Universidade do Estado do Rio de Janeiro
Centro Biomédico
Faculdade de Odontologia

Glaucia dos Santos Athayde Gonçalves

Mascaramento de opacidades do esmalte dentário em pacientes com Hipomineralização Molar Incisivo: relato de caso e ensaio clínico controlado randomizado

Rio de Janeiro
2021

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Tese apresentada como requisito parcial para obtenção do título de Doutor, ao Programa de Pós-Graduação em Odontologia, da Universidade do Estado do Rio de Janeiro. Área de concentração: Odontopediatria.

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RESUMO

GONÇALVES, Glaucia dos Santos Athayde. *Mascaramento de opacidades do esmalte dentário em pacientes com Hipomineralização Molar Incisivo: relato de caso e ensaio clínico controlado randomizado.* 2021. 105 f. *Tese (Doutorado em Odontologia) - Faculdade* de Odontologia, Universidade do Estado do Rio de Janeiro, Rio de Janeiro, 2021.

A presente tese é composta por dois estudos: relato de caso e ensaio clínico randomizado. Os protocolos foram aprovados pelo Comitê de Ética (UERJ) e os participantes/responsáveis assinaram o TCLE. O relato de caso descreveu uma abordagem minimamente invasiva, infiltração de resina de baixa viscosidade combinada com resina composta, para mascarar opacidades difusas (fluorose) e demarcadas (HMI), em dentes permanentes anteriores, de paciente com 8 anos. O caso clínico concluiu que o tratamento foi eficaz no mascaramento das opacidades e após 24 meses a cor se mostrou estável e o paciente satisfeito. O ensaio clínico randomizado objetivou avaliar o impacto do mascaramento de opacidades demarcadas por HMI em incisivos permanentes. Trinta e nove pacientes, de 8 a 18 anos, apresentando pelo menos um incisivo permanente com opacidade branco-creme, foram alocados aleatoriamente para o grupo teste ou controle. No grupo de teste foram tratados 28 dentes e 29 no grupo placebo. O teste recebeu microabrasão + infiltrante e o controle recebeu o placebo. O infiltrante e o placebo foram deixados nos dentes por 30 minutos. A avaliação do impacto do tratamento foi pelo questionário “Child's and Parent's Questionnaire about Teeth Appearance”. A análise quantitativa do mascaramento foi feita por fotografia digital, Sistema Lab, calculando o ΔE entre área da opacidade e área sadia do esmalte (Photoshop). Dois examinadores calibrados fizeram a análise qualitativa das fotografias. O impacto do tratamento dos grupos teste e placebo na percepção sobre a aparência dos dentes (pontuação média do questionário) foi avaliado pelo teste de Wilcoxon. O resultado qualitativo (mascaramento total, parcial ou nenhum) utilizou o teste Qui-quadrado, a concordância dos examinadores o kappa e Mann-Whitney para as diferenças do ΔE. Duas medidas foram os desfechos principais: o valor absoluto e a diferença percentual entre o ΔE inicial e o ΔE final/follow-up. O nível de significância de 0,05. No grupo teste, foi observada redução significativa nos escores do questionário em relação aos domínios físico ($p = 0,01$), psicológico ($p = 0,02$) e social ($p = 0,04$) na visão dos pais após o tratamento. No domínio social, também foi observada redução significativa na opinião das crianças ($p = 0,00$). Os pais ($p = 0,01$) e filhos ($p = 0,04$) do grupo de teste relataram significativamente menos preocupação com a cor dos dentes após o tratamento. Antes do tratamento, o ΔE foi de 6,45 ± 3,53 no teste e 5,98 ± 2,57 no grupo controle ($p = 0,88$) sendo observada diferença significativa entre os grupos 15 minutos após a aplicação. Após o tratamento, o ΔE foi 4,07 ± 3,07 no teste e 7,35 ± 3,54 no grupo controle ($p = 0,000$). Na consulta follow-up o ΔE foi de 4,22 ± 2,96 no teste e 6,06 ± 2,52 no grupo controle ($p = 0,002$). O mascaramento total foi obtido em 16 (57,1%) e 13 (46,4%) dentes do grupo teste, de acordo com o examinador 1 e 2, respectivamente. Como conclusão observou-se um impacto positivo do infiltrante resinoso na percepção dos pais e das crianças sobre a aparência dos dentes. O infiltrante reduziu o ΔE entre opacidade e o esmalte sadio.

Palavras-chave: Esmalte Dentário. Hipomineralização Molar Incisivo. Infiltrante resinoso. Odontologia Minimamente Invasiva. Estética dental. Crianças.

ABSTRACT

GONÇALVES, Glaucia dos Santos Athayde. *Masking dental enamel opacities in patients with Molar Incisor Hypomineralization: a case report and a randomized controlled clinical trial.* 2021. 105 f. Tese (Doutorado em Odontologia) - Faculdade de Odontologia, Universidade do Estado do Rio de Janeiro, Rio de Janeiro, 2021.

