NAYARA KELLY LYRIO FERRAZ

LONGEVIDADE, EFETIVIDADE, SEGURANÇA E IMPACTO NA QUALIDADE DE VIDA RELACIONADA À SAÚDE BUCAL DAS TÉCNICAS DE CLAREAMENTO DENTÁRIO CASEIRO E DE CONSULTÓRIO COM PERÓXIDOS DE BAIXA CONCENTRAÇÃO: *ENSAIO CLÍNICO RANDOMIZADO*

Faculdade de Odontologia
Universidade Federal de Minas Gerais
Belo Horizonte
2018

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Tese apresentada ao Colegiado de Pós-Graduação em Odontologia da Faculdade de Odontologia da Universidade Federal de Minas Gerais, como requisito parcial para obtenção do título de Doutor em Odontologia - área de Concentração: Clínica Odontológica

Orientador: Prof. (a): Claudia Silami de Magalhães
Co-orientador: Prof. (a): Allyson Nogueira Moreira

Belo Horizonte
2018

Ficha Catalográfica

F381l 2018 T

Ferraz, Nayara Kelly Lyrio.
Longevidade, efetividade, segurança e impacto na qualidade de vida relacionada à saúde bucal das técnicas de clareamento dentário caseiro e de consultório com peróxidos de baixa concentração: ensaio clínico randomizado / Nayara Kelly Lyrio Ferraz. -- 2018.

83 f. : il.

Orientadora: Claudia Silami de Magalhães.
Coorientador: Allyson Nogueira Moreira.

Tese (Doutorado) -- Universidade Federal de Minas Gerais, Faculdade de Odontologia.

1. Clareamento dental. 2. Qualidade de vida. 3. Peróxido de hidrogênio. I. Magalhães, Claudia Silami de. II. Moreira, Allyson Nogueira . III. Universidade Federal de Minas Gerais. Faculdade de Odontologia. IV. Título.

BLACK - D047

Elaborada pela Biblioteca da Faculdade de Odontologia - UFMG

FOLHA DE APROVAÇÃO

LONGEVIDADE, EFETIVIDADE, SEGURANÇA E IMPACTO NA QUALIDADE DE VIDA RELACIONADA À SAÚDE BUCAL DAS TÉCNICAS DE CLAREAMENTO DENTÁRIO CASEIRO E DE CONSULTÓRIO COM PERÓXIDOS DE BAIXA CONCENTRAÇÃO: ENSAIO CLÍNICO RANDOMIZADO

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Tese submetida à Banca Examinadora designada pelo Colegiado do Programa de Pós-Graduação em Odontologia, como requisito para obtenção do grau de Doutor, área de concentração Clínica Odontológica.

Aprovada em 13 de julho de 2018, pela banca constituída pelos membros:

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Belo Horizonte, 13 de julho de 2018.

AGRADECIMENTOS

Agradeço à Deus por ter me dado forças para continuar mesmo ante a adversidades; à minha família pelo apoio em todos os momentos da minha vida; à minha orientadora, professora Drª. Cláudia Silami de Magalhães, por ter compartilhado suas experiências e seu conhecimento; ao meu co-orientador, professor Dr. Allyson Nogueira Moreira, por ter me auxiliado na conclusão dessa etapa importante da minha vida; aos professores Drª Karine Tais Aguiar Tavano, Drª Amanda Beatriz Dahdah Aniceto Freitas, Drª Ivana Márcia Alves Diniz, Dr. Hugo Henriques Alvim, Drª Adriana Maria Botelho e Dr. Rodrigo Richard da Silveira por comporem a banca e enriquecerem este trabalho; à professora Drª Monica Yamauti, por ter contribuído no recrutamento dos pacientes; à minha amiga Lilian Capanema Nogueira, pela amizade, pelo companheirismo e por ter me ajudado a superar os desafios e os obstáculos; à minha nova amiga Isabela Moreira Neiva, pelo carinho, disponibilidade e amizade criada durante este período; às minhas amigas do grupo da revisão sistemática, Lilian, Monize, Marcela, Amanda e Ester pela amizade, ajuda e por todos os momentos que passamos no curso; aos amigos do doutorado do grupo de estatística, Dhelfeson, Carol, Alex, Leonardo, Frederico, Felipe, Clarissa, Monize e Lilian pelos momentos de estudo e descontração durante a conclusão da disciplina.
Agradeço ao CASEU por ter permitido a realização desse trabalho.

Ao professor Dr. Osmir Baptista de Oliveira Júnior, da FOAR-UNESP, pelo empréstimo de LED / laser Whitening Laser II DMC; a todos os pacientes pela colaboração e participação direta nesse trabalho; a UFMG, Faculdade de Odontologia e ao Colegiado de Pós-graduação por terem fornecido as condições necessárias para realização desse trabalho; à Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES) pelo suporte financeiro; a todos que estiveram envolvidos direta e indiretamente no desenvolvimento deste trabalho.

RESUMO

O objetivo desse estudo foi avaliar a longevidade, efetividade, segurança e o impacto na qualidade de vida relacionada à saúde bucal das técnicas de clareamento dentário utilizando baixas concentrações de peróxidos. Realizou-se um ensaio clínico randomizado, paralelo e simples cego. Os 81 participantes foram separados em três grupos (n=27): CP10%= Caseiro / peróxido de carbamida 10%(2 horas por dia durante 21 dias); HP6%= Consultório / peróxido de hidrogênio 6% (30 min/ sessão, 3 sessões, ativação luz LED/Laser); HP15%= Consultório / peróxido de hidrogênio 15% (30 min/ sessão, 3 sessões, ativação luz LED/Laser). A cor dos dentes foi avaliada em 5 momentos distintos: T1 (*Baseline*) = Antes do tratamento; T2 = 1 semana após o início do tratamento; T3 = 2 semanas após o início do tratamento; T4 = 1 semana após o final do tratamento e T5 = 6 meses após o final do tratamento, utilizando a escala de cor Vita Clássica e espectrofotômetro Vita Easy Shade Advance. A sensibilidade dentária foi avaliada utilizando a Escala Visual Numérica e a irritação gengival por meio do Índice Gengival Modificado - IGM. Para avaliação do impacto do clareamento na qualidade de vida utilizou-se o *Oral Impact on Daily Performance* (OIDP). Os dados foram analisados pelos testes de Friedman, Mann-Whitney, Qui-quadrado de Pearson e McNemar ($p<0,05$). Os resultados foram distribuídos em 2 artigos, de acordo com as comparações dos grupos CP10% e HP6% no primeiro artigo, e HP6% e HP15% no segundo artigo. No primeiro artigo, houve diferença estatisticamente significativa na mudança de cor (ΔE) de T1 para T4 em CP10% ($p<0,001$) e HP6% ($p<0,001$). Observou-se uma diferença significativa de ΔE em T4 entre CP10% (9,28) e HP6% (4,47) ($p=0,042$). A sensibilidade dentária foi significativamente maior ($p=0,008$) em CP10% (mediana=1,5) do que em HP6% (mediana=0,0), em T2. A irritação gengival diferiu significativamente ($p=0,002$) entre CP10% (mediana=0,2) e HP6% (mediana = 0,0), em T2. No segundo artigo não foram observadas diferenças significativas em relação aos parâmetros L*, a* ou b*, entre HP6% e HP15% de T1 a T5. Não foram observadas diferenças significativas entre os grupos HP6% e HP15% na sensibilidade dentária ou irritação gengival. Todos os protocolos utilizados apresentaram efetividade de clareamento. A técnica de consultório com HP6% e HP15% ocasionou baixa frequência de efeitos negativos como sensibilidade e irritação gengival. Nos dois artigos não houveram diferenças dos grupos quanto ao impacto na qualidade de vida relacionada à saúde bucal. No artigo um, a maior presença de efeitos negativos na técnica caseira não impactou significativamente a qualidade de vida relacionada à saúde bucal.

Palavras-chave: Clareamento dental. Qualidade de vida. Peróxido de hidrogênio.

ABSTRACT

Longevity, effectiveness, safety and and impact on oral health-related quality of life of at-home and in-office dental bleaching with low concentration peroxides: a randomized clinical trial

The objective of this study was to evaluate the longevity, effectiveness, safety and impact on oral health related quality of life of teeth whitening techniques using low concentrations of peroxides. A randomized, parallel and single blind trial was conducted. The 81 participants were separated into three groups (n = 27): CP10% = Homemade / 10% carbamide peroxide (2 hours per day for 21 days); HP6% = Office / Hydrogen peroxide 6% (30 min / session, 3 sessions, LED / Laser light activation); HP15% = Office / 15% hydrogen peroxide (30 min / session, 3 sessions, LED / Laser light activation). The color of the teeth was evaluated in 5 different moments: T1 (Baseline) = Before treatment; T2 = 1 week after initiation of treatment; T3 = 2 weeks after initiation of treatment; T4 = 1 week after the end of the treatment and T5 = 6 months after the end of treatment, using the Vita Classical color scale and Vita Easy Shade Advance spectrophotometer. Dental sensitivity was assessed using the Numerical Visual Scale and gingival irritation using the Modified Gingival Index - IGM. Oral Impact on Daily Performance (OIDP) was used to assess the impact of bleaching on quality of life. Data were analyzed by the Friedman, Mann-Whitney, Pearson's and McNemar's Chi-square tests ($p < 0.05$). The results were distributed in 2 articles, according to the comparisons of groups CP10% and HP6% in the first article, and HP6% and HP15% in the second article. In the first article, there was a statistically significant difference in color change (ΔE) from T1 to T4 in CP10% ($p < 0.001$) and HP6% ($p < 0.001$). A significant difference of ΔE in T4 was observed between CP10% (9.28) and HP6% (4.47) ($p = 0.042$). Dental sensitivity was significantly higher ($p = 0.008$) in CP10% (median = 1.5) than in HP6% (median = 0.0), in T2. Gingival irritation differed significantly ($p = 0.002$) between CP10% (median = 0.2) and HP6% (median = 0.0) in T2. In the second article no significant differences were observed in relation to the L *, a * or b * parameters, between HP6% and HP15% of T1 to T5. No significant differences were observed between HP6% and HP15% groups in tooth sensitivity or gingival irritation. All the protocols used showed bleaching effectiveness. The office technique with HP6% and HP15% caused low frequency of negative effects such as sensitivity and gingival irritation. In both articles there were no differences of the groups regarding the impact on quality of life related to oral health. In article one, the greater presence of negative effects in the homemade technique did not significantly affect the quality of life related to oral health.

Keywords: Dental bleaching. Quality of life. Hydrogen peroxide.

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1 CONSIDERAÇÕES INICIAIS

A preocupação com a aparência tem aumentado a busca pela odontologia estética (MEIRELES et al., 2010) . Os pacientes estão à procura não somente de dentes alinhados, mas também de dentes mais brancos (MEIRELES et al., 2010). O clareamento dentário é considerado a maneira mais conservadora para modificar a cor de dentes (MOGHADAM et al., 2013). É um tratamento não invasivo que pode alcançar resultados estéticos satisfatórios (TORRES et al., 2013). O clareamento se tornou cada vez mais popular, especialmente entre pacientes jovens (SAMORODNITZKY-NAVEH et al., 2007; TIN-OO et al., 2011), influenciando a percepção estética dos indivíduos, atratividade facial e o estatus de saúde bucal (MARQUES et al., 2009; PAULA JÚNIOR et al., 2009). Baseia-se na capacidade do peróxido de penetrar através da estrutura dentária e produzir radicais livres que oxidam as moléculas orgânicas responsáveis pela coloração dos dentes (TORRES et al., 2013). Diferentes protocolos têm sido propostos para melhorar a cor dos dentes com a maior parte das variações relacionadas aos protocolos de aplicação, concentração e ao tipo de agente clareador (AUSCHILL et al., 2005; HASSON et al., 2006; MATIS et al., 2009). O clareamento pode ser realizado no consultório, pelo dentista, ou em casa, pelos pacientes, com ou sem a supervisão do profissional (DEMARCO et al., 2011; MOGHADAM et al., 2013).

Em relação à efetividade de clareamento existem resultados divergentes. Alguns autores apontam o clareamento caseiro com resultados melhores e mais estáveis quando comparados à técnica de consultório (MATIS et al., 2007; GEUS et al., 2016). Outros autores tem demonstrado resultados similares de efetividade e durabilidade do efeito do clareador, tanto na técnica caseira quanto na de consultório (GIACHETTI et al., 2010). Apesar dos resultados efetivos produzidos por procedimentos clareadores, é importante que tanto os profissionais quanto os pacientes tenham conhecimento de certos riscos relacionados ao clareamento dental, como sensibilidade dentária e irritação gengival (CAREY, 2014). Os profissionais podem evitar o contato de géis de clareadores no consultório com o tecido gengival aplicando uma barreira gengival. No entanto, o peróxido de hidrogênio quando entra em contato com o tecido bucal, pode provocar queimaduras e ulcerações devido ao estresse oxidativo induzido por ele, o

que evidencia preocupações quanto à segurança dos protocolos de clareamento no consultório (REZENDE et al., 2016). As diferentes concentrações de peróxido utilizadas para procedimentos clareadores conduzem a uma resposta pulpar maior ou menor, uma vez que há evidências de penetração dos peróxidos através das estruturas do dente ocasionando inflamação do tecido, podendo desencadear a sensibilidade dentária durante o clareamento (DAHL; PALLESEN, 2003; VAZ et al., 2016).

Na técnica de consultório, são empregados agentes clareadores a base de peróxido de hidrogênio em concentrações que variam de 6 a 38% (JOINER, 2006; MATIS et al., 2007). O uso de concentrações mais baixas do agente clareador está associada com menores valores de sensibilidade dentária, tornando-se a primeira escolha dos profissionais, pois sugere maior biocompatibilidade e segurança quando comparados aos agentes clareadores de alta concentração (HE et al., 2012; BORTOLATTO et al., 2016). No clareamento caseiro, o agente clareador utilizado rotineiramente é o peróxido de carbamida em concentrações de 10 a 22%, aplicados em moldeiras individuais (HAYWOOD; HEYMANN, 1989; LIMA et al., 2008). Nessa técnica, a sensibilidade dentária decorrente do procedimento, geralmente está associada à concentração do agente clareador e ao regime de aplicação diária (AUSCHILL et al., 2005; BERNARDON et al., 2010, 2016). A utilização do dessensibilizante à base de oxalato de potássio à 3% associado ao fluoreto de sódio é efetiva na redução da sensibilidade dentária durante e após o clareamento, e não compromete a efetividade do tratamento (BERNARDON et al., 2016). A diminuição dos efeitos adversos decorrente do clareamento é almejada, pois pode acarretar diminuições dos impactos negativos na qualidade de vida dos indivíduos (MEIRELES et al., 2014).

Segundo a Organização Mundial da Saúde (SAXENA; ORLEY, 1997), a qualidade de vida pode ser definida como “a percepção do indivíduo de sua posição na vida, no contexto da cultura e do sistema de valores nos quais ele vive, e em relação aos seus objetivos, expectativas, padrões e preocupações”. A qualidade de vida dos indivíduos é fortemente influenciada por sua condição de saúde bucal (SHEIHAM et al., 2001). Todos os indivíduos devem dispor de uma condição de saúde bucal que lhes permita falar, mastigar, reconhecer o sabor dos alimentos, sorrir, viver livre de dor e desconforto, e se relacionar com outras pessoas sem constrangimento (PETERSEN,

2003). A qualidade de vida é uma preocupação relativamente nova na Odontologia. Os instrumentos que mensuram a qualidade de vida relacionada à saúde bucal (*Oral Health-Related Quality of Life* - OHRQoL) estão sendo cada vez mais utilizados em pesquisas odontológicas (PRECIADO et al., 2013a, 2013b).

Os instrumentos de avaliação de qualidade de vida podem ser genéricos ou específicos. Os genéricos avaliam vários aspectos da qualidade de vida e estado de saúde, podendo ser utilizados para pacientes, independentemente da doença ou condição, e também para pessoas saudáveis. Permitem comparar a qualidade de vida de portadores da mesma doença, de doenças diferentes, ou da população em geral. Contudo, podem falhar na sensibilidade para detectar aspectos particulares e específicos do impacto de determinada doença. Os específicos podem detectar particularidades da qualidade de vida em determinadas doenças e em relação a efeitos de tratamentos, podendo fornecer informações de relevância para o manejo dos pacientes, mas podem apresentar dificuldade no processo de validação psicométrica do instrumento pelo reduzido número de itens (PETERSEN, 2001).

A OHRQoL, por exemplo, tem sido utilizada como um desfecho para avaliar os tratamentos em ensaios clínicos e também para verificar efeitos adversos decorrentes do tratamento odontológico. Sabe-se que a percepção dos pacientes sobre a saúde bucal é importante na avaliação das necessidades odontológicas e na determinação dos resultados das intervenções que visam o restabelecimento da saúde bucal (MEIRELES et al., 2014). O *Oral Impact on Daily Living* (OIDP), por sua vez, é um instrumento de avaliação do impacto da qualidade de vida relacionada à saúde bucal. Ele tem sido amplamente utilizado por ser uma medida projetada para vincular problemas bucais específicos que levam aos impactos na qualidade de vida, associando tais impactos à condição bucal específica que necessite de atenção (ADULYANON et al., 1996). Este instrumento baseia-se em três dimensões principais afetadas por condições de saúde bucal: dor e desconforto, estética dentária e limitação de função (MEIRELES et al., 2014). O OIDP tenta usar uma abordagem lógica de quantificação para avaliar a gravidade e a frequência do impacto. A gravidade revela gradualmente a importância que o impacto exerce sobre os respondentes nas diferentes atividades diárias (RAMOS-JORGE, 2004).

