você receberá moldeiras plásticas e instruções para o uso de um dentifrício específico, o qual será colocado em pequenas quantidades na face vestibular da moldeira plástica na região que corresponde do 1º molar direito ao 1º molar esquerdo da arcada superior e inferior, em seguida o conjunto será levado à cavidade bucal e pressionado sobre a face vestibular dos dentes, até que se estabeleça o contato do dentifrício contido na moldeira com a estrutura dentária. Os excessos de dentifrícios extravasados deverão ser removidos e você deverá usar a moldeira com dentifrícios (por 4 horas) na mesma noite correspondente ao dia em que cada sessão do tratamento clareador for realizada. Na manhã seguinte você deverá realizar a higiene da moldeira, seca-lá e acondiciona-lá no estojo que será fornecido. Você deverá utilizar a moldeira contendo o dentifrício específico apenas na noite da sessão de clareamento. O mesmo dentifrício utilizado na moldeira plástica será colocado em pequenas quantidades sobre as cerdas macias da escova cedida pelo pesquisador para a escovação, a qual será repetida 3 vezes ao dia (após o café da manhã, após o almoço e após o jantar). Serão dadas orientações para que utilize apenas o dentifrício específico para o seu grupo de estudo (controles ou experimental) em todas as escovações realizadas ao longo do tratamento clareador.

A aplicação do gel dessensibilizante será realizada com o auxílio de um pincel. O produto permanecerá por 10 minutos sobre os dentes. Em seguida, o

dessensibilizante será removido com jato de água e cânula de sucção plástica e descartável.

Em seguida, será utilizado o gel do clareamento o qual não poderá encostar a sua gengiva e para evitar que isso ocorra será feita uma barreira de proteção que é fotopolimerizável, ou seja, endurece após aplicação de uma luz específica. Em seguida, será aplicado o gel clareador, Peróxido de Hidrogênio 35%, por 15 minutos sendo removido com ajuda de um algodão umedecido e em jatos de água e sugador. Esse procedimento será repetido 3 vezes em cada sessão.

Ao término da aplicação do gel clareador você irá relatar verbalmente se sentiu sensibilidade. O que você sentiu ou mesmo se não sentiu será classificado através de escala analógica com escores que variam de 0 a 10. Durante o decorrer da semana você pode sentir algum tipo de sensibilidade nos dentes e essa informação também será importante, portanto no início da segunda e terceira sessão e na consulta de acompanhamento essa análise de dor também será realizada. Fora isso as outras sessões serão procedidas da mesma maneira descrita. Se você sentir qualquer necessidade poderá entrar em contato com o seu dentista para os esclarecimentos.

O tratamento clareador é a forma mais conservadora de obter dentes mais brancos, porém existem tratamentos mais invasivos que seria a realização de desgaste dental e a substituição por outro material. No entanto, todo tratamento oferece riscos e o clareamento pode gerar interações com restaurações previamente existentes, alterações gengivais ou na superfície do esmalte e a sensibilidade, esses desconfortos são inerentes ao tratamento.

O risco com relação a participação da pesquisa seria a interferência do dessensibilizante no clareamento, porém a literatura (trabalhos) vigente nos mostra que isso não ocorre. Caso seja observado qualquer diferença de resultado com relação a cor final do dente será realizado mais uma sessão de clareamento para contornar este transtorno. Esta sessão a mais não acarreta nenhum dano aos dentes.

A sua vantagem como participante da pesquisa é a realização de um procedimento estético sem custos.

O tratamento e acompanhamento será realizado pelo dentista Josué Junior Araujo Pierote, aluno de mestrado de Clínica Odontológica na área de

Dentística, telefone de contato (019) 983060175 e email, josuepierote@hotmail.com, sendo o endereço comercial Av. Limeira, 901, Piracicaba. O mesmo encontra-se disponível para oferecer informações durante todo o tratamento assim como seu acompanhamento.

Em caso de dúvidas quanto aos seus direitos como voluntário de pesquisa entre em contato com o Comitê de Ética em Pesquisa da FOP: Av Limeira 901, FOP-Unicamp, CEP 13414-903, Piracicaba – SP. Fone/Fax 19-21065349, e-mail cep@fop.unicamp.br e webpage www.fop.unicamp.br/cep".

Você será esclarecido (a) sobre a pesquisa em qualquer aspecto que desejar. Você é livre para recusar-se a participar, retirar seu consentimento ou interromper a participação a qualquer momento. A sua participação é voluntária e a recusa em participar não irá acarretar qualquer penalidade ou perda de benefícios.