This thesis comprises two studies: a case report and randomized controlled trial. The protocols were approved by the Ethics Committee (UERJ) and participants/guardians signed an informed consent. A case report described a minimally invasive approach, infiltration technique with a low-viscosity resin, combined with composite restoration, to mask diffuse (fluorosis) and demarcated opacities (MIH), in permanent anterior teeth, in an eight-year-old child. The clinical report concluded that the treatment was effective in masking the opacities and after 24 months the color was stable and the patient satisfied. The randomized controlled trial that aimed to evaluate the impact of masking MIH demarcated opacities in permanent incisors. Thirty-nine patients, 8 to 18 years old, presenting at least one permanent incisor with white-creamy opacity were randomly allocated to test or control group. In the test group 28 teeth were treated and 29 in placebo group. The test received microabrasion + resin infiltration and the control received a placebo. Infiltrant and placebo were left on the teeth for 30 minutes. The evaluation of the treatment impact was carried out through the questionnaire: Child's and Parent's Questionnaire about Teeth Appearance. The masking effect was quantitatively analyzed by digital photography using the Lab System and ΔE between opacity area and sound area of the enamel (Photoshop). Two calibrated examiners did the qualitative analysis of clinical photographs. The impact of the test and placebo treatment on the perception about teeth appearance (mean score of the questionnaire) was analyzed by Wilcoxon test. The qualitative result (total, partial or no masking) was compared using Chi-square test. The examiners agreement was assessed using kappa coefficient. Mann-Whitney was used to test the difference in ΔE values in the different time points. Two summary measures were the main outcomes: the absolute and the percentage difference between initial ΔE and final/ follow-up ΔE. The level of significance was set at 0.05. In the test group, it was observed a significant reduction in the questionnaire scores in relation to physical ($p = 0.01$), psychological ($p = 0.02$), and social ($p = 0.04$) domains in parents' point of view after treatment. In the social domain a significant reduction was also seen in the children's opinion ($p = 0.00$). The parents ($p=0.01$) and children ($p=0.04$) from test group reported significantly less concern with tooth colour after treatment. Before treatment, the ΔE was 6.45 ± 3.53 in the test and 5.98 ± 2.57 in the control group ($p=0.88$). A significant difference between test and control groups was seen from 15 minutes of application onwards. After treatment, the ΔE was 4.07 ± 3.07 in the test and 7.35 ± 3.54 in the control group ($p=0.000$). In the follow up evaluation the mean ΔE was 4.22 ± 2.96 in the test and 6.06 ± 2.52 in the control group ($p=0.002$). A total masking was achieved in 16 (57.1%) and 13 (46.4%) teeth of the test group, according to the examiner 1 and 2, respectively. As a conclusion, observed a positive impact of resin infiltration on parents' and children's perception about tooth appearance. The infiltration decreased ΔE between the MIH opacities and sound enamel.

Keywords: Dental Enamel. Molar Incisor Hypomineralization. Infiltrant. Minimal Intervention. Dental Aesthetics. Children.

LISTA DE ABREVIATURAS

C-OHIP	Questionário Impacto da Saúde Bucal de Crianças
CPQ	*Child Perception Questionnaire*
DDE	Defeito de desenvolvimento do esmalte
DP	Desvio padrão
EAPD	*European Academy for Paediatric Dentistry*
HMI	Hipomineralização Molar Incisivo
MIH	*Molar Incisor Hypomineralization*
OHRQL	Impacto da Saúde Bucal nas atividades diárias
OIDP	Qualidade de vida auto relatada
OMS	Organização Mundial da Saúde
RJ	Rio de Janeiro
SPSS	*Statistical Package for the Social Science*
SD	*Standard deviation*
UERJ	Universidade do Estado do Rio de Janeiro

LISTA DE SÍMBOLOS

p	*p-value*
ΔE	Delta E
µm	Micrômetro
>	Higher
<	Lower
±	More or less
DP/SD	Standard deviation

SUMÁRIO

INTRODUÇÃO

Os defeitos de desenvolvimento de esmalte (DDE) têm ganhado atenção de muitos pesquisadores devido ao impacto significativo na saúde bucal com consequências clínicas e estéticas (1). Os defeitos do esmalte dentário são um achado prevalente na dentição decídua e permanente (2,3), sendo geralmente classificados como hipoplasias e hipomineralizações A hipoplasia é um defeito quantitativo, enquanto a hipomineralização é um defeito qualitativo, caracterizado pela translucidez anormal do esmalte, também conhecido como opacidade do esmalte (4). Essa opacidade pode ser difusa ou demarcada com coloração branca, amarelo-creme ou marrom e pode resultar de alterações de desenvolvimento ou adquiridas (5).