O clareamento de dentes vitais pode impactar na OHRQoL dos indivíduos, melhorando sua satisfação com a aparência dental, mas pode produzir desconforto e

dor (MEIRELES et al., 2014). Embora a presença de dentes clareados possa influenciar positivamente na qualidade de vida relacionada à saúde bucal (OHRQoL), poucos estudos avaliaram o efeito do clareamento dentário na qualidade de vida, com diferentes amostras e resultados (MCGRATH et al., 2005; BRUHN et al., 2012; MEIRELES et al., 2014). Um estudo avaliou os efeitos do clareamento em indivíduos jovens e demostrou que os dentes mais brancos afetam positivamente a OHQoL. Foi utilizada também a escala de limitação funcional do *Oral Health Impact Profile* (OHIP), e os participantes relataram menor dificuldade de mastigação e melhor aparência global de seus dentes (MCGRATH et al., 2005). Outro estudo avaliou uma amostra de adultos mais velhos e o autor não detectou diferença estatisticamente significativa na OHIP global após o clareamento (BRUHN et al., 2012). Para avaliar as mudanças da saúde bucal e qualidade de vida, um estudo utilizou o *Oral Impact on Daily Living* (OIDP) em pacientes que foram submetidos ao clareamento caseiro. Observou-se que o clareamento tem efeito positivo na qualidade de vida, mas também tem efeitos negativos como dor e dificuldade de higienização (MEIRELES et al., 2014).

Os poucos estudos que avaliaram a influência do clareamento dentário na saúde bucal e qualidade de vida (MCGRATH et al., 2005; BRUHN et al., 2012; MEIRELES et al., 2014), compararam o impacto da técnica de clareamento caseiro, mas não compararam com a técnica de consultório. Ambas as técnicas de clareamento possuem particularidades que podem gerar efeitos que impactam positiva e negativamente a qualidade de vida dos indivíduos (MEIRELES et al., 2014). Dentre os aspectos positivos, podem estar relacionados os benefícios das mudanças de cor oriundas do clareamento, favorecendo o aumento da autoestima. Por outro lado, os efeitos adversos como a sensibilidade dentária, irritação gengival e o desconforto gerado pelo uso de moldeiras podem gerar uma influência negativa na vida cotidiana dos indivíduos (MEIRELES et al., 2014). A redução da concentração dos agentes clareadores visa diminuir os efeitos adversos oriundos do clareamento. Pode-se observar uma escassez de estudos que comparam o impacto das duas técnicas de clareamento utilizando baixa concentração do agente clareador na qualidade de vida relacionada à saúde bucal.

1.1. Objetivo geral

O objetivo deste estudo foi avaliar a longevidade, efetividade, a segurança e o impacto na qualidade de vida relacionada à saúde bucal das técnicas de clareamento dentário caseiro e de consultório utilizando peróxidos com baixa concentração.

1.2. Objetivos específicos

Avaliar e comparar a efetividade do clareamento realizado pela técnica caseira realizada com peróxido de carbamida a 10% e a técnica de consultório utilizando peróxido de hidrogênio a 6% e 15%.

Comparar a sensibilidade e irritação gengival em cada protocolo de clareamento avaliado.

Observar o impacto na qualidade de vida relacionada à saúde bucal do clareamento realizado pelos protocolos propostos.

2 METODOLOGIA EXPANDIDA

2.1. Desenho do estudo

Realizou-se um ensaio clínico randomizado, paralelo e simples cego. O pesquisador responsável pelas avaliações foi mascarado quanto ao tipo de clareamento, caseiro ou de consultório. Avaliou-se a longevidade, efetividade, sensibilidade e irritação gengival resultantes das técnicas e dos protocolos de clareamento, caseiro e de consultório, e seus impactos na qualidade de vida relacionada à saúde bucal. O clareamento dentário estendeu-se do segundo pré-molar do lado direito ao segundo pré-molar do lado esquerdo, das arcadas dentárias superior e inferior, em ambas as técnicas propostas. Os tempos de avaliações dos estudos foram definidos como: T1 (*Baseline*) = Antes do tratamento; T2 = 1 semana após o início do tratamento; T3 = 2 semanas após o início do tratamento; T4 = 1 semana após o final do tratamento e T5 = 6 meses após o final do tratamento. No decorrer do estudo, os indivíduos foram avaliados quanto à alteração de cor em 5 momentos. Sensibilidade dentária e irritação gengival foram avaliadas de T1 a T4. O impacto das duas técnicas de clareamento na vida cotidiana dos indivíduos e por consequência na qualidade de vida foi mensurado por meio do instrumento *Oral Impact on Daily Performance* (OIDP) para as duas técnicas e avaliado em T1 e T4. A descrição da metodologia do estudo foi conduzida de acordo com o *CONSORT Statement (Consolidated Standards of Reporting Trials)* (SCHULZ et al., 2010). Todos os indivíduos foram convidados a participarem da pesquisa, e após a breve explanação sobre os objetivos do estudo, aqueles que concordaram em participar, assinaram o Termo de Consentimento Livre e Esclarecido. O estudo foi aprovado pelo Comitê de ética em Pesquisa da Universidade Federal de Minas Gerais (Nº 1.269.466) e registrado no *Clinical Trials (*NCT02816593 https://clinicaltrials.gov/ct2/results?term=NCT02816593&Search=Pesquisa).

2.2. Cálculo do tamanho amostral e estudo piloto

Foram realizados dois cálculos amostrais utilizando o software Lee (http://www.lee.dante.br/pesquisa/amostragem/amostra.html), considerando as duas variáveis dependentes principais: a efetividade de clareamento e qualidade de vida

relacionada à saúde bucal. Considerando-se um nível de confiança de 95% e poder de 80%, realizou-se o cálculo amostral para comparação de duas médias utilizando como variável dependente a efetividade de clareamento (ΔE). Admitiu-se o desvio padrão de 3.71 (MARTÍN; VILDÓSOLA; et al., 2015) e uma diferença de 3.1 pontos na efetividade entre as técnicas de clareamento, considerada clinicamente relevante. Admitindo-se como variável dependente a qualidade de vida relacionada à saúde bucal, foi realizado o cálculo para testes de hipóteses para uma proporção. Considerou-se a proporção de impacto do clareamento na qualidade de vida relacionada à saúde bucal de 41,76% (MEIRELES et al., 2014), nível de confiança de 95%, poder de 80% e uma proporção esperada de impacto de 14,5%. Em ambos os cálculos, a amostra mínima necessária para o desenvolvimento do estudo foi de 22 pacientes por grupo. Para compensar possíveis perdas, foram acrescentados 20% ao cálculo, perfazendo um total de 27 participantes por grupo, totalizando 81 participantes. Um estudo piloto foi realizado com o objetivo de testar a metodologia sugerida e não constatou a necessidade de adequação da metodologia. Os participantes desse estudo não foram incluídos na amostra do estudo principal.

2.3. Seleção dos participantes

Participaram do estudo 81 adultos de 18 a 40 anos, de ambos os sexos. O recrutamento foi realizado dentre os usuários das clínicas de atenção odontológica da Faculdade de Odontologia da Universidade Federal de Minas Gerais (UFMG). Conjuntamente, foram recrutados indivíduos que demonstraram interesse em participar da pesquisa divulgada por meio de cartazes afixados nas dependências da UFMG. Os indivíduos foram selecionados por meio do exame clínico e anamnese. As avaliações de cor e a execução do clareamento foram realizadas nas clínicas da Faculdade de Odontologia da UFMG. Os critérios de inclusão englobaram pacientes sem doenças sistêmicas que contraindicassem o clareamento, coloração dentária variando entre A1 ou mais escuro, dentes com ausência de manchas e restaurações na região onde sereia realizado o tratamento e participantes sem experiência de clareamento prévia. Não foram incluídos no estudo participantes com gengivite e doença periodontal, apinhamento dental severo, fumantes, com sensibilidade dentária grave e mulheres grávidas. Os pacientes que não se enquadravam nos critérios de

elegibilidade e possuíam o desejo de realizar o clareamento foram encaminhados para a clínica de extensão em clareamento da UFMG.

2.4. Aleatorização e mascaramento

Os indivíduos que se enquadraram nos critérios de elegibilidade foram selecionados e alocados em três grupos. Previamente à aleatorização, todos os participantes foram moldados com alginato para confecção de modelos individuais em gesso. A aleatorização foi realizada utilizando 81 envelopes lacrados e numerados sequencialmente, designando um envelope para cada participante. Cada envelope continha uma técnica de clareamento, sendo 27 envelopes com a técnica caseira supervisionada (grupo 1), 27 com técnica de consultório 6% (grupo 2) e 27 com técnica de consultório 15% (grupo 3).

Durante a pesquisa, os pacientes passaram por duas salas: na primeira sala foram realizadas as avaliações de cor, sensibilidade, irritação gengival e aplicação do OIDP, por um pesquisador, sem tomar conhecimento do tipo de clareamento realizado. Na segunda sala foram realizados os procedimentos clareadores por outro pesquisador, independente das avaliações.

2.5. Procedimentos para avaliação de cor

Previamente à avaliação da cor inicial, foi realizada profilaxia dental com escova de Robson e pasta profilática em todos os pacientes, para eliminação de manchas extrínsecas.

Para o registro da cor antes, durante e após o tratamento clareador, foram utilizados dois métodos de avaliação: avaliação visual, utilizando escala de cor Vita Clássica (Vita-Zahnfabrik, Bad Säckingen, Baden-Württemberg, Alemanha); e avaliação quantitativa, utilizando espectrofotômetro Easy Shade (Easy Shade Advance ® Wilcos, Petrópolis, RJ, Brasil).

A avaliação de cor foi realizada em tempos pré-determinados, incluindo os segundos pré-molares do lado direito ao elemento correspondente do lado oposto, em

ambas as arcadas dentárias utilizando a escala Vita Clássica e no elemento 11 utilizando o espectrofotômetro Vita Easy Shade.

2.5.1. Avaliação visual – Escala de cor

A avaliação visual foi realizada por um examinador previamente treinado, calibrado e certificado pelo programa Toothguider Trainer Web (870 pontos dos 1000 avaliados) para a utilização da escala de cor Vita Clássica (Vita-Zahnfabrik, Bad Säckingen, Baden-Württemberg, Alemanha). A cor foi determinada no terço médio dos dentes. A escala de cor foi organizada por ordem decrescente de valor atribuindo um escore para cada valor, para fins de análise estatística: B1=1, A1=2, B2=3, D2=4, A2=5, C1=6, C2=7, D4=8, A3=9, D3=10, B3=11, A3,5=12, B4=13, C3=14, A4=15, C4=16 (MARTÍN; OVIES; et al., 2015). Foi selecionada a cor da escala que mais se aproximava à do dente avaliado e, em caso de dúvida, foi considerada a pior situação ou menor valor de cor. As avaliações de cor foram realizadas sob as mesmas condições de luz artificial obtidas pelo padronizador de luz Rite-Lite 2 (Rite-Lite 2®, Addent, Danbury, CT, USA). A cor total avaliada pela escala Vita foi considerada a cor mais prevalente nos dentes avaliados.

2.5.2. Avaliação quantitativa – Espectrofotômetro

Previamente à avaliação de cor foi confeccionado um guia de silicone de condensação para orientação e padronização da mensuração da cor usando o espectrofotômetro (Vita Easy Shade Advance®, Wilcos, Petrópolis, Rj, Brasil). Na superfície externa vestibular do guia de silicone foi criado orifício compatível com a ponta ativa do aparelho, localizado no terço médio da superfície vestibular. No momento da mensuração, a ponta do aparelho foi posicionada no orifício e, então, a cor foi avaliada 3 vezes no elemento 11, sendo o resultado final a média dos 3 valores (L*, a* e b*).

O espectrofotômetro mede a gradação de cor baseado no espaço de cor da CIEL*a*b, permitindo a determinação de cor tridimensional. É definido pela Comissão Internacional de Iluminação como CIELAB. O L representa o valor (claridade ou escuridão), o valor do a* é uma medida avermelhada (a* positivo) ou esverdeada (a*

negativo); o valor do b* é uma medida amarelada (b* positivo) ou azulada (b* negativo). O delta E foi obtido por meio da seguinte fórmula: $\Delta E^*=[(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}$. O clareamento é efetivo quando se observa, primordialmente, uma redução no amarelamento (um b* mais baixo) e um aumento no branqueamento (L* mais elevado) (MEIRELES et al., 2008). Para obtenção do ΔE, foi considerada a variação de cor em relação ao *baseline.*

2.6. Técnica de consultório

Após afastamento dos lábios utilizando o *expandex*, a mucosa foi protegida com vaselina sólida e foi confeccionada uma barreira para a proteção gengival (Lase protect, DMC Equipaments, São Carlos, SP, Brasil). No grupo HP6% foi aplicado o gel com peróxido de hidrogênio a 6% (Laser Peroxide Lite, DMC Equipaments, São Carlos, SP, Brasil). No grupo HP15% foi aplicado o gel com peróxido de hidrogênio a 15% (Laser Peroxide Lite, DMC Equipaments, São Carlos, SP, Brasil). Em ambos os grupos foram realizadas três aplicações de 10 minutos em cada consulta, em um total de 3 consultas, com intervalo de 7 dias entre elas (TAVARES et al., 2003). Os agentes clareadores foram ativados por meio de luz híbrida LED/laser (Whitening Laser II DMC Equipments, São Carlos, SP, Brasil) composto por 6 LEDs (470 nm / luz azul; Potência= 1.800 mW) e 3 lasers de baixa intensidade (808 nm / luz infravermelha; Potência= 600 mW) com área total de irradiação = 8,5 cm^2 e densidade de potência = 300 mW / cm^2. Em cada sessão de clareamento, o gel foi irradiado com 5 ciclos de 1 minuto por arco, alternando em ambos os arcos por 10 minutos.

2.7. Técnica caseira supervisionada

Para os participantes do grupo CP10%, foram confeccionadas moldeiras individuais em copolímero Etileno/Acetato de Vinila. No início do tratamento, todas as informações referentes ao uso do agente clareador foram fornecidas ao paciente, verbalmente e por escrito, no momento da entrega do gel clareador e da moldeira, no início do tratamento. O grupo 1 utilizou o peróxido de carbamida a 10% (Power Bleaching, BM4, Maringá, PR, Brasil). Os participantes foram orientados a

permanecerem com a moldeira durante 2 horas por dia, no decorrer de 3 semanas (MEIRELES et al., 2010).

2.8. Avaliação da segurança do clareamento - sensibilidade e irritação gengival

2.8.1. Avaliação de sensibilidade dentária

A sensibilidade dentária foi avaliada em quatro momentos distintos. Os participantes foram questionados quanto à incidência e intensidade da sensibilidade dentária total no decorrer da última semana de tratamento. O grau de sensibilidade relatado foi registrado de acordo com a Escala Visual Numérica (EVN), segundo os critérios: nenhuma (0), leve (1-2), moderada (3-7) ou intensa (8-10).

2.8.2. Avaliação da segurança - Índice Gengival Modificado

Empregou-se o Índice Gengival Modificado (IGM) (LOBENE et al., 1986), criado para a avaliação da condição gengival, registrando mudanças qualitativas na gengiva. O índice pontua a superfície marginal e os tecidos inter proximais separadamente com pontuação variando de 0 a 4. Os critérios usados foram os seguintes:

- ✓ 0 → Ausência de inflamação;
- ✓ 1 → Inflamação leve - ligeira alteração na cor e textura em parte da gengiva;
- ✓ 2 → Inflamação leve envolvendo toda a margem gengival;
- ✓ 3 → Inflamação moderada, superfície brilhante e edema;
- ✓ 4 → Inflamação grave, sangramento espontâneo e edema acentuado.

O IGM total por indivíduo foi obtido pela adição dos valores de cada dente e dividindo-se pelo número de dentes analisados. O índice gengival foi avaliado em quatro momento distintos de T1 à T4. A avaliação foi realizada por um examinador treinado e calibrado por um *expert* (Kappa inter examinador= 0,76; Kappa intraexaminador= 0,79).

2.9. Avaliação do impacto na qualidade de vida

A versão brasileira do *Oral Impact on Daily Performance* (OIDP) foi utilizada para avaliar o impacto na qualidade de vida (ABEGG et al., 2015). O instrumento foi

aplicado na forma de entrevista em dois momentos distintos, no *baseline* (T1) e uma semana após o final do tratamento (T4), para avaliar a percepção de mudanças na saúde bucal após o tratamento. De acordo com o instrumento, cada indivíduo foi questionado se, no último mês, ele havia enfrentado qualquer problema na sua saúde bucal que causou dificuldades como: comer e desfrutar de comida, falar e pronunciar claramente as palavras, higienizar os dentes, dormir, sorrir, sorrir mostrando seus dentes sem constrangimento, manter seu estado emocional sem se tornar aborrecido, a realizar seu trabalho ou estudos e desfrutar de contato com outras pessoas. As possíveis respostas foram sim e não. O participante que respondeu afirmativamente as perguntas e consequentemente que tenha relatado impacto em seu desempenho diário, foi indagado sobre o principal sintoma (dor, desconforto, limitação no trabalho, insatisfação com a própria aparência ou outro) e a principal condição bucal que, em sua opinião, que causou a dificuldade. O escore do impacto da qualidade de vida de cada condição bucal relatada pelos pacientes foi obtido multiplicando a frequência (1= menos de uma vez por mês; 2= de 1-2 vezes por mês; 3= de 1-2 vezes por semana; 4= de 3-4 vezes por semana; 5= todos os dias ou quase todos os dias) pela severidade (0= não tem afetado; 1= tem afetado muito pouco; 2= tem afetado pouco; 3= tem afetado mais ou menos; 4= tem afetado bastante; 5= tem afetado demais). O impacto total na qualidade de vida foi obtido pelo somatório de todos os escores de cada condição relatada pelo paciente (ALLEN, 2003).