O (s) pesquisador (es) irá (ão) tratar a sua identidade com padrões profissionais de sigilo.

Os resultados serão enviados para você e permanecerão confidenciais. Seu nome ou o material que indique a sua participação não será liberado sem a sua permissão. Você não será identificado (a) em nenhuma publicação que possa resultar deste estudo.

Não haverá previsão de ressarcimento, pois a participação na pesquisa não causará despesas adicionais ao voluntário. Assim como não há previsão de ressarcimento, pois não há risco previsível pela participação na pesquisa.

Uma cópia deste consentimento informado será arquivada e outra será fornecida a você com todas as páginas rubricadas.

Declaro que concordo em participar desse estudo. Recebi uma cópia deste termo de consentimento livre e esclarecido e me foi dada a oportunidade de ler e esclarecer as minhas dúvidas.

Assinatura do Voluntário

Identidade ou CPF

Telefone

Assinatura do Pesquisador



Anexo 2 – Ficha clínica
 UNIVERSIDADE ESTADUAL DE CAMPINAS
 FACULDADE DE ODONTOLOGIA DE PIRACICABA
 Programa de Pós-Graduação em Clínica Odontológica
 Mestrado - Área de Dentística



FICHA CLÍNICA

Código: _____ Telefone: _____

ANAMNESE

1. Nome: _____
2. Sexo: () F () M
3. Data de Nascimento: ____/____/____
4. Idade: ____
5. Tem algum problema de saúde geral ou alterações sistêmicas?
 () Não; () Doenças cardiovasculares; () Diabetes; () Desordens alimentares; ()
 Outros – Quais? _____
6. Tem o hábito de fumar? () Sim () Não
7. Está grávida ou amamentando? () Sim () Não
8. Tem hábitos parafuncionais? () Sim () Não
9. Já realizou clareamento dentário? () Sim () Não
10. Tem sensibilidade dentinária? () Sim () Não

EXAME CLÍNICO

D	18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	28
D	48	47	46	45	44	43	42	41	31	32	33	34	35	36	37	38

11. Tem lesões cariosas? () Sim () Não
12. Tem dentes anteriores com restauração? () Sim () Não
13. Tem dentes posteriores com restaurações insatisfatórias? () Sim () Não

Observação: _____

AVALIAÇÃO DE TRATAMENTO

ADEQUAÇÃO DO MEIO BUCAL: (___ / ___ / ___)

Raspagem supragengival _____

Outro procedimento _____

1º SESSÃO DE CLAREAMENTO: (___ / ___ / ___)

Início - Avaliação da cor: _____

Escala Vita:

1ª medição	2ª medição	3ª medição

Easyshade:

1ª medição			2ª medição			3ª medição		
L	a	B	L	A	b	L	a	B

Início – Avaliação da sensibilidade: _____

Escala de dor (0-10)

0	1	2	3	4	5	6	7	8	9	10

Final - Avaliação da sensibilidade: _____

Escala de dor (0-10)

0	1	2	3	4	5	6	7	8	9	10

2º SESSÃO DE CLAREAMENTO: (___ / ___ / ___)

Início - Avaliação da sensibilidade: _____

Escala de dor (0-10)

0	1	2	3	4	5	6	7	8	9	10

Final - Avaliação da sensibilidade: _____

Escala de dor (0-10)

0	1	2	3	4	5	6	7	8	9	10

3º SESSÃO DE CLAREAMENTO: (___ / ___ / ___)

Início - Avaliação da sensibilidade: _____

Escala de dor (0-10)										
0	1	2	3	4	5	6	7	8	9	10

Final - Avaliação da sensibilidade: _____

Escala de dor (0-10)										
0	1	2	3	4	5	6	7	8	9	10

4º SESSÃO - PROSERVAÇÃO: (__ / __ / __)

Avaliação da cor: _____

Escala Vita:

1ª medição	2ª medição	3ª medição

Easyshade:

1ª medição			2ª medição			3ª medição		
L	a	b	L	A	b	L	a	B

Avaliação da sensibilidade: _____

Escala de dor (0-10)										
0	1	2	3	4	5	6	7	8	9	10

Assinatura Voluntário

Assinatura do Pesquisador

ANEXO 3 – Carta de aprovação do comitê de ética em pesquisa

COMITÊ DE ÉTICA EM PESQUISA
FACULDADE DE ODONTOLOGIA DE PIRACICABA
UNIVERSIDADE ESTADUAL DE CAMPINAS



CERTIFICADO

O Comitê de Ética em Pesquisa da FOP-UNICAMP certifica que o projeto de pesquisa **"Influência de dentifrícios dessensibilizantes na redução da sensibilidade causada por clareamento dental de consultório"**, protocolo nº **104/2015**, dos pesquisadores **LUIS ALEXANDRE MAFFEI SARTINNI PAULILLO e JOSUÉ JUNIOR ARAUJO PIEROTE**, satisfaz as exigências do Conselho Nacional de Saúde – Ministério da Saúde para as pesquisas em seres humanos e foi aprovado por este comitê em 07/06/2016.