2.10. Análise estatística

A análise estatística foi realizada por um pesquisador, mascarado quanto à identificação dos grupos avaliados. A análise dos dados foi realizada utilizando-se o programa Statistical Package for Social Sciences (SPSS for Windows, versão 24.0, SPSS Inc. Chicago, IL, EUA). As variáveis dependentes do estudo foram: efetividade de clareamento (ΔE avaliada do T1 a T5), sensibilidade (nenhuma (0); leve (1-2); moderada (3-7); intensa (8-10), avaliada do T1 a T4), irritação gengival (ausência de inflamação, inflamação leve, inflamação leve envolvendo toda a margem gengival, inflamação moderada e inflamação grave, avaliada do T1 a T4), qualidade de vida relacionada à saúde bucal (Alterações bucais: dor, desconforto, limitação no trabalho, a insatisfação com a própria aparência ou outro; Atividades diárias: comer, falar,

higienizar, sorrir, relações sociais, estado emocional, atividades cotidianas, dormir e relaxar; OIDP total, avaliado no T1 e T4). As variáveis independentes principais foram as técnicas de clareamento (caseira 10% e de consultório 6 e 15%) e os tempos das avaliações. Foram realizados análise descritiva, testes de comparação para variáveis categóricas (Qui-quadrado, Exato de Fisher e teste de McNemar), testes de comparação para uma variável quantitativa e uma categórica com dois fatores (Mann-Whitney e Wilcoxon) e testes de comparação para uma variável quantitativa e uma variável categórica com três ou mais fatores (Anova, Friedman e Kruskal-wallis), de acordo com o padrão de distribuição dos dados e homocedasticidade (Shapiro-Wilk e Levene $p<0,05$).

3 ARTIGO 1 SUBMETIDO À REVISTA BRAZILIAN ORAL RESEARCH

At-home and in-office dental bleaching with low concentration peroxides: a randomized clinical trial

Title Page

At-home and in-office dental bleaching with low concentration peroxides: a randomized clinical trial

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At-home and in-office dental bleaching with low concentration peroxides: a randomized clinical trial

Abstract

This single-blinded, randomized and parallel clinical trial aimed to evaluate the effectiveness, safety and impact on oral health-related quality of life of at-home and in-office dental bleaching using low concentration peroxides. 54 participants were allocated into G1= at-home/ 10% carbamide peroxide (2 hours per day during 3 weeks), and G2= in-office/ 6% hydrogen peroxide with total time of contact of 90 min under irradiation of LED/Laser. Tooth color was evaluated in: baseline (T1), 1 week of bleaching (T2), 2 weeks of bleaching (T3) and 1 month after the beginning of bleaching (T4), using the Classical Vita® scale and spectrophotometer. Tooth sensitivity and gingival irritation were measured by the numeric visual scale and the modified gingival index, respectively. The impact on quality of life was evaluated using the Oral Impact on Daily Performance. Data were analysed using Friedman, Mann-Whitney and McNemar tests ($p<0.05$). There was a statistically significant difference in shade (ΔE) from T1 to T4 in G1 ($p<0.001$) and G2 ($p<0.001$). There was a significant difference in ΔE at T4 between G1 (9.28) and G2 (4.47) ($p=0.042$). The tooth sensitivity ($p=0.008$) and gingival irritation ($p=0.002$) presented in group 1 (CP10%) were statistically higher than in group 2 (HP6%) at times T2 and T4. Both techniques presented bleaching effectiveness. The techniques did not differ in the impact on quality of life related to oral health. The greater presence of negative effects for the at-home technique did not significantly affect quality of life related to oral health.

Keywords: Dental bleaching, Quality of life, Hydrogen peroxide, Bleaching agents.

I. INTRODUCTION

The most effective, minimally invasive and biologically safe method for modifying tooth colour is the bleaching procedure [1–4]. Basically, there are two bleaching techniques that are performed in the office by the dentist or at home by the patients with the professional's supervision [5,6]. At-home bleaching is often indicated for vital teeth; however, due to the reluctance of some patients to use trays daily for several weeks, the in-office technique has been an option to produce more immediate results[5]. The two techniques present different protocols that aim to improve the colour of the teeth, with most of the variations related to the concentration and type the peroxide employed [7–9]. Peroxides are highly unstable and when in contact with the outer surface of the enamel, they decompose into water, oxygen and free radicals. The latter diffuse through the enamel, causing oxidation and elimination of organic pigments from dentin [4,10]. The decomposition of hydrogen peroxide (HP) causes a decrease in the environment pH that could promote tooth demineralization. The 10% carbamide peroxide (CP), when degraded, releases 3% hydrogen peroxide and urea, which help maintain pH at neutral levels, thus reducing the possibility of mineral losses [2,6,8]. Teeth bleaching results depend mainly on the concentration of the bleaching agent, on the ability of the agent to reach the chromophore molecules and on the duration and number of times the agent is in contact with these molecules [11].

At-home bleaching may employ different concentrations of carbamide peroxide and hydrogen peroxide, which are placed in an individualized tray and administered daily for 2 to 6 weeks [1–3,12]. The 10% carbamide peroxide can be considered the standard product for at-home bleaching [3], in addition to having established safety and effectiveness in clinical trials [9,10,13]. At-home bleaching has a low incidence of tooth sensitivity or gingival irritation and lowers the need to visit the dental office [9,10,13]. However, at-home bleaching requires direct patient collaboration [14]. In-office bleaching uses different concentrations of hydrogen peroxide, which is applied directly to the dental surface [4,15,16]. In-office bleaching may show significant results after only one application but may require longer application times for better results [17] .However, increasing the time of application and the number of sessions may increase the risk of tooth sensitivity [14]. The American Dental Association (ADA) [18] considers products with concentrations of up to 3.5% hydrogen peroxide as safe to use, whereas the Scientific Committee on Consumer Products (SCCP) [19] of the European Union approves of

products with up to 6.0% hydrogen peroxide. Higher concentrations of peroxides result in more adverse effects, such as sensitivity and gingival irritation [20]. Bleaching agents for use in a clinic with a lower concentration of hydrogen peroxide (3.5-15%) and containing a semiconductor agent (nanoparticles of titanium dioxide doped with nitrogen, TiO_N) were developed with the aim of increasing safety and maintaining effectiveness compared to the conventional formulations [21].

Quality of life is considered an indicator of health and is markedly influenced by satisfaction or dissatisfaction with oral health [23]. The individuals' concerns are essentially related to comfort, function and aesthetics [23]. When these factors do not meet the expectations of the patient, psychosocial responses, such as anxiety, insecurity, reduced self-esteem and introversion, can be triggered [23]. People perceive the importance of oral health for quality of life in a variety of forms in the physical, social and psychological domains [23]. Tooth bleaching can generate a positive effect on aesthetic perception and on the psychosocial comfort of individuals [24]. Aesthetics is a subjective perception that varies from individual to individual. The assessment of the dental aesthetics or the effectiveness of any intervention designed to alter such aesthetics should consider the patient's perception and the clinical observation of the professional [25]. Although the improvement in the perception of aesthetics with the presence of bleached teeth could interfere with the oral health-related quality of life (OHRQoL), few studies have evaluated the effect of bleaching and its adverse effects on individuals' quality of life [12,24,26–28]. Controversial results have been observed in studies that evaluated the impact of home bleaching on individuals' quality of life [10,26,27]. Whiter teeth have been reported to positively affect OHRQoL by improving the overall appearance of teeth [26]. However, there are reports that tooth bleaching did not positively or negatively affect individuals [27].

The instruments for assessing oral health and quality of life are considered subjective and seek to evaluate the impact of oral health status on quality of life [29]. The Oral Impact on Daily Performance (OIDP) measures the consequences of oral disease on three levels, including oral health status, changes in oral tissues and ability to perform daily activities [30]. This instrument has the advantages of having an objective approach that encompasses the main consequences, avoids overlapping of repeated scores of the same impact and records only the significant impact [30]. At-home bleaching had a positive effect on quality of life, as measured by OIDP but also had

negative effects, such as pain and oral hygiene difficulty [28]. It was also reported that in-office bleaching with low concentration peroxides positively affected aesthetics and had less adverse factors that impact oral health-related quality of life (Oral Health Impact Profile, OHIP) compared to high-concentration peroxides [12,24].

Previous studies have evaluated the impact of dental bleaching on oral health-related quality of life [12,24,26–28] and considered only one bleaching technique, at-home or in-office, using different concentrations of peroxides. The impact of at-home bleaching with low concentration of peroxide was evaluated using OIDP [28] and OHIP [26,27]. On the other hand, the impact of in-office bleaching on the quality of life related to oral health was evaluated using OHIP, and low- and high-concentration peroxides were compared [12,24]. There is a shortage of studies comparing the effect of different bleaching techniques with low concentration peroxides on the quality of life related to the oral health of the individuals observed. Thus, the objective of the present study was to evaluate the effectiveness, safety and impact on oral health-related quality of life of at-home and in-office teeth bleaching techniques using low-concentration peroxides.

II. METHODOLOGY

A randomized, parallel and single-blinded clinical trial was designed to evaluate the effectiveness, tooth sensitivity and gingival irritation of at-home and in-office bleaching, as well as their impact on quality of life related to oral health. The study was approved by the University Ethics Committee (Process nº 1.269.466), registered in the Clinical Trials (NCT02816593 - https://clinicaltrials.gov/ct2/results?term=NCT02816593&Search=Pesquisa) and was reported in accordance with the CONSORT Statement (Consolidated Standards of Reporting Trials) [31].

The examiners were blinded to the bleaching techniques. The individuals were invited to participate, and after a brief explanation of the objectives of the study, those who agreed signed the informed consent form. For both techniques, the participants had tooth bleaching from the second premolar on the right side to the second premolar on the left side and the upper and lower dental arches. The evaluation times were defined as follows: before bleaching (T1), 1 week after the initiation of bleaching (T2),

2 weeks after the initiation of bleaching (T3) and 1 month after the beginning of bleaching (T4). The participants were assessed for shade change, tooth sensitivity and gingival irritation from T1 to T4. The impact of tooth bleaching on the daily life of individuals, and consequently, on quality of life, was measured using the Oral Impact on Daily Performance (OIDP) instrument for both techniques at T1 and T4.

Two sample calculations were performed for the two main dependent variables: the effectiveness of bleaching and the quality of life related to oral health. Considering the standard deviation of 3.71 [24] and a difference of 3.1 points in the effectiveness (ΔE) between the bleaching techniques that is considered clinically relevant, the sample calculation was performed with a 95% confidence level and 80% power. With quality of life related to oral health as the dependent variable, the calculation for the hypothesis test for a proportion of bleaching impact was considered to be 41.76% [28], assuming a 95% confidence level, 80% power and an expected impact ratio of 14.5%. In both calculations, the minimum sample size required for the development of the study was 22 participants per group. To offset possible losses, 20% was added to the calculation, resulting in a total of 27 participants per group and totalling 54 participants.

Users of the university dental care clinics and individuals interested in participating in the research, as advertised through posters on the university premises, were recruited. All evaluations and procedures were carried out at the university clinics. We included 54 adults of both genders between 18 and 40 years of age. Inclusion criteria were as follows: good general health status and an absence of systemic diseases; dental shades ranging from A1 or more darkened, according to the Classical Vita Scale; teeth without blemishes or restorations in the region of bleaching; and no previous bleaching experience. Individuals with severe dental crowding or severe tooth sensitivity or those who were pregnant or smokers were excluded from the study.

Individuals who met the eligibility criteria were selected and allocated to two groups. Prior to randomization, alginate impressions from all participants were made and cast in plaster. Randomization was performed using 54 sealed envelopes that were sequentially numbered, with one envelope designated for each participant. Each envelope contained a bleaching technique, such that 27 envelopes had the 10% carbamide peroxide at-home technique (group 1) and 27 had the 6% hydrogen peroxide in-office technique (group 2).

During the experiment, in a first room, one examiner blinded to the bleaching technique assessed the patients for shade, tooth sensitivity, gingival irritation and questionnaire application. In a second room, one operator independently performed the bleaching procedures.

Prior to the initial shade evaluation, all patients had dental prophylaxis with Robinson brush and prophylactic paste to eliminate extrinsic stains. The evaluations of color were on upper and lower dental arches from the right second premolar to the left second premolar. Tooth shade was evaluated before, during and after the bleaching treatment using Classical Vita Scale (Vita-Zahnfabrik, Bad Säckingen, Baden-Württemberg, Germany) and the Vita Easy Shade spectrophotometer (Easy Shade Advance® Wilcos, Petrópolis, RJ, Brazil). A trained examiner, calibrated and certified by the Toothguide Trainer Web programme (870 points of the 1000 evaluated) performed the visual evaluation using the Classical Vita Scale (Vita-Zahnfabrik, Bad Säckingen, Baden-Württemberg, Germany) on the middle third of the teeth. Shade evaluations were performed under the same conditions of artificial light obtained by the Rite-Lite 2 light standardizer (Rite-Lite 2®, Addent, Danbury, CT, USA). The 16 shade guide tabs were arranged from highest (B1) to lowest (C4) value, and each tab was given an ordered number (from 1 to 16) [15]. The total shade evaluated by the Vita scale was the most frequent shade of the evaluated teeth, and the worst situation was chosen in the case of a tie.

A condensation silicone guide was prepared for orientation and standardization of the shade measurement using the spectrophotometer (Vita Easy Shade Advance®, Wilcos, Petrópolis, RJ, Brazil). The tip of the device was placed in the hole made in the middle third of the vestibular surface of the silicone guide, and the shade was evaluated 3 times in tooth 11. The final result was the mean of 3 values (L, a* and b*). The spectrophotometer measures the shade gradation based on the shade space CIEL*a*b, allowing the determination of three-dimensional shade. It is defined by the International Commission on Illumination as CIELab. L represents the value lightness (or darkness); the value of a * is a reddish (a * positive) or greenish (a * negative) measure; and the value of b * is a yellowish (b * positive) or blue (b * negative) measure. Shade change ΔE was obtained by the following formula: $\Delta E^* = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}$. Bleaching is effective when there is primarily a reduction in

yellowing (a lower b *) and an increase in lightness (L *) [32]. To obtain ΔE, the shade variation was considered in relation to the baseline.

For at-home bleaching (group 1), individual trays were made in ethylene vinyl acetate copolymer. At the start of the treatment, verbal and written information regarding the use of the bleaching gel was given to the patient. Participants were instructed to fill the tray with 10% carbamide peroxide (Power Bleaching, BM4, Maringá, PR, Brazil) and wear it for 2 hours a day over the course of 3 weeks [13]. For in-office bleaching (group 2), the mucosa of the lips was protected with solid petroleum jelly, and a gingival barrier (Lase protect, DMC Equipment, São Carlos, SP, Brazil) was applied and light cured (10 s). Three applications (10 minutes each) of 6% hydrogen peroxide gel (Lase Peroxide Lite, DMC Equipment, São Carlos, SP, Brazil) per consultation were performed in a total of three consultations, with a 7-day interval among them.[33] The bleaching agent was activated via hybrid LED/laser light (Whitening Laser II DMC Equipment, São Carlos, SP, Brazil) consisting of 6 LED (470 nm / blue light; Power =1,800 mW), and 3 low-intensity lasers (808 nm / infrared light; Power = 600 mW) with total area of irradiation= 8.5 cm^2 and power density = 300 mW/cm^2. In each bleaching session, the gel was irradiated with 5 cycles of 1 minute per arch, alternating in both arches for 10 minutes. [22].

Tooth sensitivity was assessed from T1 to T4. Participants were asked about the presence and intensity of tooth sensitivity or pain during the last week of treatment. The degree of tooth sensitivity reported was recorded according to the visual numeric scale (VNS) using the following criteria: none (0), mild (1 and 2), moderate (3 to 7) or intense (8 to 10).

Gingival irritation was assessed using a calibrated examiner (intra-examiner kappa of 0.79) using the Modified Gingival Index (MIG) [34]**.** The index scores the marginal surface and interproximal tissues separately, with scores ranging from 0 to 4: 0-No inflammation; 1-Mild inflammation—slight change in colour and texture in part of the gingiva; 2-Mild inflammation involving the entire gingival margin; 3-Moderate inflammation, shiny surface and edema; and 4-Severe inflammation, spontaneous bleeding, and marked edema. The total MGI per individual was obtained by adding the values of each tooth and dividing by the number of teeth analysed.

The Brazilian version of Oral Impact on Daily Performance (OIDP) [35] was administered as an interview at the baseline (T1) and one week after the end of

treatment (T4) to evaluate the perception of changes in oral health after treatment. Each individual was asked if, in the last month, he had faced any problem in his oral health that caused difficulties in the following activities: eating and enjoying food, speaking and pronouncing words clearly, cleaning teeth, sleeping, smiling, smiling while showing your teeth without embarrassment, maintaining your emotional state without becoming bored, carrying out your work or studies and enjoying contact with other people. The possible answers were yes and no. When the participant reported impacts on their daily performance, he was asked about the main symptom (pain, discomfort, limitations at work, dissatisfaction with one's appearance, or other symptom) and the main oral condition that, in his opinion, caused the difficulty. The impact of each oral condition reported by the patients was evaluated according to the frequency (1: less than 1 time per month, 2: 1-2 times a month, 3: 1-2 times a week; 4: 3-4 times a week, 5: every day or almost every day) and severity (1: No effect, 2: Very little effect, 3: Little effect, 4: Moderate effect, 5: Extreme effect). The OIDP for each domain was obtained by multiplying the frequency by severity. The total impact on quality of life was the sum of all scores for each condition reported by the patient.

Statistical analysis was performed by a researcher, who was blinded to the identification of the groups evaluated, using the Statistical Package for Social Sciences (SPSS for Windows, version 24.0, SPSS Inc. Chicago, IL, USA). The dependent variables were as follows: bleaching effectiveness (ΔE evaluated from T1 to T4), tooth sensitivity (none, mild, moderate or severe, assessed from T1 to T4), gingival irritation (absence of inflammation, mild inflammation, mild inflammation involving all gingival margins, moderate inflammation and severe inflammation, evaluated from T1 to T4) and quality of life related to oral health (oral changes: pain, discomfort, work limitation, dissatisfaction with one's appearance or other changes; talking, hygiene, smiling, social relations, emotional state, daily activities, sleeping and relaxing; total OIDP evaluated in T1 and T4). The independent variables were bleaching techniques (at-home: 10% carbamide peroxide; in-office: 6% hydrogen peroxide) and time of evaluation (T1 to T4). In the comparisons of the whitening technique with the categorical variables, socioeconomic factors, OIDP domains and total OIDP, linear associations, chi-square tests and McNemar tests were performed, respectively. Before performing the comparison of the quantitative variables, the distributions and homoscedasticity of the parameters of colour, tooth sensitivity and gingival irritation,

were verified (Shapiro-Wilk and Levene, $p<0.05$). Quantitative variables were compared in relation to the groups and the time of evaluation using the tests for comparisons of quantitative variables and a categorical variable with two levels (Mann-Whitney and Wilcoxon) and comparative tests of quantitative variables and a categorical variable with three or more factors (ANOVA, Friedman and Kruskal-Wallis).

III. RESULTS

Figure 1 specifies the patient flow in the course of the study. Both groups started treatment with 27 participants and concluded with 26 individuals.

Figure 2 depicts the distribution of patients in the groups according to the shade value belong the bleaching. At the end of the bleaching, 16 participants reached B1 in at-home bleaching and 12 reached B1 in in-office bleaching.

Table 1 describes the socioeconomic characteristics of the participants according to the treatment groups. There was no statistically significant difference between the groups, demonstrating the similarity between them.

Figure 3 presents the results of ΔE relative to the baseline comparisons and the evaluation times. Considering the effectiveness of the bleaching in intragroup comparisons, the two techniques showed statistically significant differences in the ΔE from T1 to T4. In the intergroup comparison at T4, the bleaching effectiveness of group 1 (CP10%) was significantly greater ($p=0.042$) than that of group 2 (HP6%).

Tooth sensitivity was reported by 57.7% of the participants with at-home bleaching and 29.6% with in-office bleaching at T2. Gingival irritation was observed in 76.9% of the participants with at-home bleaching and 48.1% with in-office bleaching at T2, demosntated in the Figure 4. Table 2 shows the comparison of tooth sensitivity and gingival irritation between groups and among evaluation times. The tooth sensitivity and gingival irritation presented in group 1 (CP10%) were statistically higher than in group 2 (HP6%) at times T2 and T4.

Table 3 reports the domains and the initial and final total OIDP according to the groups. There was no statistically significant difference between the groups in relation to the domains and global OIDP.

IV. DISCUSSION

In the present study, at-home and in-office techniques showed bleaching effectiveness and low levels of tooth sensitivity and gingival irritation. The bleaching techniques did not affect the quality of life related to the oral health of the participants. At-home bleaching using 10% carbamide peroxide has shown several levels of bleaching effectiveness (ΔE): 4.18[36], 4.3 [10], 6.6 [37], 6.9 [1], 8.9 [38], and 9.3 [39], with different application protocols and trademarks of bleaching agents. In the present study, the bleaching effectiveness of CP10% at home was higher (ΔE=9.28) than that of other techniques that used different brands [1,10,36–38] and was equal to that using the same trademark, with ΔE=9.3 [39]. In the present study, the effectiveness of HP6% in-office bleaching (ΔE=4.47) was similar to that of other studies that used the same HP concentrations and protocols presented [21,24,40]. The parameter ΔE is the shade difference between two objects or the same object evaluated in two distinct moments, calculated within the CIELAB colour system [41]. The naked eye is able to distinguish colour differences if the value of ΔE is higher than 3.3.[18] In the present study, both bleaching techniques had values of ΔE higher than 3.3, confirming the clinical effectiveness of tooth bleaching observed with the naked eye.

Tooth sensitivity is one of the most common side effects associated with whitening therapy [2,8]. In the present study, 57% of the participants from at-home bleaching reported tooth sensitivity (median=1.5 at T2). The in-office bleaching group reported tooth sensitivity in 29.6% of participants (median=0.0 at T2). The tooth sensitivity of at-home bleaching was significantly higher than that of in-office bleaching. These results corroborate the tooth sensitivity rate found in studies using CP10% from different brands [36–38,42]. However, our results contrast with those of the study using the bleaching agent of the same trademark, in which 100% of the sample reported zero tooth sensitivity [39]. The divergence between the studies can be attributed to the frequency and instruments of evaluations. In the present study, the evaluations were weekly using numeric visual scale, becoming susceptible to the memory bias, whereas in the other study, the evaluations were daily with visual analogue scale. For HP6% in-office bleaching, the tooth sensitivity rate found in the present study was higher than that presented in Bortolato et al., (2016) [21] and lower than the rate of 50% [24] from Martin et al., (2015). The tooth sensitivity caused by bleaching may interfere with the

level of patient satisfaction with the procedure, and in cases of greater intense tooth sensitivity, treatment discontinuation may occur [6].

Gingival irritation from at-home bleaching is mainly associated with trauma due to the tray and the extravasation of the products resulting from the decomposition of carbamide peroxide that reaches the gingival tissue [2]. In the present study, among the participants who performed the at-home bleaching, 76.9% had gingival irritation (median=0.20 at T2). For the in-office technique, 48.1% of the patients had gingival irritation in at least one site (median=0.0) at T2. In both groups, the median gingival irritation was considered mild, although the gingival irritation of participants performing the at-home technique was statistically higher at T2 and T4. Previous studies that evaluated gingival irritation with the visual analogue scale found a rate of 2% [37], which is lower than the results of the present study, and found an irritation mean of 0.38 [7], which is higher than that observed in the present study. In the study by Bizhang (2009), the rate of gingival irritation for at-home bleaching (28%) was lower than the rate found in the present study [36]. This difference may have occurred due to the higher tooth sensitivity index used in the present study. However, Bernardon et al. (2016) did not observe gingival irritation during the course of an at-home treatment [39], even when using the gingival index of Löe. The frequency of gingival irritation for the HP6% in-office bleaching in the present study (48.1%) was similar to the rate of 52% [36] found with HP 15%. Despite this similarity, the index of the evaluation of the gingival irritation index used in the present study presents higher tooth sensitivity compared to that shown in the patient's report. The comparison of gingival irritation from at-home and in-office bleaching in the present study corroborates the findings of Zekonis et al. (2003) [42]. Both studies found statistically higher gingival irritation for at-home compared to in-office bleaching, even when they used CP10% and HP 35%, respectively. Despite the different peroxide concentrations, gingival irritation is more associated with the at-home bleaching.

Considering the impact of the in-office bleaching on quality of life related to oral health, a greater number of patients reported difficulties in different domains, although none of the domains presented statistically significant differences. Meireles et al. (2014) used OIDP to evaluate the impact of at-home bleaching on oral health-related quality of life. They observed statistically significant differences in the domains of hygiene and smile when comparing the evaluations before and after the tooth

bleaching [28], in contrast to the results of the present study. This finding may be due to the greater number of participants in the Meireles study, as all participants from two protocols (CP 10 and 16%) were joined in a single group, since there was no difference in the effect of bleaching and tooth sensitivity before and after treatment. The study by Martin et al. (2015) evaluated the oral health-related quality of life of HP6% and 35% bleaching practices using the OHIP-14. They observed a statistically significant difference in the domains of functional limitation, psychological discomfort and global impact [24], in contrast to the results of the present study. Despite the similarity in sample size, the difference in the instruments used may have contributed to the difference in results.

In the present study, positive or negative impacts of the bleaching effect on individuals' lives were not observed. The positive effect on quality of life can be observed when there is a reduction in the negative impacts evaluated by the OIDP. However, the sample selected had no negative impacts of dental staining before the treatment, which could be a limitation of this study. Despite the change resulting from bleaching, shade modification did not result in a reduction of negative impacts, since such negative impacts did not exist from the beginning of treatment. The deleterious effects of bleaching, such as tooth sensitivity and gingival irritation, were mild and did not negatively impact the individuals' quality of life.

V. CONCLUSION

At-home and in-office bleaching using low concentration peroxides showed significantly effective bleaching results. At-home bleaching with CP10% promoted greater bleaching effectiveness than HP6% in-office bleaching. The at-home bleaching technique presented tooth sensitivity and gingival irritation that were significantly greater than those of the in-office technique. Despite the higher levels of irritation and tooth sensitivity in the at-home technique, both techniques were similar and did not impact oral health-related quality of life.

ACKNOWLEDGMENTS

The authors are grateful to CAPES (Coordenação de Aperfeiçoamento de Pessoal de Nível Superior) for the scholarship to Nayara Kelly Lyrio Ferraz and to the Postgraduate Collegiate (Faculty of Dentistry, Universidade Federal de Minas Gerais).

We thank Prof. Dr. Osmir Batista de Oliveira Júnior, FOAR-UNESP, for loaning the LED/laser equipment Whitening Laser II DMC.

INTEREST CONFLICTS

The authors declare that they have no conflicts of interest.

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Tables

Table 1: Description of socioeconomic factors of the groups evaluated

	G1 CP[1] 10% n (%)	G2 HP[2] 6% n (%)	*p**
Gender			
Male	13(48.1)	11(40.7)	
Female	14(51.9)	16(59.3)	0.411
Total	27(100)	27(100)	
Age			
18-29	19(70.4)	18(66.7)	0.362
30-40	8(29.6)	9(33.3)	
Civil status			
Single	19(70.4)	17(63.0)	
Married	7 (25.9)	9(33.3)	0.433
Divorced	1(3.7)	1(3.7)	
Education			
≤ High school	6(22.2)	7(25.9)	0.507
≥ College	21(88.8)	20(74.1)	
Mother			
≤ High school	24(88.9)	21(87.8)	0.446
≥ College	3(11.1)	6(22.2)	
Father			
≤ High school	22(81.5)	21(77.8)	0.296
≥ College	5(18.5)	6 (22.2)	
Monthly income[3]			
< 2 Minimum wages	2(7.4)	1(3.7)	1.00
≥ 2 Minimum wages	25(92.6)	26(96.3)	
Number of children			
≤ One	25(92.6)	24(88.9)	0.261
> Two	2(7.4)	3(11.1)	
People living on income			
≤ Three	17(63.0)	21(77.8)	
> Four	10(17.0)	6(22.2)	0.770

* Linear Association [1] Carbamide Peroxide [2] Hydrogen Peroxide
[3]Minimum wages ($ 296.68)

Table 2: Tooth sensitivity and gingival irritation assessment reported for groups and times of application

Tooth sensitivity					
Protocol	**T1**	**T2**	**T3**	**T4**	***p*****
	Median (ID[1])	Median (ID[1])	Median (ID[1])	Median (ID[1])	
G1 – CP[2] 10%	1.00 (3)[a]	1.50 (5)[b]	0.00 (2)[ca]	0.00 (3)[abc]	0.09
G2 – HP[3] 6%	0.00 (2)[a]	0.00 (2)[a]	0.00 (0)[a]	0.00 (0)[a]	0.15
P* Value	0.312	0.008	0.504	0.044	
Gingival irritation					
Protocol	**T1**	**T2**	**T3**	**T4**	
	Median (ID[1])	Median (ID[1])	Median (ID[1])	Median (ID[1])	***p*****
G1 – CP[2] 10%	0.10 (0.16)[a]	0.20 (0.46)[b]	0.07 (0.16)[a]	0.07 (0.15)[a]	0.05
G2 – HP[3] 6%	0.10 (0.36)[a]	0.00 (0.10)[b]	0.05 (0.10)[b]	0.00 (0.05)[cb]	0.004
P* Value	0.365	0.002	0.168	0.013	

[1] Interquartile distance [2] Carbamide Peroxide [3] Hydrogen Peroxide

** Mann Whitney comparison of lines **Friedman /Post hoc on the same line: different lowercase letters - statistical difference

Table 3: Oral impact on daily performance, according to OIDP domains, before and after bleaching (Belo Horizonte, MG, Brazil)

	OIDP										
	G1 – CP[1] 10% Impact (n)					**G2 –**HP[2] 6% Impact (n)					**G1/G2**	**G1/G2**
	Before		After			Before		After			Before	After
Domains	Yes	No	Yes	No	*p**	Yes	No	Yes	No	*p**	*p***	*p***
Eat	0	26	3	23	0.25	4	22	6	20	0.72	0.063	0.524
Talk	0	26	0	26	-	0	26	0	26	-	-	0.363
Oral hygiene	0	26	1	25	1.00	1	25	2	24	1.00	0.159	0.333
Smile	0	26	0	26	-	1	25	2	24	1.00	0.599	0.115
Social relationships	0	26	0	26	-	0	26	0	26	-	-	0.363
Emotional state	1	25	0	26	1.00	2	24	1	25	1.00	0.354	0.363
Occupational activities	0	26	0	26	-	0	26	0	26	-	-	0.128
Sleep-relax	1	25	1	25	1.00	0	26	2	24	0.50	0.354	0.582
OIDP Total	2	25	3	23	1.00	6	21	8	18	0.72	0.251	0.176

[1]Carbamide Peroxide [2]Hydrogen Peroxide * McNemar test: Intragroup comparison ** Qui-square test: Intergroup comparison