The Ethics Committee in Research of the Piracicaba Dental School, University of Campinas, certify that the project **"Influence of desensitizing dentifrices on sensitivity reduction caused bytooth whitening in a dental office"**, register number **104/2015**, of **LUIS ALEXANDRE MAFFEI SARTINNI PAULILLO and JOSUÉ JUNIOR ARAUJO PIEROTE**, comply with the recommendations of the National Health Council – Ministry of Health of Brazil for research in human subjects and therefore was approved by this committee on Jun 07, 2016.

Prof. Jacks Jorge Junior

Coordenador
 CEP/FOP/UNICAMP

Nota: O título do protocolo aparece como fornecido pelos pesquisadores, sem qualquer edição.
 Notice: The title of the project appears as provided by the authors, without editing.

ANEXO 4 – Carta de aprovação (ClinicalTrials)

ClinicalTrials.gov PRS
Protocol Registration and Results System

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: January 11, 2017

ClinicalTrials.gov ID: NCT03019224

Study Identification

Unique Protocol ID: 104/2015

Brief Title: Effects of Desensitizing Dentifrices on the Reduction of Pain Sensitivity Caused by In-office Dental Whitening

Official Title: Effects of Desensitizing Dentifrices on the Reduction of Pain Sensitivity Caused by In-office Dental Whitening: Double Blind Controlled Clinical Study

Secondary IDs:

Study Status

Record Verification: January 2015

Overall Status: Completed

Study Start: January 2016

Primary Completion: April 2016 (Actual)

Study Completion: August 2016 (Actual)

Sponsor/ Collaborators

Sponsor: University of Campinas, Brazil

Responsible Party: Principal Investigator

Investigator: Josué Junior Araujo Pierola (japierola)

Official Title: Principal Investigator

Affiliation: University of Campinas, Brazil

Collaborators:

Oversight

FDA Regulated?: Yes

Applicable Trial?: Section 801 Clinical Trial? Yes
Delayed Posting? No

IND/IDE Protocol?: No

Review Board: Approval Status: Approved

Approval Number: 104/2015

Board Name: Ethics Committee of the Piracicaba Dental School

Board Affiliation: National Health Council HEALTH DEFINITIONS OF HEALTH substantive the state of being free from illness or injury. he was restored to health sinônimos: well-being, healthiness, fitness, good condition, good shape, fine fettle, strength, vigor, wellness

Phone: (19) 2106-5200
 Email: osp@fop.unicamp.br

Data Monitoring?: No

Plan to Share IPD?: Undecided

Oversight Authorities: Brazil: Ethics Committee

Study Description

Brief Summary: Introduction: The pain sensitivity associated with whitening is the main problem reported by patients during dental whitening, and the use of desensitizing dentifrices is an alternative for the treatment of sensitivity.

Objective: To evaluate clinically the influence of desensitizing dentifrices applied through a plastic tray, reducing the pain sensitivity and color variation caused by the technique of in-office dental whitening, through a controlled double-blind clinical study.

Methods: A longitudinal prospective study was conducted with 48 individuals, 18 years and 30 years of age, without gender distinction, who underwent in-office dental whitening using 35% hydrogen peroxide (Whiteneas HP, FGM, Joinville, SC, Brazil) in three clinical sessions with a one-week interval between them. The volunteers used in the night for each bleaching session a plastic tray for 4 hours containing one of the dentifrices related to the experimental groups: Group 1 (Control) - Sucrose (S) (Biotype - Manipulation pharmacy); Group 2 (Active control) - Sodium fluoride (FS) with 1450ppm of fluoride (Close up triple, Unilever); Group 3 - Arginine, calcium carbonate (ACC) and sodium monofluorophosphate with 1450 ppm fluoride (Colgate sensitive pro-relief, Colgate-Palmolive); Group 4 - 5% potassium nitrate (NP) and sodium fluoride with 1450 ppm fluoride (Sensodyne pro-enamel, GlaxoSmithKline). The evaluation of the sensitivity associated with the times of use of the plastic tray in the first session (S1: sensitivity before the tray, S2: sensitivity after the tray), in the second session (S3: sensitivity before the tray, S4: in the third session (S5: sensitivity before the tray, S6: sensitivity after the tray) used the analog numerical scale with scores from 0 to 10 and for the color evaluation the spectrophotometer (Easyshade, Vident, Brea, CA, Obtaining the data that were used in the CIELab system. The data were submitted to the multivariate analysis of variance (MANOVA) with repeated measurements and Lambda Wilks test with a 5% probability level to differentiate the groups. In addition, the factorial variance analysis (ANOVA) in one criterion was applied. Values of $p < 0.05$ were considered statistically significant.