Figure

Figure 1: Diagram of participant flow

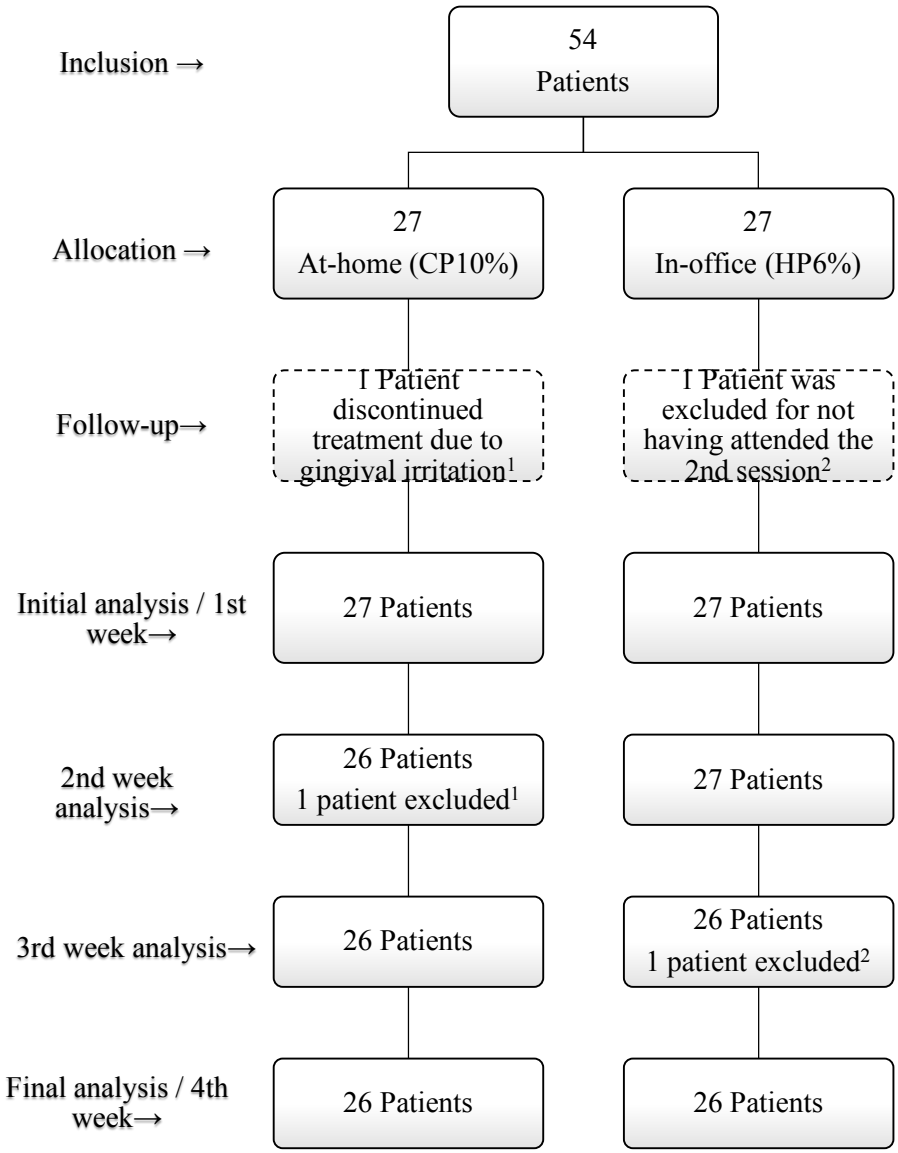


Figure 2: Shade value frequency evaluated in patients along the bleaching

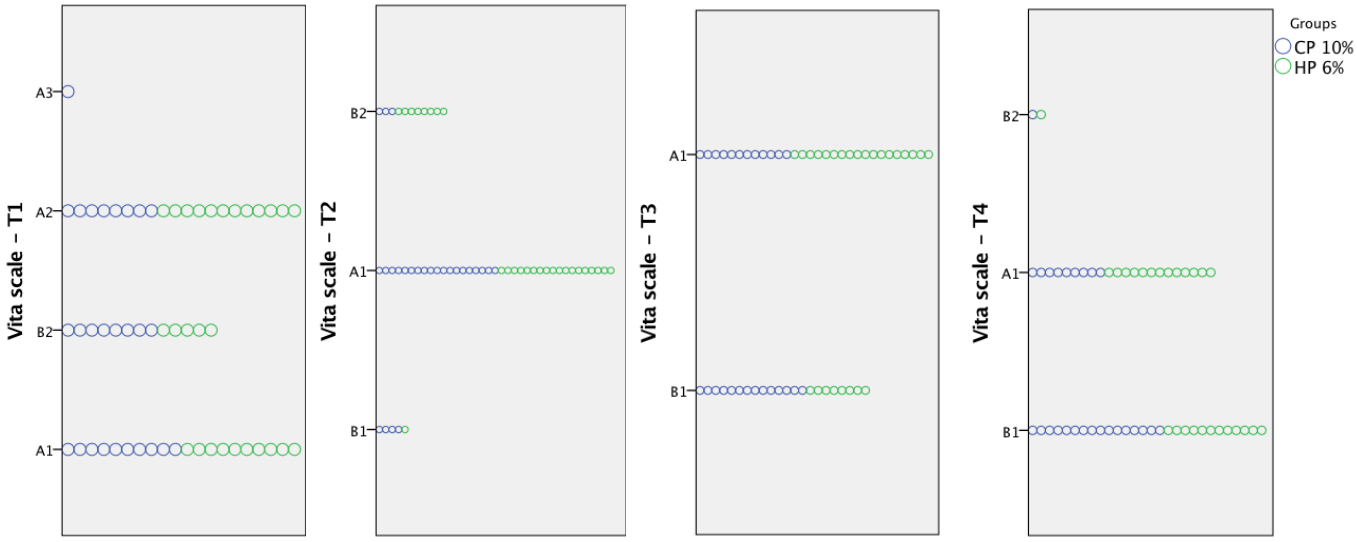
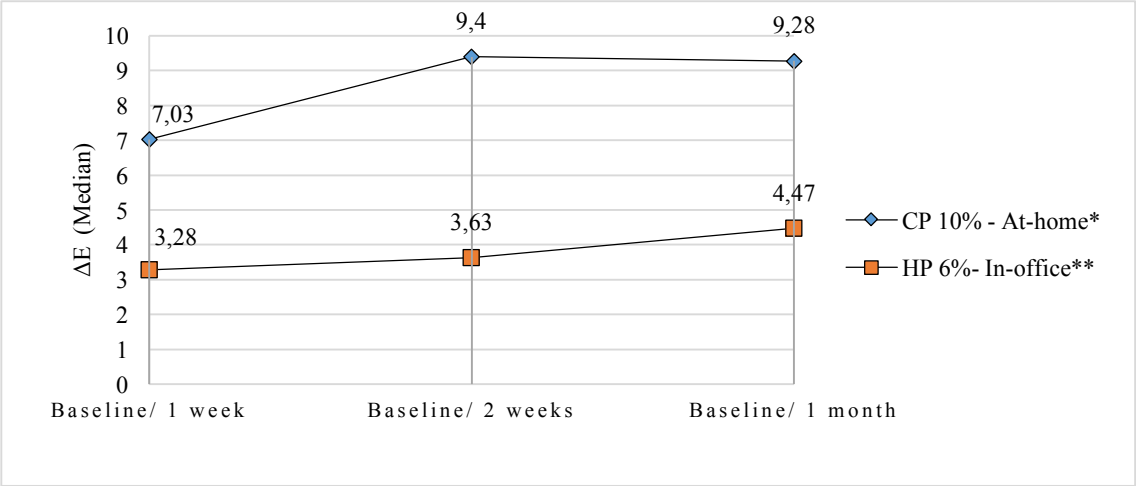
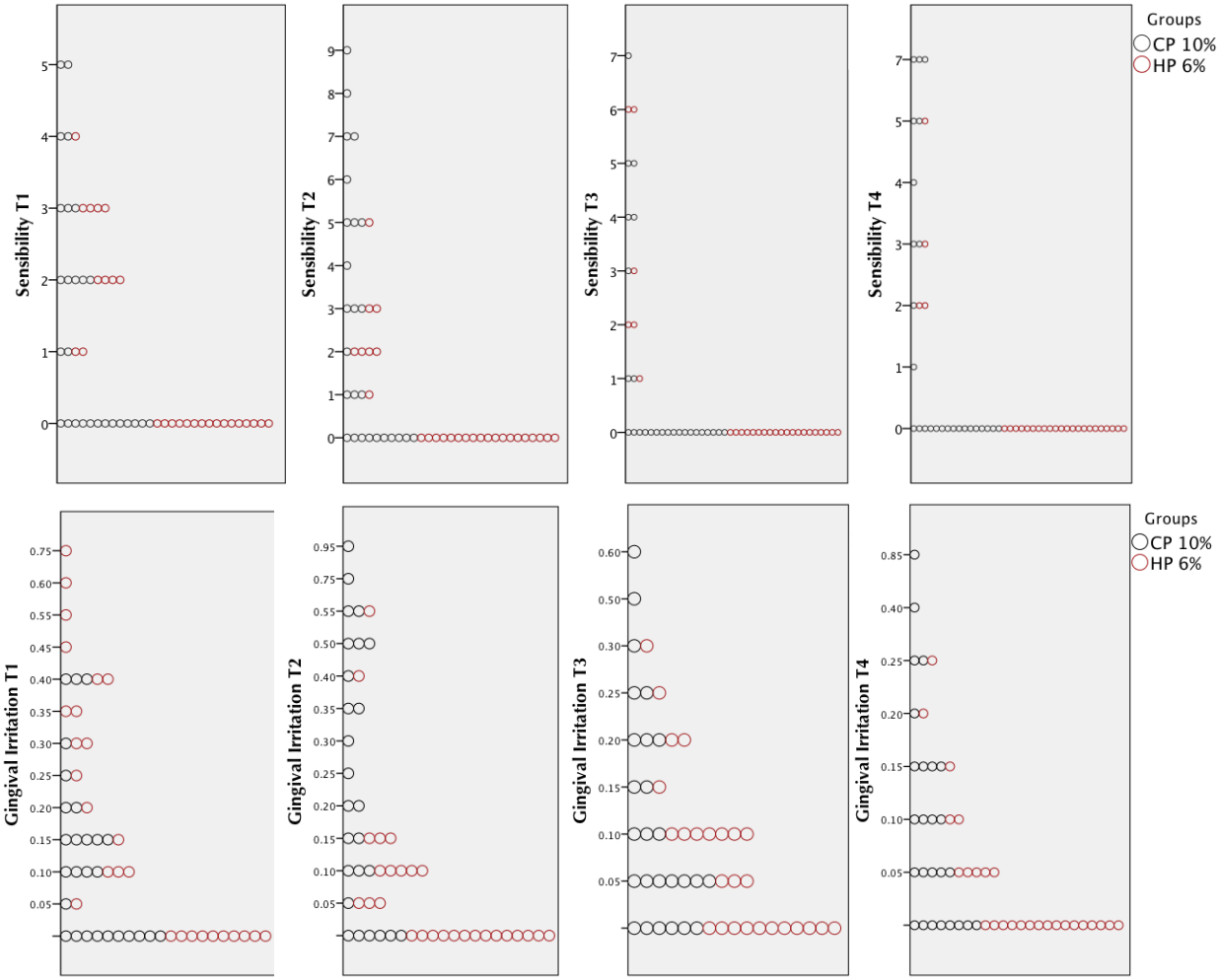


Figure 3: Median shade change **(**ΔE) for at-home and in-office bleaching, according evaluation time



*Friedman (p<0,001) **Friedman (p<0,001); Baseline/ 1 week: Mann Whitney (p=0,16) Baseline/ 2 weeks: Mann Whitney (p=0,035); Baseline/ 1 month: Mann Whitney (p=0,042)

Figure 4: Sensibility and gingival irritation frequencies evaluated in patients along the bleaching



4 ARTIGO 2 SUBMETIDO À REVISTA CLINICAL ORAL INVESTIGATION

Longevity, effectiveness, safety and impact on quality of life of low concentration hydrogen peroxides in-office bleaching: a randomized clinical trial

Title Page

Longevity, effectiveness, safety and impact on quality of life of low concentration hydrogen peroxides in-office bleaching: a randomized clinical trial

Short title: **Low concentration peroxides in-office dental bleaching: a randomized clinical trial**

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ACKNOWLEDGEMENTS

The authors are grateful to CAPES (Coordenação de Aperfeiçoamento de Pessoal de Nível Superior) for providing the scholarship to Nayara Kelly Lyrio Ferraz and to the Postgraduate Collegiate (Faculty of Dentistry, Universidade Federal de Minas Gerais). We thank Prof. Dr. Osmir Batista de Oliveira Júnior, FOAR-UNESP for loaning the LED/laser equipment Whitening Laser II DMC.

Longevity, effectiveness, safety and impact on quality of life of low concentration hydrogen peroxides in-office bleaching: a randomized clinical trial

Abstract

Objective. The study evaluated the longevity, effectiveness, safety and impact on the oral health-related quality of life of in-office dental bleaching using low concentrations hydrogen peroxides. *Materials and methods.* Randomized, parallel and double-blinded clinical trial was performed with 54 participants using 6% or 15% hydrogen peroxide (HP) in-office bleaching activated via hybrid LED/Laser light. Tooth color was evaluated at: baseline (T1), 1 week of bleaching (T2), 2 weeks of bleaching (T3) and 1 week (T4) and 6 months (T5) after finishing the bleaching using the Classical Vita^{TM} scale and spectrophotometer. Tooth sensitivity and gingival irritation were measured with Visual Numeric Scale and Modified Gingival Index. The impact on quality of life was evaluated using the Oral Impact on Daily Performance. The data were analyzed using Friedman, Mann-Whitney and McNemar tests ($p<0.05$). *Results.* The group HP15% presented significant color change (ΔE) from T1 to T4 ($p=0.002$) and T1 to T5 ($p<0.001$). Parameters L, a* and b* differed significantly at T3, T4 and T5 compared T1 for both groups. At 6-month follow-up, 57.1% of HP6% and 43.7% of HP15% participants migrated from B1 to a darker color. No significant differences were observed between the groups in tooth sensitivity, gingival irritation or impact on quality of life. *Conclusions.* Both agents showed bleaching effectiveness, but HP15% presented greater color stability than HP6%, at 6-month follow-up. The agents showed low levels of tooth sensitivity, gingival irritation and did not affected the oral health-related quality of life of the participants.

Keywords: Dental bleaching, Quality of life, Hydrogen peroxide, Longevity

Clinical Relevance: Despite the greater presence of sensitivity during treatment compared with 6% hydrogen peroxide, 15% hydrogen peroxide demonstrated better bleaching effectiveness and greater color stability at the end of bleaching and at 6-month follow-up. The use of 15% hydrogen peroxide presents more suitable results.

VI. INTRODUCTION

Bleaching techniques are effective but the results vary by dental staining, patient age, the concentration of the active agent and the time and frequency of treatment [1]. In-office bleaching has traditionally been performed with high concentrations of hydrogen peroxide (HP), usually varying from 35-40% [2, 3]. However, the American Dental Association (ADA) [1] considers products with concentrations of up to 3.5% hydrogen peroxide as safe to use, whereas the Scientific Committee on Consumer Products (SCCP) [4] of the European Union approves of products with up to 6.0% hydrogen peroxide. Higher concentrations of peroxides result in more adverse effects, such as sensitivity and gingival irritation [5].

The amount and concentration of peroxide applied during in-office bleaching can alter the potential for harm [1]. Dental sensitivity during and after bleaching has been associated with microscopic surface defects and enamel pores that allow rapid entry of the bleaching agent into the pulp, resulting in sensitivity [6–8]. Hydrogen peroxide has irritant and cytotoxic potential [9–11]. Clinical studies have reported a higher prevalence of gingival irritation in patients who used bleaching materials with higher concentrations of peroxide [1, 12]. Hydrogen peroxide concentrations of 10% or more are potentially corrosive to the mucous membranes and skin [4].

To improve the safety of bleaching, some manufacturers have released low-concentration bleaching gels (6-20%) for in-office use; although these gels minimize tooth sensitivity, unfortunately, they do not achieve the same bleaching efficacy as high-concentration agents [13]. The TiO_N semiconductor agent (nanoparticles of titanium dioxide doped with nitrogen) was combined with the products of low concentrations (3.5-15%) of hydrogen peroxide to increase the safety and efficacy of bleaching compared with conventional formulations [14]. Although these agents increased the effectiveness of bleaching, they did not reach the same levels as the high-concentration (35 e 38%) agents did [14–16]. The biocompatibility and safety of low concentration agents should be considered compared with those of conventional agents when choosing a bleaching agent that could have adverse effects on patients' lives [14].

Previous studies have compared effectiveness and safety of low-concentration agents (6-15%) with those of conventional bleaching agents (35-38%) [14–20]. Considering the indications of the ADA [1] and the SCCP [4] regarding the use of

products with hydrogen peroxide concentrations of up to 6%, few studies have compared low-concentration bleaching agents in terms of their effectiveness, safety or effects on oral health-related quality of life (OHRQL). The objective of this study was to evaluate the longevity, effectiveness, safety and impact on the OHRQL of patients given in-office dental bleaching with concentrations of 6% and 15% hydrogen peroxide catalyzed with titanium dioxide nanoparticles and activated via hybrid light. This randomized clinical trial tested the null hypotheses that there are no differences between in-office dental bleaching using 6% and 15% hydrogen peroxide catalyzed with titanium dioxide nanoparticles and activated via hybrid light, considering the outcomes: longevity, effectiveness, safety and impact on the OHRQL.

VII. MATERIALS AND METHODS

This randomized, parallel and double-blinded clinical trial evaluated the longevity, effectiveness, tooth sensitivity and gingival irritation associated with low-concentration hydrogen peroxides in-office bleaching as well as its impact on OHRQL. This study followed the ethical principles established in the Helsinki Declaration of 1964, and was approved by the University Ethics Committee (Process nº 1.269.466). The study was registered as clinical trial (NCT02816593- https://clinicaltrials.gov/ct2/results?term=NCT02816593&Search=Pesquisa) and reported in accordance with the CONSORT Statement (Consolidated Standards of Reporting Trials) [21].

The examiners and the participants were blind to the concentrations of the bleaching agents. Individuals were invited to participate and those who agreed signed an informed consent document. The participants received tooth bleaching on upper and lower dental arches from the right second premolar to the left second premolar. The evaluation times were defined as follows: baseline (T1), 1 week after the beginning of bleaching (T2), 2 weeks after the beginning of bleaching (T3) and 1 week (T4) and 6 months (T5) after finishing the bleaching. The participants were assessed for color change from T1 to T5, tooth sensitivity and gingival irritation from T1 to T4. The impact of tooth bleaching on the individual daily lives was measured using the Oral Impact on Daily Performance (OIDP) instrument for both groups at T1 and T4.

Sample size

Two sample calculations were performed for the major dependent variables: bleaching effectiveness and oral health-related quality of life. Considering the clinically relevant difference between the bleaching techniques effectiveness (ΔE=3.1), standard deviation of 3.71 [16] 95% confidence level and 80% power, a sample estimation was performed. Using oral health-related quality of life as the dependent variable, the calculation considered 41.76% bleaching effect ratio [22], 95% confidence level, 80% power and 14.5% expected effect ratio. The minimum sample size required in both calculations was 22 participants per group. To offset possible losses, 20% was added to the sample, resulting in a total of 27 participants per group and 54 participants in total.

Recruitment

Sixty nine individuals who were interested in participating in the research as advertised through posters on the university campus were recruited. All evaluations and procedures were conducted at the dentistry faculty clinics. We included 54 men and women between 18 and 40 years of age. The inclusion criteria were: good general health status and an absence of systemic diseases; dental color ranging from A1 to darker assessed by the Classical Vita™ Scale; teeth without blemishes or restorations in the region of bleaching; and no previous bleaching treatment. Individuals with severe dental crowding, severe tooth sensitivity, pregnant and smokers were not included.

Randomization and blinding

Individuals who met the eligibility criteria were selected and allocated into two groups. Randomization was performed using 54 sealed envelopes that were sequentially numbered, such that 27 envelopes had the 6% hydrogen peroxide (HP6%) and 27 had the 15% hydrogen peroxide (HP15%).