Detailed Description:

Conditions

Conditions: Tooth Whitening
 Sensitivity

Keywords: Tooth whitening
 Dentifrice
 Sensitivity

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 4

Intervention Model: Factorial Assignment

Number of Arms: 4

Masking: Double Blind (Caregiver, Investigator)

Allocation: Randomized

Endpoint Classification:

Enrollment: 4 [Actual]

Arms and Interventions

Arms	Assigned Interventions
<p>Placebo Comparator: Group 1 The use of desensitizing dentifrice [Sucralose (S) Control dentifrice] in plastic tray.</p>	<p>Procedure/Surgery: Selection and preparation of the volunteers Patients who sought the postgraduate dental clinic for whitening were invited to participate in the study. They were informed by the researcher (dentist) about all the aspects of the study and who might participate or discontinue the participation at any moment during the treatment. In addition, it was clarified that their participation was voluntary and refusal to participate would not result in any penalty or loss of benefits.</p> <p>Procedure/Surgery: Evaluation of the tooth color The evaluation of the tooth color was performed by using a spectrophotometer (Easysshade, Vident, Brea, CA, USA). The color was analysed with the tooth hydrated before of the start the first whitening session and one week after. The spectrophotometer was always used in the same position by a silicon guide, which was prepared with dental arch molds by adding high viscosity vinyl polysiloxane material (Express XT, 3M ESPE, Sumaré, SP, Brazil). After polymerization, an opening was made in the mold corresponding to the buccal surface of the upper central incisors, allowing the color of the tooth to be evaluated with the tip of the spectrophotometer at the height of the middle third.</p> <p>Procedure/Surgery: Relative isolation The clinical procedures were performed under relative isolation using lip retractor (Arclex, FGM, Joinville, SC, Brazil) and dental cotton rollers to apply a gingival protection barrier (Top Dam, FGM, Joinville, SC, Brazil) extending from right first molar to left first molar in both arches.</p> <p>Procedure/Surgery: Gingival protection barrier The gingival protection barrier was placed over the margins and gingival papilla corresponding to the areas receiving the whitening gel with approximately 3 mm in height and photopolymerized for 20 seconds in each group of three tooth. Photo-activation was performed with high power LEDs (light intensity = 600mw / cm²) (Radical, São Paulo, SP, Brazil).</p> <p>Procedure/Surgery: Application of desensitizing gel The desensitizing gel containing 5% potassium nitrate associated with 2% sodium fluoride (Desensibiliza KF 2%, FGM, Joinville, SC, Brazil) was applied with a microbrush (Brush KG, KG Sorensen, Coila, SP) on the buccal surface from right first molar to left first molar in both arches and remaining for 10 minutes.</p>