During the experiment, a blinded investigator in one room evaluated the patients with regard to color, tooth sensitivity and gingival irritation and administered the questionnaire to assess the oral health-related quality of life. An operator in a second

room independently performed the bleaching procedures without showing the concentration of bleaching agent to the participants.

Bleaching protocol

A gingival barrier (Lase protect, DMC Equipment, São Carlos, SP, Brazil) was applied and light cured (10 s). Three applications (10 minutes each) of bleaching agents per consultation were made, for a total of three consultations, with 7-day intervals among them [23]. Group HP6% used 6% hydrogen peroxide gel (Lase Peroxide Lite DMC Equipment, São Carlos, SP, Brazil), whereas Group HP15% used 15% hydrogen peroxide (Lase Peroxide Lite DMC Equipment, São Carlos, SP, Brazil). The bleaching agents were activated via hybrid LED/laser light (Whitening Laser II DMC Equipment, São Carlos, SP, Brazil) consisting of 6 LED (470 nm / blue light; Power =1,800 mW), and 3 low-intensity lasers (808 nm / infrared light; Power = 600 mW) with total area of irradiation= 8.5 cm^2 and power density = 300 mW/cm^2. In each bleaching session, the gel was irradiated with 5 cycles of 1 minute per arch, alternating in both arches for 10 minutes.

Color evaluation

Tooth color was evaluated before, during and after bleaching using the Classical Vita™ Scale (Vita-Zahnfabrik, Bad Säckingen, Baden-Württemberg, Germany) and Vita™ Easy Shade spectrophotometer (Easy Shade Advance™ Wilcos, Petrópolis, RJ, Brazil).

Subjective evaluation

A trained examiner calibrated and certified by the Toothguide Trainer Web (870 points of the 1000 evaluated) performed the visual evaluation using the Classical Vita™ Scale (Vita-Zahnfabrik, Bad Säckingen, Baden-Württemberg, Germany) positioned on the middle third of the teeth. The subjective color evaluations were made on upper and lower dental arches from the right second premolar to the left second premolar. Color evaluations were made under the same conditions of artificial light obtained with the Rite-Lite 2 light standardizer (Rite-Lite 2®, Addent, Danbury, CT, USA). The 16-color guide tabs were arranged from highest (B1) to lowest (C4) value, and each tab was

given an ordered number from 1 to 16. The total color was the most frequent color of the evaluated teeth, and the worst situation was chosen in the case of a tie.

Objective evaluation

The objective color evaluations were made on the upper right central incisor. A silicone guide was prepared to standardize the color measurement using the spectrophotometer (Vita Easy Shade Advance^{TM}, Wilcos, Petrópolis, RJ, Brazil). The device tip was placed in the hole made in the middle third of the vestibular surface of the guide, and the color was evaluated 3 times for the tooth 11. The final result was the mean of the 3 values for L *, a * and b *.

Color change values (ΔE) were calculated considering L *, a * and b *parameters measured at baseline (before bleaching) and one week after beginning the bleaching (ΔE at T2), two weeks after beginning (ΔE at T3), one week after finishing the beaching (ΔE at T4) and six months after finishing the bleaching (ΔE at T5. All color changes (ΔE) were calculated with respect to the L *, a * and b * baseline values, using the following formula:

$$\Delta E = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}$$

Tooth sensitivity and Gingival irritation evaluation

Participants were asked about the presence and intensity of tooth sensitivity or pain from T1 to T4. The degree of tooth sensitivity reported was recorded using a Visual Numeric Scale (VNS), using the following categories: none, mild, moderate and severe.

Gingival irritation was assessed by a calibrated examiner (intra-examiner kappa = 0.79) using the Modified Gingival Index (MIG) [24]. The marginal and interproximal tissues were scored separately as follows: 0-no inflammation; 1-mild inflammation, a slight change in color and texture in part of the gingiva; 2-mild inflammation involving the entire gingival margin; 3-moderate inflammation, shiny surface and edema; and 4-severe inflammation, spontaneous bleeding, and marked edema. The total MGI per individual was obtained by adding the values of tooth sites and dividing by the number of teeth analyzed.

Oral health-related quality of life

The Brazilian version of the OIDP scale [25] was administered as an interview at baseline (T1) and one month after the beginning of treatment (T4) to evaluate the perception of changes in oral health after bleaching. Each individual was asked whether, in the last month, he had experienced any problem with his oral health that caused difficulties with the following activities: eating or enjoying food, speaking and pronouncing words clearly, cleaning teeth, sleeping, smiling, smiling while showing your teeth without embarrassment, maintaining an emotional state without becoming bored, performing work or studies and enjoying contact with other people. The possible answers were: yes or no. When the participants reported effect on their daily performance, they were asked about their major symptoms (e.g., pain, discomfort, limitations at work, dissatisfaction with one's appearance, or others) and the main oral conditions that caused the difficulty. The frequency and severity of the effects on each oral condition was recorded. The OIDP scale for each domain was obtained by multiplying the frequency by severity. The total effect on quality of life was the sum of the all scores for each condition reported by the patient.

Statistical analysis

A blind researcher performed the statistical analyses using the Statistical Package for Social Sciences (SPSS for Windows, version 24.0, SPSS Inc. Chicago, IL, USA). Linear associations, chi-square and McNemar tests compared, respectively, the bleaching groups with regard to categorical variables, OIDP domains and total OIDP. Mann Whitney and Wilcoxon tests compared respectively the evaluation times and color parameters. Mann Whitney and Friedman tests were used in the comparisons of evaluation times and sensibility and gingival irritation. Inter-groups and intra-groups comparisons of evaluation times and OIDP parameters were made using chi-square and McNemar tests respectively.

VIII. RESULTS

Of the 54 participants, 33 were women; 16 were in the HP6% group, and 17 were in HP15% group. The mean age was 26.38 years, and 66.7% of participants in the HP6% group and 77.8% of those in HP15% group were aged 18-29.

Figure 1 shows the patient flow throughout in the course of the study. Both groups began with 27 participants and concluded the bleaching with 26 individuals. Six months after bleaching, 19 participants from each group returned for the evaluation.

The frequency of patients distributed according to the color evaluated along the bleaching was demonstrated in the Figure 2. It was observed that 57.1% of HP6% and 43.7% of HP15% participants showing B1 color in T4 migrated to a darker color in T5. Table 1 shows the color parameters according to the evaluation times. Intergroup comparisons at the same time interval revealed a significant difference on the Vita^{TM} scale values at the end of bleaching and 6 months after bleaching. Intragroup comparisons between baseline and T3, T4 and T5 showed significant difference in the parameters L, a * and b * and Vita^{TM} scale, in both groups. Intragroup comparisons between baseline and T4 and T5 showed that ΔE differed significantly for PH15% group.

Approximately 29.6% of the participants in HP6% and 44.4% in HP15% reported tooth sensitivity one week after the beginning of bleaching. Approximately 57.7% of the participants in HP6% and 53.8% of those in HP15% reported gingival irritation two weeks after the beginning of bleaching. Table 2 compares tooth sensitivity and gingival irritation between groups and across evaluation times. No significant differences were observed between groups in relation to tooth sensitivity or gingival irritation.

Table 3 reports the domains as well as the initial and final total OIDP total scores by groups. No significant between-groups differences were found in relation to the domains or global OIDP score.

IX. DISCUSSION

In the present study, low-concentration hydrogen peroxides used for in-office bleaching were effective and showed low levels of tooth sensitivity and gingival irritation. The bleaching with low-concentration peroxides did not generated adverse

effects that affected the oral health-related quality of life of the participants. The color stability was low, and the groups did not keep the same color obtained at the end of treatment six months after bleaching. In the present study, the effectiveness of in-office bleaching for the HP6% (ΔE=4.9) and HP15% (ΔE=8.2) was similar to that of other studies that used the same HP concentrations and protocols presented [14–16]. The parameter ΔE is the shade difference between two objects or the same object evaluated in two distinct moments, calculated within the CIELAB colour system [26]. The naked eye is able to distinguish colour differences if the value of ΔE is higher than 3.3 [1]. In the present study, both bleaching groups had values of ΔE higher than 3.3, confirming the clinical effectiveness of tooth bleaching observed with the naked eye.

Quantitative color assessment is more objective, which eliminates the bias potential and variability of human judgment [27]. A spectrophotometer enables a color evaluation through the CIEL a*b* system. In this system, L * represents the value of luminosity or darkness, a * is the measure along the red-green axis and b * is the measure along the yellow-blue axis. A value a * positive indicates the red direction, a negative value of a * represents the green direction. A positive value of b * denotes a color in the yellow direction, whereas a negative value of b * indicates a color in the blue direction [26]. Bleaching it is expected to increase the value in the parameter L, and the values of the parameters a * and b * should approach zero [26]. In the present study, the HP6% group showed an increase in L at the end of treatment compared with baseline, indicating higher luminosity. The initial values for parameter a * were negative, consequently closer to green. With bleaching, these values became even more negative, bringing even more of the green. The parameter b * decreased in yellowing, approaching zero. The HP15% group showed tooth bleaching, despite a slight decrease in the L and a * parameters and a greater reduction in b *. These changes in color parameters were lower than those found in the other studies that using the same concentrations of the bleaching agents [14, 27, 28]. Yellower teeth at baseline showed better tooth bleaching results [29]. The minimum color change observed in the present study after treatment compared with others might be because the initial color was lighter than that normally used in other studies. The current patients desired to undergo the bleaching procedure, despite their lighter initial dental color. A decrease of 1 unit in the yellowing entails a color improvement of approximately 10% [30].

Dental bleaching has become one of the fastest growing areas of dentistry for patients and industry investment [31]. The incorporation of the nanoparticles TiO_N into hydrogen peroxide reduces the concentration of the latter, improves the biocompatibility of therefore prevents postoperative sensitivity and increases the safety of bleaching procedures. Irradiation with an appropriate light source will generate high concentrations of free radicals and other reactive oxygen species that are necessary to break down the molecular bonds of pigments within the tooth structure [32]. Titanium oxide nanoparticles doped with nitrogen enables the catalytic activity to occur when exposed to wavelengths in the band of the visible light, avoiding the use of ultraviolet light [15, 33]. The interaction between reduced concentration of hydrogen peroxide and the photocatalyzation by LED/ laser light can result as low sensitivity [15]. Infrared lasers promote a high polarization of the nervous membrane, thus reducing action potentials and the occurrence and the intensity of the sensitivity [30, 34].

When a lower concentration of hydrogen peroxide is used, it is necessary to have a greater number of applications to optimize the results of tooth bleaching [35]. In the present study, the number of applications and the contact time of the bleaching gel with the dental surface were the same for both groups. The results did not reveal significant differences in the color changes between the concentrations of bleaching agents considering the parameters L*, a* and b*. This null result demonstrates the greater performance of HP6% with TIO_N nanoparticles because although the peroxide concentration was halved, changes in the color parameters were practically the same between the groups. These results corroborate those of Matis et al. [2007] [36] and Bortolatto et al. [2014] [15], who observed that the contact time might be important in the bleaching process, and the concentration of the bleaching agent is not the most relevant factor. In the present study, cases of a dental darkening of approximately 57.1% and 43.7% were observed in HP6% and HP15%, respectively, 6 months after the bleaching. These results demonstrate that HP15% obtained higher color stability. The results of the present study corroborate with those of a study that evaluated the 9-month stability of HP6%, reporting a color return greater than 50% [33].

Reports of dental sensitivity are greater during the first 24 hours after treatment, and can extend for approximately 5 days [37]. In the present study, both groups showed the rates of tooth sensitivity superior of 50% one week after bleaching. The

sensitivity of 15% hydrogen peroxide was reported from 31% [15] to 64% [27]. Considering a scale from 0 to 10, the sensitivity of agents with low concentration varies from 0.6 [7, 38] to 2.4 [15]. In the present study, the sensitivity rate was higher than 40%. Although this rate was higher than that found in other studies, the median was lower, which demonstrated that many patients reported low-intensity dental sensitivity. The tooth sensitivity rate found for HP6% in-office bleaching group in the present study was higher than that presented by Bortolatto et al. [2016] [14] but lower than the rate of 50% [16] presented by Martin et al. [2015]. We did not find previous studies comparing the sensibility of 6% and 15% hydrogen peroxides. In the present study, the sensibility of HP 15% was statistically higher than HP6% one week after the beginning of bleaching. The higher HP15% sensibility is probably due to the concentration twice as higher than the HP6% agent.

Hydrogen peroxide can cause a burning sensation and tissue damage such as destruction and detachment of the epithelial layer when in contact with the gum [4]. In the present study, both groups had a gingival irritation rate greater than 50%, similar to the rate of 52% [27] previously found with HP15%. In both groups the intensity of irritation was considered mild. Both groups had similar frequencies of gingival irritation rates in the course of treatment, without significant differences between them. The hypersensitivity and gingival irritation in the current study were minor and disappeared spontaneously without requiring an interruption in treatment; these results match those of Bizhang et al. [2009] [27]. No significant between-groups differences in sensitivity or gingival irritation were found, showing that despite the higher frequencies of sensitivity and low gingival irritation, HP15% should be considered the first choice for bleaching since it presented a higher effectivity and stability.

Patient perceptions are important when assessing oral health needs and for determining the outcomes of dental procedures [39]. It is important to incorporate the assessment of the perception of changes after dental treatments into clinical trials [39]. The instruments that evaluate oral health-related quality of life are being increasingly used in dentistry research [40]. Bleaching can produce positive or negative effects on oral health-related quality of life [22]. The positive effects are related to the improvements in aesthetics and appearance, which increase the ease of smiling [22]. The positive effects on quality of life are detected when major changes of color occur,

especially when the teeth are no longer very yellowish [22, 29]. The negative effects are related to pain, discomfort and difficulty with oral hygiene caused by sensitivity or gingival irritation [22]. The Oral Impact on Daily Performance (OIDP) scale measures the consequences of oral disease on three levels, including oral health status, changes in oral tissues and ability to perform daily activities [41]. This instrument has the advantages of using an objective approach that encompasses the main consequences of bleaching, avoids overlapping repeated scores of the same effect and records only the significant effects [41]. The present study did not observed positive or negative effects of bleaching on oral health-related quality of life as assessed by the OIDP. The absence of a positive effect was most likely due to the discreet color change because the participants began with a light color and therefore did not experience large color variations. The low intensity of sensitivity and gingival irritation from bleaching might have contributed to the absence of negative effects.

One drawback of this study was a high dropout rate that reached 29.6% in 6-months follow-up. This dropout rate is an imminent bias source, decreasing the test power to reject the null hypothesis when the alternative hypothesis is true. Nevertheless, the losses were identical in both treatments and did not affect the balance between the comparison groups.

Despite the greater frequency of sensitivity, 15% hydrogen peroxide demonstrated higher bleaching effectiveness at the end of treatment and greater color stability at 6- month follow-up, compared to 6% hydrogen peroxide.

X. CONCLUSIONS

The low-concentrations bleaching agents used for in-office tooth bleaching were effective and showed low levels of tooth sensitivity and gingival irritation. These bleaching agents did not generate adverse effects that affected the oral health-related quality of life of the participants. At 6-month follow-up, HP15% presents greater color stability than HP6%. At 6-month follow-up, HP15% presented greater color stability than HP6%.

COMPLIANCE WITH ETHICAL STANDARDS

CONFLICT OF INTEREST

The author Nayara Kelly Lyrio Ferraz declare that they have no conflicts of interest.

The author Lilian Capanema Nogueiradeclare that they have no conflicts of interest.

The author Isabela Moreira Neiva declare that they have no conflicts of interest.

The author Raquel Conceição Ferreira declare that they have no conflicts of interest.

The author Allyson Nogueira Moreira declare that they have no conflicts of interest.

The author Claudia Silami Magalhães declare that they have no conflicts of interest.

FUNDING

No funding was received

ETHICAL APPROVAL

This study followed the ethical principles established in the Helsinki Declaration of 1964, and was approved by the University Ethics Committee (Process nº 1.269.466). The study was registered as a clinical trial (NCT02816593- https://clinicaltrials.gov/ct2/results?term=NCT02816593&Search=Pesquisa) and reported in accordance with the CONSORT Statement (Consolidated Standards of Reporting Trials)

INFORMED CONSENT

Informed consent was obtained from all individual participants included in the study.