Arms	Assigned Interventions
	<p>Then, the desensitizer was then removed with water jet and disposable plastic suction cannula.</p> <p>Drug: Hydrogen peroxide The handling of 35% hydrogen peroxide (Whiteness HP, FGM, Joinville, SC, Brazil) followed the manufacturer's recommendations, which consisted of mixing 3 drops of 35% hydrogen peroxide for 1 drop of thickener, with this mixture being sufficient for application to at least three tooth. The gel remained in contact with the buccal surface of the tooth for 15 minutes and was removed with disposable plastic suction cannula and water wash. This procedure was performed three times per clinical session. The volunteers underwent three whitening clinical sessions with one week interval between them.</p> <p>Procedure/Surgery: Used a dentifrice Among the clinical whitening sessions, each volunteer used an unidentified dentifrice corresponding to their experimental group, which was previously defined by means of a draw made by a dentist who did not participate in the study. Thus, the researcher (dentist) who provided the dentifrice and the volunteer were not aware of which experimental group belonged (i.e. double blind).</p>
<p>Experimental Group 2 The use of desensitizing dentifrice (Sodium fluoride (FS) with 1450ppm of fluorine (Close up triple, Unilever) in plastic tray.</p>	<p>Procedure/Surgery: Selection and preparation of the volunteers Patients who sought the postgraduate dental clinic for whitening were invited to participate in the study. They were informed by the researcher (dentist) about all the aspects of the study and who might participate or discontinue the participation at any moment during the treatment. In addition, it was clarified that their participation was voluntary and refusal to participate would not result in any penalty or loss of benefits.</p> <p>Procedure/Surgery: Evaluation of the tooth color The evaluation of the tooth color was performed by using a spectrophotometer (Easshade, Vident, Brea, CA, USA). The color was analysed with the tooth hydrated before of the start the first whitening session and one week after. The spectrophotometer was always used in the same position by a silicon guide, which was prepared with dental arch molds by adding high viscosity vinyl polysiloxane material (Express XT, 3M ESPE, Sumaré, SP, Brazil). After polymerization, an opening was made in the mold corresponding to the buccal surface of the upper central incisors, allowing the color of the tooth to be evaluated with the tip of the spectrophotometer at the height of the middle third.</p> <p>Procedure/Surgery: Relative isolation The clinical procedures were performed under relative isolation using lip retractor (Arclex, FGM, Joinville, SC, Brazil) and dental cotton rollers to apply a gingival protection barrier (Top Dem, FGM, Joinville, SC, Brazil) extending from right first molar to left first molar in both arches.</p> <p>Procedure/Surgery: Gingival protection barrier</p>

Aims	Assigned Interventions
	<p>The gingival protection barrier was placed over the margins and gingival papilla corresponding to the areas receiving the whitening gel with approximately 3 mm in height and photopolymerized for 20 seconds in each group of three tooth. Photo-activation was performed with high power LEDs (light intensity = 800mw / cm²) (RadiiCal, São Paulo, SP, Brazil).</p> <p>Procedure/Surgery: Application of desensitizing gel The desensitizing gel containing 5% potassium nitrate associated with 2% sodium fluoride (Desensibilize KF 2%, FGM, Joinville, SC, Brazil) was applied with a microbrush (Brush KG, KG Sorensen, Colla, SP) on the buccal surface from right first molar to left first molar in both arches and remaining for 10 minutes. Then, the desensitizer was then removed with water jet and disposable plastic suction cannula.</p> <p>Drug: Hydrogen peroxide The handling of 35% hydrogen peroxide (Whitensec HP, FGM, Joinville, SC, Brazil) followed the manufacturer's recommendations, which consisted of mixing 3 drops of 35% hydrogen peroxide for 1 drop of thickener, with this mixture being sufficient for application to at least three tooth. The gel remained in contact with the buccal surface of the tooth for 15 minutes and was removed with disposable plastic suction cannula and water wash. This procedure was performed three times per clinical session. The volunteers underwent three whitening clinical sessions with one week interval between them.</p> <p>Procedure/Surgery: Used a dentifrice Among the clinical whitening sessions, each volunteer used an unidentified dentifrice corresponding to their experimental group, which was previously defined by means of a draw made by a dentist who did not participate in the study. Thus, the researcher (dentist) who provided the dentifrice and the volunteer were not aware of which experimental group belonged (i.e. double blind).</p>
<p>Experimental: Group 3 The use of desensitizing dentifrice [Arginine, calcium carbonate (ACC) and sodium monofluorophosphate with 1450 ppm fluoride (Colgate sensitive pro-relief, Colgate-Palmolive)] in plastic tray.</p>	<p>Procedure/Surgery: Selection and preparation of the volunteers Patients who sought the postgraduate dental clinic for whitening were invited to participate in the study. They were informed by the researcher (dentist) about all the aspects of the study and who might participate or discontinue the participation at any moment during the treatment. In addition, it was clarified that their participation was voluntary and refusal to participate would not result in any penalty or loss of benefits.</p> <p>Procedure/Surgery: Evaluation of the tooth color The evaluation of the tooth color was performed by using a spectrophotometer (Easysshade, Vivident, Brea, CA, USA). The color was analysed with the tooth hydrated before of the start the first whitening session and one week after. The spectrophotometer was always used in the same position by a silicon guide, which was prepared with dental arch molds by adding high viscosity vinyl polysiloxane material (Express XT, 3M ESPE, Sumaré, SP, Brazil). After polymerization,</p>

Aims	Assigned Interventions
	<p>an opening was made in the mold corresponding to the buccal surface of the upper central incisors, allowing the color of the tooth to be evaluated with the tip of the spectrophotometer at the height of the middle third.</p> <p>Procedure/Surgery: Relative isolation The clinical procedures were performed under relative isolation using lip retractor (Arcflex, FGM, Joinville, SC, Brazil) and dental cotton rollers to apply a gingival protection barrier (Top Dam, FGM, Joinville, SC, Brazil) extending from right first molar to left first molar in both arches.</p> <p>Procedure/Surgery: Gingival protection barrier The gingival protection barrier was placed over the margins and gingival papilla corresponding to the areas receiving the whitening gel with approximately 3 mm in height and photopolymerized for 20 seconds in each group of three tooth. Photo-activation was performed with high power LEDs (light intensity = 600mw / cm²) (Radical, São Paulo, SP, Brazil).</p> <p>Procedure/Surgery: Application of desensitizing gel The desensitizing gel containing 5% potassium nitrate associated with 2% sodium fluoride (Desensibilize KF 2%, FGM, Joinville, SC, Brazil) was applied with a microbrush (Brush KG, KG Sorensen, Coto, SP) on the buccal surface from right first molar to left first molar in both arches and remaining for 10 minutes. Then, the desensitizer was then removed with water jet and disposable plastic suction cannula.</p> <p>Drug: Hydrogen peroxide The handling of 35% hydrogen peroxide (Whiteness HP, FGM, Joinville, SC, Brazil) followed the manufacturer's recommendations, which consisted of mixing 3 drops of 35% hydrogen peroxide for 1 drop of thickener, with this mixture being sufficient for application to at least three tooth. The gel remained in contact with the buccal surface of the tooth for 15 minutes and was removed with disposable plastic suction cannula and water wash. This procedure was performed three times per clinical session. The volunteers underwent three whitening clinical sessions with one week interval between them.</p> <p>Procedure/Surgery: Used a dentifrice Among the clinical whitening sessions, each volunteer used an unidentified dentifrice corresponding to their experimental group, which was previously defined by means of a draw made by a dentist who did not participate in the study. Thus, the researcher (dentist) who provided the dentifrice and the volunteer were not aware of which experimental group belonged (i.e. double blind).</p>
<p>Experimental Group 4 The use of desensitizing dentifrice [Sodium fluoride based dentifrice with 1450 ppm of fluorine associated with 5% potassium nitrate] in plastic tray.</p>	<p>Procedure/Surgery: Selection and preparation of the volunteers Patients who sought the postgraduate dental clinic for whitening were invited to participate in the study. They were informed by the researcher (dentist) about all the aspects of the study and who might participate or discontinue the participation at any moment during</p>

Aims	Assigned interventions
	<p>the treatment. In addition, it was clarified that their participation was voluntary and refusal to participate would not result in any penalty or loss of benefits.</p> <p>Procedure/Surgery: Evaluation of the tooth color The evaluation of the tooth color was performed by using a spectrophotometer (Easysshade, Vident, Brea, CA, USA). The color was analysed with the tooth hydrated before of the start the first whitening session and one week after. The spectrophotometer was always used in the same position by a silicon guide, which was prepared with dental arch molds by adding high viscosity vinyl polysiloxane material (Express XT, 3M ESPE, Sumaré, SP, Brazil). After polymerization, an opening was made in the mold corresponding to the buccal surface of the upper central incisors, allowing the color of the tooth to be evaluated with the tip of the spectrophotometer at the height of the middle third.</p> <p>Procedure/Surgery: Relative Isolation The clinical procedures were performed under relative isolation using lip retractor (Arclex, FGM, Joinville, SC, Brazil) and dental cotton rollers to apply a gingival protection barrier (Top Dem, FGM, Joinville, SC, Brazil) extending from right first molar to left first molar in both arches.</p> <p>Procedure/Surgery: Gingival protection barrier The gingival protection barrier was placed over the margins and gingival papilla corresponding to the areas receiving the whitening gel with approximately 3 mm in height and photopolymerized for 20 seconds in each group of three tooth. Photo-activation was performed with high power LEDs (light intensity = 600mw / cm²) (Radical, São Paulo, SP, Brazil).</p> <p>Procedure/Surgery: Application of desensitizing gel The desensitizing gel containing 5% potassium nitrate associated with 2% sodium fluoride (Desensitize KF 2%, FGM, Joinville, SC, Brazil) was applied with a microbrush (Brush KG, KG Sorensen, Coita, SP) on the buccal surface from right first molar to left first molar in both arches and remaining for 10 minutes. Then, the desensitizer was then removed with water jet and disposable plastic suction cannula.</p> <p>Drug: Hydrogen peroxide The handling of 35% hydrogen peroxide (Whiteness HP, FGM, Joinville, SC, Brazil) followed the manufacturer's recommendations, which consisted of mixing 3 drops of 35% hydrogen peroxide for 1 drop of thickener, with this mixture being sufficient for application to at least three tooth. The gel remained in contact with the buccal surface of the tooth for 15 minutes and was removed with disposable plastic suction cannula and water wash. This procedure was performed three times per clinical session. The volunteers underwent three whitening clinical sessions with one week interval between them.</p> <p>Procedure/Surgery: Used a dentifrice Among the clinical whitening sessions, each volunteer used an unidentified dentifrice corresponding to their</p>