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Tables

Table 1. Comparison of color parameters according to the evaluation times

Protocol	N	L Value (mean ± SD[1])	CI[2] of 95% Down	CI[2] of 95% Up	a* Value (mean ± SD)	CI[2] of 95% Down	CI[2] of 95% Up	b* Value (mean ± SD)	CI[2] of 95% Down	CI[2] of 95% Up	ΔE median (ID[4])	Vita Scale median (ID[4])
Color parameters - Baseline (T1)												
HP[3] 6%	27	87.50 ± 4.02	77.30	95.70	-1.54 ± 1.11	-3.30	1.20	18.42 ± 4.88	16.49	20.35	-	3.00 (3)
HP 15%	27	86.81 ± 3.37	79.50	92.70	-1.81 ± 1.11	-2.26	-1.38	17.73 ± 4.99	15.76	19.71	-	3.00 (1)
***p** Value**		0.494			0.357			0.614			-	0.140
Color parameters - 1 week of bleaching (T2)												
HP[3] 6%	27	88.20 ± 3.38	86.84	89.57	-1.93 ± 0.94	-2.31	-1.55	16.53 ± 4.43	14.74	18.32	3.6 (7.6)	2.00 (1)
HP 15%	27	87.78 ± 3.07	86.54	89.02	-2.22 ± 0.82	-2.56	-1.89	15.71 ± 4.60	13.85	17.56	2.1 (4.5)	2.00 (0)
***p** Value**		0.478			0.232			0.505	0.478		0.79	0.092
Color parameters - 2 weeks of bleaching(T3)												
HP[3] 6%	26	88.72 ± 3.96	87.12	90.32	-1.89 ± 0.99	-2.29	-1.49	16.56 ± 4.67	14.67	18.45	3.5 (6.02)	2.00 (1)
HP 15%	26	88.10 ± 3.62	86.63	89.56	-2.26 ± 0.77	-2.58	-1.95	15.40 ± 4.17	13.71	17.09	2.8 (6.4)	1.00 (1)
***p** Value**		0.390			0.181			0.437			1.00	0.095
Color parameters - 1 week after bleaching finishing (T4)												
HP 6%	26	87.53 ± 3.94	85.94	89.12	-1.74 ± 1.06	-2.17	-1.31	16.42 ± 4.56	14.57	18.26	3.7 (7.1)	2.00 (1)
HP 15%	26	85.29 ± 17.29	78.45	92.13	-2.08 ± 0.89	-2.43	-1.73	14.61 ± 5.06	12.61	16.62	5.2 (7.8)	1.00 (0)
***p** Value**		0.288			0.113			0.313			0.53	0.021
Color parameters - 6 months after bleaching finishing (T5)												
HP 6%	19	87.36 ± 3.44	85.71	89.02	-1.80 ± 1.10	-2.33	-1.27	16.48 ± 3.79	14.65	18.31	4.9 (8.8)	2.00 (0)
HP 15%	19	88.44 ± 3.15	86.92	89.96	-2.35 ± 0.59	-2.63	-2.06	14.62 ± 3.85	12.76	16.48	8.2 (16,2)	2.00 (1)
***p** Value**		0.322			0.064			0.142			0.95	0.029
p Value**												
T1 X T2												
HP 6%	27	0.124			0.004			<0.001			-	0.001
HP 15%	27	0.118			0.004			<0.001			-	0.001
T1X T3												
HP 6%	26	0.015			0.041			<0.001			0.21[a/b]	<0.001
HP 15%	26	0.023			0.001			<0.001			0.45[a/b]	<0.001
T1X T4												
HP 6%	26	<0.001			<0.001			<0.001			0.18[a/c]	<0.001
HP 15%	26	0.001			<0.001			<0.001			0.002[a/c]	<0.001
T1X T5												
HP 6%	19	<0.001			<0.001			<0.001			0.26[a/d]	0.001
HP 15%	19	0.064			0.003			<0.001			0.001[a/d]	<0.001

[1]Standard Deviation [2]Confidence interval [3]Hydrogen Peroxide [4]Interquartile distance

**p* value obtained from the T test for independent samples (L, a*, b*) and Mann Whitney test for ΔE and Vita™ scale

***p* value obtained from the T-test for repeated measures (L, a*, b*) and Wilcoxon test for ΔE and Vita™ scale

[a]ΔEcalculated considering the values of L, a * and b * at T1 and T2

[b]ΔEcalculated considering the values of L, a * and b * at T1 and T3

[c]ΔEcalculated considering the values of L, a * and b * at T1 and T4

[d]ΔEcalculated considering the values of L, a * and b * at T1 and T5

Table 2: Tooth sensitivity and gingival irritation assessment for groups and times of evaluation

Protocol	Tooth sensitivity				
	Baseline	**1 week**	**2 weeks**	**1 month**	
	Median (ID[1])	Median (ID[1])	Median (ID[1])	Median (ID[1])	***p*****
HP[2] 6%	0.00 (2)^{A}	0.00 (2)^{A}	0.00 (0)^{A}	0.00 (0)^{A}	0.159
HP 15%	2.00 (3)^{ab}	0.00 (3)^{b}	0.00 (0)^{c}	0.00 (0)^{cd}	0.002
***p** Value**	0.06	0.168	0.758	0.667	
Protocol	**Gingival irritation**				
	Baseline	**1 week**	**2 weeks**	**1 month**	
	Median (ID[1])	Median (ID[1])	Median (ID[1])	Median (ID[1])	***p*****
HP 6%	0.10 (0.35)^{A}	0.00 (0.10)^{B}	0.05 (0.10)^{CB}	0.00 (0.05)^{BCD}	0.004
HP 15%	0.10 (0.20)^{a}	0.00 (0.05)^{bc}	0.05 (0.15)^{ab}	0.00 (0.05)^{c}	0.019
***p** Value**	0.264	0.458	0.900	0.743	

[1] Interquartile distance [2] Hydrogen Peroxide

**p*: Mann Whitney test in the comparision of the medians in the columns

***p*: Friedman test; medians followed by equal capital letters in the group HP6% and lowercase letters equal in the group HP15% did not differ in the comparisons in lines in the post hoc test

Table 3: Oral impact on daily performance according to OIDP domains, before and after bleaching (Belo Horizonte, MG, Brazil)

	OIDP											
	HP[1] 6% Impact (n)					HP[1] 15% Impact (n)					HP6%/HP15%	HP6%/HP15%
	Baseline		1 month			Baseline		1 month			Baseline	1 month
Domains	Yes	No	Yes	No	*p**	Yes	No	Yes	No	*p**	*p***	*p***
Eat	4	22	6	20	0.72	1	25	4	22	0.18	0.063	0.524
Talk	0	26	0	26	-	0	26	1	25	0.31	-	0.363
Oral hygiene	1	25	2	24	1.00	4	22	3	23	0.65	0.159	0.333
Smile	1	25	2	24	1.00	2	24	1	25	0.08	0.599	0.115
Social relationships	0	26	0	26	-	1	25	0	26	0.31	-	0.363
Emotional state	2	24	1	25	1.00	0	26	0	26	-	0.354	0.363
Occupational activities	0	26	0	26	-	0	26	2	24	0.15	-	0.128
Sleep-relax	0	26	2	24	0.50	2	24	3	23	0.56	0.354	0.582
OIDP Total	6	21	8	18	0.72	6	21	4	23	0.41	0.022	0.271

[1]Hydrogen Peroxide * McNemar test: Intragroup comparison ** Qui-square test: Intergroup comparison

Figure

Figure 1: Diagram of participant flow

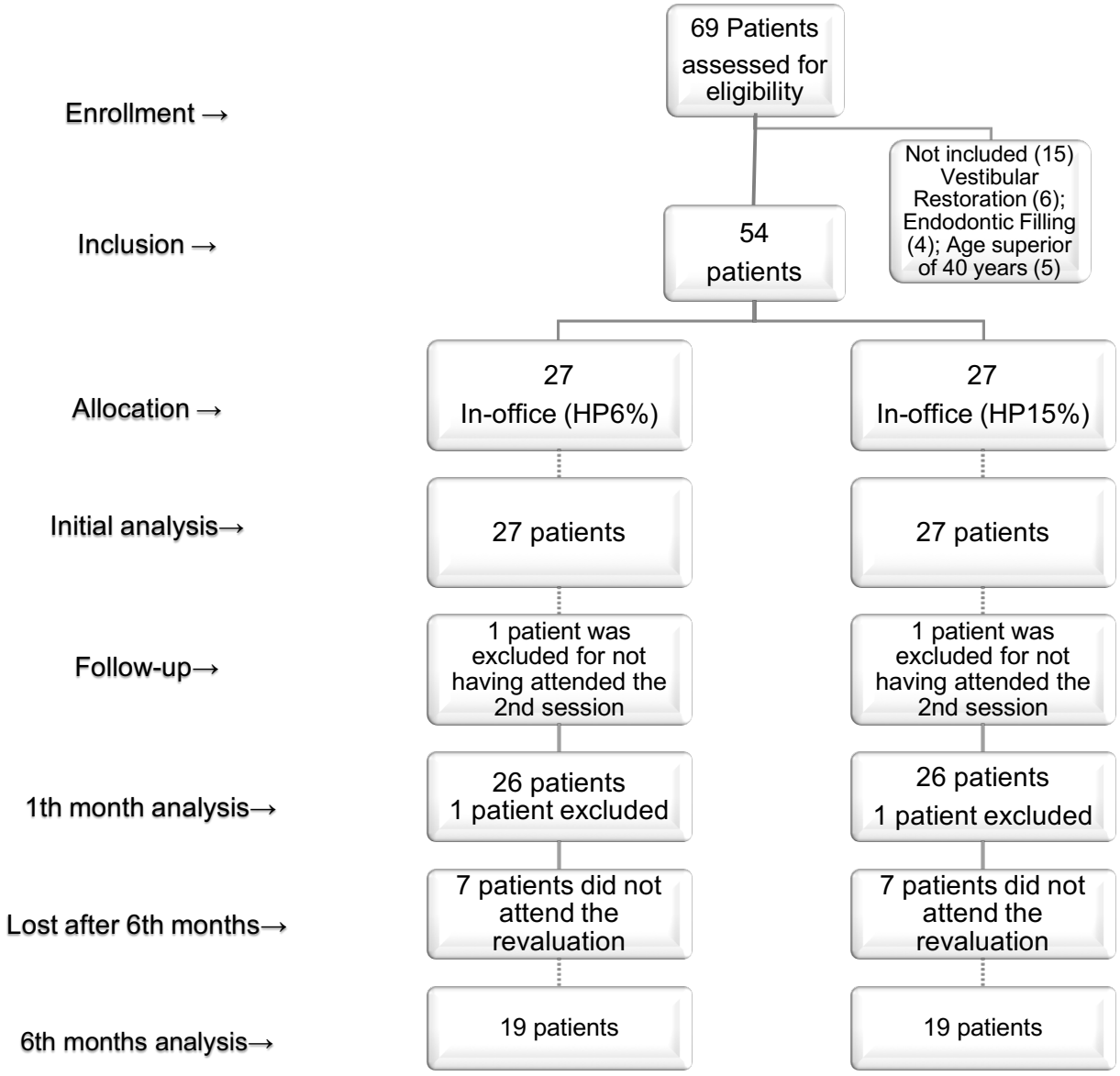
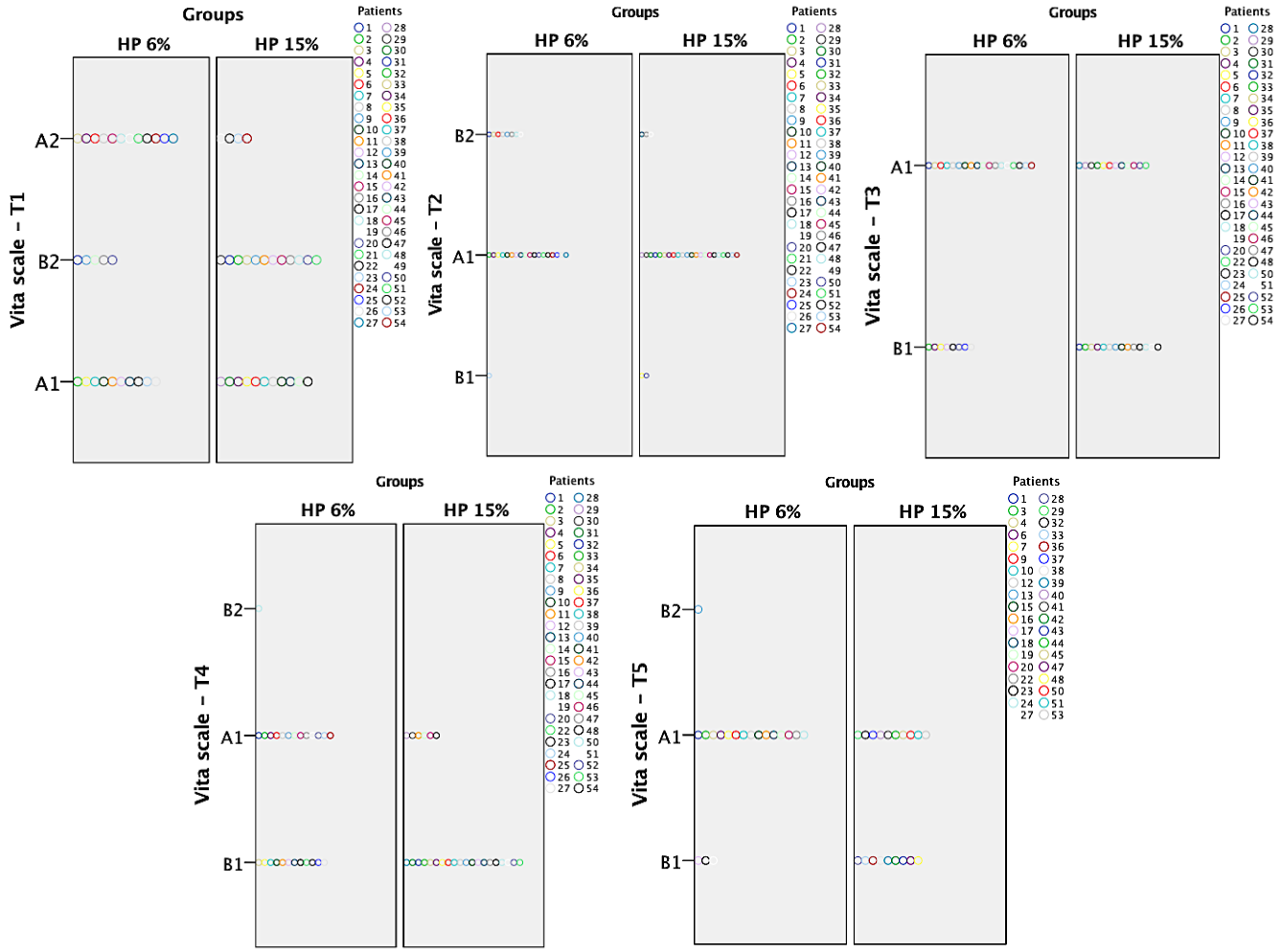


Figure 2: Shade value frequency evaluated in patients along the bleaching



*The numbers of 1-27 represent the patients HP6% and the 28-54 represent the patients HP15%

5 CONSIDERAÇÕES FINAIS

O propósito desse trabalho foi verificar a longevidade, efetividade, segurança e impacto na qualidade de vida das técnicas de clareamento caseira e de consultório, utilizando agentes clareadores de baixa concentração. Para o presente estudo optou-se por utilizar o peróxido de carbamida 10% para a técnica caseira, por ser o peróxido de mais baixa concentração presente no mercado e por ser considerado o padrão ouro em termos de clareamento caseiro. Para a técnica de consultório optou-se por utilizar os peróxidos de hidrogênio 6% e 15% da DMC, por serem as concentrações mais baixas do mercado, além da tendência a uma diminuição da concentração dos agentes clareadores visando à redução dos efeitos adversos, e por consequência, a diminuição dos impactos negativos na qualidade de vida.

Os resultados do presente estudo indicaram que ambas as técnicas foram efetivas no clareamento, apesar da técnica caseira ter apresentado uma maior taxa de branqueamento dental. Em relação à segurança, as duas técnicas apresentaram baixos níveis de sensibilidade e de irritação gengival, apesar da técnica caseira ter apresentado maiores taxas das duas respostas que caracterizam a segurança. Ainda que a presença mais pronunciada de efeitos adversos tenha sido observada na técnica caseira, esses efeitos não impactaram negativamente a qualidade de vida dos participantes. O instrumento utilizado para avaliação do impacto da qualidade de vida na saúde bucal avalia tanto o impacto positivo quanto negativo na vida diária dos indivíduos. No entanto devido à própria característica do instrumento, os impactos negativos são explorados e evidenciados nos resultados. A ausência de impacto significativo do clareamento das duas técnicas de clareamento empregadas pode ser considerada satisfatória, pois mesmo presentes, os efeitos adversos foram de baixa intensidade e não afetaram a vida cotidiana dos indivíduos. Em relação à longevidade e estabilidade de cor, decorridos 6 meses do clareamento, a técnica de consultório utilizando peróxido de hidrogênio a 15% apresentou mais estabilidade de cor quando comparada ao peróxido de hidrogênio a 6%. Na técnica de consultório, ambas as concentrações apresentaram baixas frequências de sensibilidade e irritação gengival, embora o PH6% tenha apresentaram menores índices desses efeitos. Em relação a efetividade de clareamento e estabilidade de cor, o PH15% apresentou resultados mais satisfatórios.

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ANEXO 1

Parecer Aprovado do Comitê de Ética em Pesquisa

UNIVERSIDADE FEDERAL DE MINAS GERAIS
COMITÊ DE ÉTICA EM PESQUISA - COEP

Projeto: CAAE – 49553315.0.0000.5149

Interessado(a): Profa. Cláudia Silami de Magalhães
Departamento de Odontologia Restauradora
Faculdade de Odontologia - UFMG

DECISÃO

O Comitê de Ética em Pesquisa da UFMG – COEP aprovou, no dia 08 de outubro de 2015, o projeto de pesquisa intitulado **"Clareamento dentário caseiro e de consultório: eficácia, segurança e impacto na qualidade de vida relacionada à saúde"** bem como o Termo de Consentimento Livre e Esclarecido.

O relatório final ou parcial deverá ser encaminhado ao COEP um ano após o início do projeto através da Plataforma Brasil.