Arms	Assigned Interventions
	experimental group, which was previously defined by means of a draw made by a dentist who did not participate in the study. Thus, the researcher (dentist) who provided the dentifrice and the volunteer were not aware of which experimental group belonged (i.e. double blind).

Outcome Measures

Primary Outcome Measure:

1. The analysis of the reduction of sensitivity using the toothpaste during whitening.
[Time Frame: Through study completion up to 4 weeks placement of the tray.] [Safety Issue: No]
For sensitivity analysis was used the numerical analogue scale with scores ranging from 0 to 10.
2. The evaluation of the tooth color using the toothpaste during whitening.
[Time Frame: Through study completion up to 4 weeks placement of the tray.] [Safety Issue: No]
For evaluation of the tooth color was performed by using a spectrophotometer. (Easshade, Vident, Brae, CA, USA). The color was determined by EasyShade device.

Eligibility

Minimum Age: 18 Years

Maximum Age: 30 Years

Gender: Both

Accepts Healthy Volunteers?: Yes

Criteria: Inclusion Criteria:

- age of 18 years or older
- good oral and general health
- hygid anterior tooth with color shade higher than A2 on the Vita Classic scale (VITA Zahnfabrik, Bad Säckingen, Germany).

Exclusion Criteria:

- smoking, pregnancy or breastfeeding
- previous dental whitening
- para-functional habits
- dentin sensitivity
- anterior tooth with restorations and carious lesions
- non-vital decoloration
- unsatisfactory restorations

Contacts/Locations

Study Officials:

Locations:

References

Citations:

Links:

ANEXO 5 – Checklist Consort



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	13
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	13
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	14 and 15
	2b	Specific objectives or hypotheses	15
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	16
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Not applicable
Participants	4a	Eligibility criteria for participants	16 and 17
	4b	Settings and locations where the data were collected	16 and 17
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	18 to 19
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	20 to 23
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Not applicable
Sample size	7a	How sample size was determined	20

	7b	When applicable, explanation of any interim analyses and stopping guidelines	20
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	16 and 17
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	16 and 17
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	16 and 19
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	16 and 19
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	19
	11b	If relevant, description of the similarity of interventions	19
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	20
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	20
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	20
	13b	For each group, losses and exclusions after randomisation, together with reasons	20
Recruitment	14a	Dates defining the periods of recruitment and follow-up	20
	14b	Why the trial ended or was stopped	20

Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	20
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	20
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	21 and 22
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	21 and 22
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Not applicable
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Not applicable
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	24
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	22 to 24
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	22 to 24
Other information			
Registration	23	Registration number and name of trial registry	15 and 16
Protocol	24	Where the full trial protocol can be accessed, if available	15 and 16
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	24

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

ANEXO 6 – Carta de submissão da Revista (Brazilian Oral Research)

Submission Confirmation

Thank you for your submission

Submitted to

Brazilian Oral Research

Manuscript ID

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Title

Effects of desensitizing dentifrices on the reduction of pain sensitivity caused by in-office dental whitening

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ANEXO 7 – Normas da Revista (Brazilian Oral Research)



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Tables: These must be numbered and cited consecutively in the main text, in Arabic numerals. Tables must be submitted separately from the text in DOC, DOCX, or RTF format.

Discussion: This must discuss the study results in relation to the work hypothesis and relevant literature. It should describe the similarities and differences of the study in relation to similar studies found in literature, and provide explanations for the possible differences found. It must also identify the study's limitations and make suggestions for future research.