Telma Campos Medeiros Lorentz

Profa. Dra. Telma Campos Medeiros Lorentz
Coordenadora do COEP-UFMG

Av. Pres. Antonio Carlos, 6627 – Unidade Administrativa II - 2° andar – Sala 2005 – Cep:31270-901 – BH-MG
Telefax: (031) 3409-4592 - e-mail: coep@prpq.ufmg.br

ANEXO 2

Ficha clínica

FICHA CLÍNICA

UFMG – Programa de Pós-Graduação em Odontologia Clínica Odontológica

Clareamento dentário: Eficácia, segurança e impacto na qualidade de vida

Número da ficha:_____ Data:_____

Formulário 1 – Identificação

Nome_____

Idade:_____anos Data de nascimento ____/____/____ Gênero: ( ) Masculino ( ) Feminino

Endereço:_____Bairro:_____

Cidade:_____ Tel._____

Email:_____

Questionário socioeconômico

1- Estado civil:
( ) solteiro; ( ) casado; ( ) divorciado; ( ) outro
2- Nível de escolaridade:
( ) Nenhum; ( ) Ensino fundamental incompleto até a 4ª série; ( ) Ensino fundamental incompleto após a 4ª série; ( ) Ensino fundamental completo; ( ) Ensino médio incompleto; ( ) Ensino médio completo; ( ) Ensino superior incompleto; ( ) Ensino superior completo; ( ) Pós-graduação; ( ) Desconheço
3- Nível de escolaridade da mãe:
( ) Nenhum; ( ) Ensino fundamental incompleto até a 4ª série; ( ) Ensino fundamental incompleto após a 4ª série; ( ) Ensino fundamental completo; ( ) Ensino médio incompleto; ( ) Ensino médio completo; ( ) Ensino superior incompleto; ( ) Ensino superior completo; ( ) Pós-graduação; ( ) Desconheço
4- Nível de escolaridade do pai:
( ) Nenhum; ( ) Ensino fundamental incompleto até a 4ª série; ( ) Ensino fundamental incompleto após a 4ª série; ( ) Ensino fundamental completo; ( ) Ensino médio incompleto; ( ) Ensino médio completo; ( ) Ensino superior incompleto; ( ) Ensino superior completo; ( ) Pós-graduação; ( ) Desconheço
5- Qual é a renda mensal de seu grupo familiar?
( ) menos de um salário mínimo; ( ) de um a menos de dois salários mínimos; ( ) de dois a menos de cinco salários mínimos; ( ) de cinco a menos de dez salários mínimos; ( ) acima de quinze salários mínimos
6- Número de filhos:
( ) Nenhum; ( ) Um; ( ) Dois; ( ) Três; ( ) Quatro; ( ) Cinco; ( ) Mais de cinco
7- Quantas pessoas, incluindo você próprio, vivem da renda mensal do seu grupo familiar?
( ) Uma; ( ) Duas ou três; ( ) Quatro ou cinco; ( ) Seis ou sete; ( ) Oito ou nove; ( ) Dez ou mais

Formulário 2- Avaliação da cor- Critérios de avalição

Escala Vita

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

Mudança de cor = Score inicial - Score final
(Unidades de tons)

Espectrofotômetro

L: eixo luminosidade
a*: eixo vermelho verde
b*: eixo amarelo azul

$$\Delta E^* = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}$$

Primeira avaliação: _____/_____/_____

		15	14	13	12	11	21	22	23	24	25
Vita											
L	1										
	2										
	3										
a*	1										
	2										
	3										
b*	1										
	2										
	3										
ΔE											
		45	**44**	**43**	**42**	**41**	**31**	**32**	**33**	**34**	**35**
Vita											
L	1										
	2										
	3										
a*	1										
	2										
	3										
b*	1										
	2										
	3										
ΔE											

Vita: Escala Vita **Espectrofotômetro- L:** Eixo l **a:** Eixo a **B:** Eixo b

Segunda avaliação: _____/_____/_____

		15	14	13	12	11	21	22	23	24	25
Vita											
L	1										
	2										
	3										
a*	1										
	2										
	3										
b*	1										
	2										
	3										
ΔE											
		45	**44**	**43**	**42**	**41**	**31**	**32**	**33**	**34**	**35**
Vita											
L	1										
	2										
	3										
a*	1										
	2										
	3										
b*	1										
	2										
	3										
ΔE											

Vita: Escala Vita **Espectrofotômetro- L:** Eixo l **a:** Eixo a **B:** Eixo b

Terceira avaliação: _____/_____/_____

		15	14	13	12	11	21	22	23	24	25
Vita											
L	1										
	2										
	3										
a*	1										
	2										
	3										
b*	1										
	2										
	3										
ΔE											
		45	**44**	**43**	**42**	**41**	**31**	**32**	**33**	**34**	**35**
Vita											
L	1										
	2										
	3										
a*	1										
	2										
	3										
b*	1										
	2										
	3										
ΔE											

Vita: Escala Vita **Espectrofotômetro- L:** Eixo l **a:** Eixo a **B:** Eixo b

Quarta avaliação: _____/_____/_____

		15	14	13	12	11	21	22	23	24	25
Vita											
L	1										
	2										
	3										
a*	1										
	2										
	3										
b*	1										
	2										
	3										
ΔE											
		45	**44**	**43**	**42**	**41**	**31**	**32**	**33**	**34**	**35**
Vita											
L	1										
	2										
	3										
a*	1										
	2										
	3										
b*	1										
	2										
	3										
ΔE											

Vita: Escala Vita **Espectrofotômetro- L:** Eixo l **a:** Eixo a **B:** Eixo b

Quinta avaliação: _____/_____/_____

		15	14	13	12	11	21	22	23	24	25
Vita											
L	1										
	2										
	3										
a*	1										
	2										
	3										
b*	1										
	2										
	3										
ΔE											
		45	**44**	**43**	**42**	**41**	**31**	**32**	**33**	**34**	**35**
Vita											
L	1										
	2										
	3										
a*	1										
	2										
	3										
b*	1										
	2										
	3										
ΔE											

Vita: Escala Vita **Espectrofotômetro- L:** Eixo l **a:** Eixo a **B:** Eixo b

Formulário 3- Avaliação da segurança

Sensibilidade

Inicial	Após 1 semana	Após 2 semanas	Após 3 semanas	Após 30 dias

Irritação Gengival - Índice Gengival Modificado (LOBENE et al., 1986)

- 0 → Ausência de inflamação;
- 1 → Inflamação leve - ligeira alteração na cor e textura em parte da gengiva;
- 2 → Inflamação leve envolvendo toda a margem gengival;
- 3 → Inflamação moderada, superfície brilhante e edema;
- 4 → Inflamação grave, sangramento espontâneo e edema acentuado.

$$\Delta IGM = \frac{\Sigma \text{ escores de cada dente}}{N^{o} \text{ de dentes}}$$

	15	14	13	12	11	21	22	23	24	25
1ª										
2ª										
3ª										
4ª										
	45	**44**	**43**	**42**	**41**	**31**	**32**	**33**	**34**	**35**
1ª										
2ª										
3ª										
4ª										

1ª- 5ª: sequências de avaliações

Formulário 4- Avaliação do impacto na qualidade de vida (OIDP) Questionário Estruturado

Eu vou lhe fazer umas perguntas para saber se o(a) senhor(a) tem tido problemas na sua boca, dentes e quais as dificuldades que esses problemas tem trazido para o seu dia a dia nos últimos 6 meses.

P1. Nos últimos 06 meses, você tem tido alguma dificuldade... (ATIVIDADE/COMPORTAMENTO) ... devido a problemas em sua boca e dentes?

MARQUE "SIM" OU "NÃO".
PARA CADA ATIVIDADE/COMPORTAMENTO MARCADO COMO "SIM", FAÇA AS PERGUNTAS DE P2 ATÉ P6.

P2. Você tem tido essa dificuldade...(ATIVIDADE/COMPORTAMENTO)... devido a problemas em sua boca e dentes?

Seguidamente	1 - **VÁ PARA P3**
Em parte desse período	2 - **VÁ PARA P4**

MARQUE APENAS UMA E ENTÃO PERGUNTE P3 OU P4, CONFORME INDICADO.
CASO SEJA "SEGUIDAMENTE" (MARCADO 1 NA P2)

P3. Nos últimos 06 meses, com que frequência você tem tido essa dificuldade... (ATIVIDADE/COMPORTAMENTO)...?

Todos os dias ou quase todos os dias	5
De 3-4 vezes por semana	4
De 1-2 vezes por semana	3
De 1-2 vezes por mês	2
Menos de 1 vez por mês?	1

ANOTE O CÓDIGO EM P3, NA GRADE DE RESPOSTAS. VÁ PARA P5.
CASO SEJA "EM PARTE DESSE PERÍODO" (MARCADO COMO 2 EM P2).

P4. Por quanto tempo nos últimos 06 meses você tem tido essa dificuldade... (ATIVIDADE/COMPORTAMENTO)...?

Mais de 3 meses	5
De 2 a 3 meses	4
De 1 a 2 meses	3
De 5 dias a 1 mês	2
Por 5 dias ou menos?	1

ANOTE O CODIGO EM P4, NAGRADE DE RESPOSTAS. VÁ PARA P5.

P5. Em uma escala de 0 a 5, onde 0 significa não ter afetado e 5 significa tem afetado demais, quanto você diria que essa dificuldade... (ATIVIDADE/COMPORTAMENTO)... tem afetado o seu dia a dia?

Não tem afetado	0
Tem afetado muito pouco	1
Tem afetado pouco	2
Tem afetado mais ou menos	3
Tem afetado bastante	4
Tem afetado demais	5

ANOTE O CÓDIGO EM P5, NA GRADE DE RESPOSTAS.
VÁ PARA P6.

P6. Qual/quais problema(s) bucal(ais) causou/causaram essa dificuldade... (ATIVIDADE/COMPORTAMENTO)...?

Dor de dente	1	Gengiva inchada (abscesso gengival)	11
Dente sensível	2	Gengiva retraída (gengiva que subiu ou desceu)	12
Cárie dentária (buraco no dente)	3	Tártaro	13
Dente quebrado	4	Úlcera, ferida ou mancha na boca	14
Perda de dente/dentes	5	Mau hálito	15
Dente frouxo/mole	6	Deformidade bucal ou no rosto (ex. lábio leporino, fenda palatina, abertura no céu da boca)	16
Cor dos dentes	7	Mandíbula com estalido ou rangido na mandíbula	17
Posição dos dentes (ex. torto ou para frente, espaço entre os dentes)	8	Obturação ou coroa com defeito (ex. quebrado, por causa da cor)	18
Forma ou tamanho dos dentes	9	Aparelhos nos dentes (ortodôntico)	19
Gengiva sangrando	10	Ou qualquer outra razão? (por favor, diga qual)	88

ANOTE O CÓDIGO EM P6 NA GRADE DE RESPOSTAS. É PERMITIDO MARCAR MAIS DE UMA RESPOSTA. SE MAIS DE UMA RESPOSTA FOR APLICAVEL, ENTÃO MARQUE AS RESPOSTAS POR ORDEM DE IMPORTANCIA SEGUNDO O ENTREVISTADO.

Primeira avaliação:	**P1)**		**P2)**		**P3)**	**P4)**	**P5)**	**P6)**
	SIM	NÃO	Seguidamente	Parte do período	Com que frequência?	Por quanto tempo?	Efeito (0-5)	Problema (s)
Para comer	1	2	1 → P3	2 →P4				
Para falar claramente	1	2	1 → P3	2 → P4				
Para limpar seus dentes	1	2	1 → P3	2 → P4				
Para realizar atividades físicas leves, como trabalhos domésticos	1	2	1 → P3	2 → P4				
Para sair (ex. ir às compras ou visitar alguém)	1	2	1 → P3	2 → P4				
Para dormir	1	2	1 → P3	2 → P4				
Para sorrir, dar risadas e mostrar os dentes sem ficar envergonhado	1	2	1 → P3	2 → P4				
Com seu estado emocional, por ex., se incomodar mais do que o normal	1	2	1 → P3	2 → P4				
Para trabalhar (se não se aplica = código 66)	1	2	1 → P3	2 → P4				
Em aproveitar o convívio com as pessoas, tais como parentes, amigos ou vizinhos	1	2	1 → P3	2 → P4				
Para descansar	1	2	1 → P3	2 → P4				
Para realizar atividades físicas pesadas	1	2	1 → P3	2 → P4				

Segunda avaliação:	**P1)**		**P2)**		**P3)**	**P4)**	**P5)**	**P6)**
	SIM	NÃO	Seguidamente	Parte do período	Com que frequência?	Por quanto tempo?	Efeito (0-5)	Problema (s)
Para comer	1	2	1 → P3	2 →P4				
Para falar claramente	1	2	1 → P3	2 → P4				
Para limpar seus dentes	1	2	1 → P3	2 → P4				
Para realizar atividades físicas leves, como trabalhos domésticos	1	2	1 → P3	2 → P4				
Para sair (ex. ir às compras ou visitar alguém)	1	2	1 → P3	2 → P4				
Para dormir	1	2	1 → P3	2 → P4				
Para sorrir, dar risadas e mostrar os dentes sem ficar envergonhado	1	2	1 → P3	2 → P4				
Com seu estado emocional, por ex., se incomodar mais do que o normal	1	2	1 → P3	2 → P4				
Para trabalhar (se não se aplica = código 66)	1	2	1 → P3	2 → P4				
Em aproveitar o convívio com as pessoas, tais como parentes, amigos ou vizinhos	1	2	1 → P3	2 → P4				
Para descansar	1	2	1 → P3	2 → P4				
Para realizar atividades físicas pesadas	1	2	1 → P3	2 → P4				

ANEXO 3

Termo de consentimento livre e esclarecido

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Você está sendo convidado a participar de uma pesquisa chamada "Clareamento dentário caseiro e de consultório: eficácia, segurança e impacto na qualidade de vida relacionada à saúde bucal. O objetivo da pesquisa é avaliar o efeito das técnicas de clareamento nos seus dentes e na sua vida diária. O clareamento é realizado pela aplicação de um agente clareador (peróxido) na superfície do dente, no consultório, pelo dentista ou em casa pelos pacientes, com o acompanhamento do profissional. Sua participação nessa pesquisa não é obrigatória e você poderá desistir de participar a qualquer momento e retirar seu consentimento. Sua recusa não trará nenhum prejuízo na relação entre você e seu dentista ou no tratamento realizado nas clínicas da faculdade de odontologia.

Caso aceite participar da pesquisa você receberá o tratamento de clareamento dentário. A escolha da técnica de clareamento será definida por sorteio. Você receberá todas as explicações sobre as técnicas em um roteiro escrito e suas dúvidas poderão ser esclarecidas com as pesquisadoras. Para participar, você deverá comparecer à clínica da faculdade uma vez por semana, durante 3 semanas, para o clareamento e após 30 dias, 6 e 12 meses, para reavaliação, nos dias e horários previamente marcados pelas pesquisadoras. Antes e após o clareamento seus dentes serão fotografados e você responderá a uma entrevista sobre suas atividades de vida diária. O tempo total gasto em cada consulta será de aproximadamente 60 minutos.

Os riscos associados ao agente clareador são a possibilidade de seus dentes ficarem sensíveis e sua gengiva irritada. Para diminuir esses efeitos serão seguidas as instruções de uso dos produtos, recomendadas pelos fabricantes. Em caso de sensibilidade dentária ou irritação gengival intensas, o tratamento será interrompido. Em caso de efeitos indesejáveis leves ou moderados, serão feitas aplicações de laser. Para diminuir o risco de desconforto ou constrangimento durante a aplicação do questionário, ele será respondido, individualmente, em local tranquilo. As despesas do clareamento serão de responsabilidade das pesquisadoras. Todos os materiais e instrumentos utilizados serão descartáveis ou esterilizados. O benefício relacionado de sua participação será a possibilidade do clareamento de seus dentes. Você não terá qualquer tipo de despesa para participar da pesquisa e não receberá nenhum tipo de pagamento por sua participação. Os dados obtidos durante a pesquisa são confidenciais, mas poderão ser divulgados em encontros científicos ou em revistas científicas, sem revelar sua identidade, sendo garantido o sigilo na participação. As imagens dos dentes registradas serão armazenadas pela pesquisadora responsável, em local seguro, por até 5 (cinco) anos. Você receberá uma via deste termo onde constam o telefone e o endereço da pesquisadora responsável, com a qual você poderá tirar suas dúvidas sobre a pesquisa e sua participação, a qualquer momento.

Eu,_____, documento de identidade _____, declaro que entendi os objetivos, riscos e benefícios da participação na pesquisa e dou meu consentimento em participar.

Assinatura do participante: _____

Assinatura da pesquisadora responsável: _____

Cláudia Silami de Magalhães. Faculdade de Odontologia. Campus Pampulha. Avenida Antônio Carlos, 6627. Sala 3342. Belo Horizonte. MG. Fone: 31 34092456. E-mail: silamics@yahoo.com

Qualquer dúvida quanto ao compromisso ético desta pesquisa, você poderá consultar o COMITÊ DE ÉTICA EM PESQUISA DA UFMG. COEP-UFMG. Av. Antônio Carlos, 6627. Unidade Administrativa II - 2º andar - Sala 2005. Campus Pampulha. Belo Horizonte, MG – Brasil. CEP: 31270-901. E-mail: coep@prpq.ufmg.br. Tel: 34094592