Conclusions: These must be presented in a concise manner and be strictly based on the results obtained in the research. Detailing of results, including numerical values, etc., must not be repeated.

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Reference citations must be identified in the text with superscript Arabic numerals. The complete reference list must be presented after the "Acknowledgments" section, and the references must be numbered and presented in Vancouver Style in compliance with the guidelines provided by the International Committee of Medical Journal Editors, as presented in Uniform Requirements for Manuscripts Submitted to Biomedical Journals (<http://www.ncbi.nlm.nih.gov/books/NBK7256/>). The journal titles should be abbreviated according to the List of Journals Indexed in Index Medicus

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- Results
- Discussion
- Conclusion
- Acknowledgments
- Tables
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Letters must include evidence to support an opinion of the author(s) about the scientific or editorial content of the BOR, and must be limited to 500 words. No figures or tables are permitted.

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 - Photographs, microradiographs, and radiographs (10 cm minimum width, 500 dpi minimum resolution) in TIFF format. (<http://www.ncbi.nlm.nih.gov/pmc/pub/filespec-images/>)
 - Charts, drawings, layouts, and other vector illustrations in a PDF format.
 - Each figure should be submitted individually in separate files (not inserted in the text file).

PUBLICATION FEES

Authors are not required to pay for the submission or review of articles.

EXAMPLES OF REFERENCES

Journals

Goracci C, Tavares AU, Fabianelli A, Monticelli F, Raffaelli O, Cardoso PC, et al. The adhesion between fiber posts and root canal walls: comparison between microtensile and push-out bond strength measurements. *Eur J Oral Sci.* 2004 Aug;112(4):353-61.

Bhutta ZA, Darmstadt GL, Hasan BS, Haws RA. Community-based interventions for improving perinatal and neonatal health outcomes in developing countries: a review of the evidence. *Pediatrics.* 2005;115(2 Suppl):519-617. doi:10.1542/peds.2004-1441.

Usunoff KG, Itzev DE, Rolfs A, Schmitt O, Wree A. Nitric oxide synthase-containing neurons in the amygdaloid nuclear complex of the rat. *Anat Embryol (Berl).* 2006 Oct 27. Epub ahead of print. doi: 10.1007/s00429-006-0134-9

Walsh B, Steiner A, Pickering RM, Ward-Basu J. Economic evaluation of nurse led intermediate care versus standard care for post-acute medical patients: cost minimisation analysis of data from a randomised controlled trial. *BMJ.* 2005 Mar 26;330(7493):699. Epub 2005 Mar 9.

Papers with Title and Text in Languages Other Than English

Li YJ, He X, Liu LN, Lan YY, Wang AM, Wang YL. [Studies on chemical constituents in

herb of Polygonum orientale]. Zhongguo Ahong Yao Za Zhi. 2005 Mar;30(6):444-6. Chinese.

Supplements or Special Editions

Pucca Junior GA, Lucena EHG, Cawahisa PT. Financing national policy on oral health in Brazil in the context of the Unified Health System. Braz Oral Res. 2010 Aug;24 Spec Iss 1:26-32.

Online Journals

Barata RB, Ribeiro MCSA, De Sordi M. Desigualdades sociais e homicídios na cidade de São Paulo, 1998. Rev Bras Epidemiol. 2008;11(1):3-13 [cited 2008 Feb 23]. Available from: <http://www.scielosp.org/pdf/rbepid/v11n1/01.pdf>.

Books

Stedman TL. Stedman's medical dictionary: a vocabulary of medicine and its allied sciences, with pronunciations and derivations. 20th ed. Baltimore: Williams & Wilkins; 1961. 259 p.

Books Online

Foley KM, Gelband H, editors. Improving palliative care for cancer [monograph on the Internet]. Washington: National Academy Press; 2001 [cited 2002 Jul 9]. Available from: <http://www.nap.edu/books/0309074029/html/>.

Websites

Cancer-Pain.org [homepage on the Internet]. New York: Association of Cancer Online Resources, Inc.; c2000 [cited 2002 Jul 9]. Available from: <http://www.cancer-pain.org/>.

Instituto Brasileiro de Geografia e Estatística [homepage]. Brasília (DF): Instituto Brasileiro de Geografia e Estatística; 2010 [cited 2010 Nov 27]. Available from: <http://www.ibge.gov.br/home/default.php>.

World Health Organization [homepage]. Geneva: World Health Organization; 2011 [cited 2011 Jan 17]. Available from: <http://www.who.int/en/>

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12 January 2017

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