Entre as alterações de desenvolvimento do esmalte, destaca-se a Hipomineralização Molar Incisivo (HMI) que é uma condição de origem sistêmica de alta prevalência (6), caracterizada por defeitos na mineralização do esmalte dos primeiros molares e incisivos permanentes (7,8). O esmalte defeituoso apresenta-se clinicamente como opacidade demarcada que pode variar no que se refere à cor, do branco-creme ao amarelo-acastanhado (9). O esmalte hipomineralizado apresenta menor conteúdo mineral do que o esmalte normal e, por isso, é propenso a sofrer fratura pós-eruptiva (10,11). As opacidades amarelo-acastanhadas apresentam conteúdo mineral ainda mais reduzido e são, portanto, mais susceptíveis a fraturas do que as opacidades brancas. Em incisivos, o esmalte defeituoso geralmente é menos propenso à quebra do que nos molares (12). A HMI está associada a índices mais altos de cárie dentária em crianças (13,14).

As opacidades em esmalte localizadas em dentes anteriores podem interferir na vida social de crianças e adolescentes (15,16) que algumas vezes procuram esconder o sorriso (17). A severidade da opacidade e o desejo do paciente por melhorar a estética guiam o clínico na melhor escolha do tratamento. Alternativas para se obter uma melhora estética de opacidades de esmalte variam de estratégias como clareamento dental e microabrasão (18–20) a técnicas mais invasivas através de restaurações diretas em resina composta ou facetas em porcelana (21,22). Entre os métodos minimamente invasivos, está o clareamento com peróxido de hidrogênio ou peróxido de carbamida (23). O uso de resinas compostas e facetas de porcelana

proporcionam bons resultados estéticos, mas acarretam invariavelmente em maior desgaste da estrutura dentária (21,22,24).

Mais recentemente, o uso de um infiltrante resinoso, ou resina de baixa viscosidade, vem representando uma proposta minimamente invasiva para mascarar opacidades no esmalte. O infiltrante quando usado no tratamento de leões de mancha branca por cárie tem demonstrado excelente resultado estético (25–27). Experiências bem sucedidas também têm sido relatadas no mascaramento de opacidades relacionadas à fluorose e a opacidades causadas por trauma no dente decíduo antecessor entre outras (25,28–33). A técnica de infiltrar a opacidade com resina de baixa viscosidade baseia-se no fato de que a resina apresenta índice de refração similar ao do esmalte sadio. Assim, quando a resina penetra e preenche as porosidades de lesões cariosas, faz com que o índice de refração que havia sido alterado pela existência de água nas porosidades, retome valores muito próximos ao do esmalte sadio, tornando a opacidade pouco ou nada perceptível (30,34)

Enquanto lesões cariosas são mais facilmente infiltradas pela resina de baixa viscosidade, o mesmo não parece ocorrer nas opacidades demarcadas. Por isso, o efeito desejado do mascaramento de opacidades demarcadas em dentes anteriores nem sempre é alcançado apenas com uso de infiltrante. Kim e colaboradores (27) analisaram o efeito do infiltrante resinoso tanto em dentes com defeito de desenvolvimento de esmalte quanto em dentes com lesões iniciais de cárie que se desenvolveram ao redor de bráquetes ortodônticos, as manchas brancas pós tratamento ortodôntico (MB/PO). As lesões cariosas foram mascaradas com mais sucesso do que lesões decorrentes de DDE. O trabalho realizado por Mazur e colaboradores (31) objetivou avaliar a performance estética do infiltrante resinoso em opacidades de esmalte causadas tanto por cárie pós tratamento ortodôntico quanto por DDE. Concluíram que o infiltrante resinoso tem efeito estético positivo forte sobre as lesões de esmalte (MB/PO) e DDE, em adultos jovens sendo que opacidades por HMI não foram incluídas neste estudo.

Na revisão sistemática sobre a efetividade da infiltração com resina de baixa viscosidade no mascaramento de opacidades em esmalte (26), verificou-se que a maior parte dos estudos avaliou o mascaramento de lesões cariosas formadas ao redor de bráquetes ortodônticos (MB/PO) as quais costumam apresentar alto percentual de mascaramento total ou parcial. Apenas um estudo comparou mascaramento de lesões de MB/PO com opacidades por HMI. Dois estudos

avaliaram o infiltrante em opacidades por fluorose. Os autores pontuaram possíveis fatores que poderiam ter influenciado no resultado do mascaramento das opacidades pelo infiltrante tais como a profundidade e extensão da lesão.

Existem vários métodos utilizados para avaliar mudanças de cor no elemento dental. Estes métodos podem ser qualitativos, análise visual das fotografias com ou sem uso de escala visual analógica (31,35) ou ainda com auxílio de uma escala de cor (36) e, quantitativos onde são empregados espectrofotômetros e/ou técnicas de análise de imagem com ajuda de *softwares* (31,33,37). Estudos clínicos analisaram o efeito do mascaramento de opacidades de esmalte empregando desde métodos de avaliação mais simples e de baixo custo como fotografias digitais até espectrofotômetros que quantificam a cor e a luminosidade dentária de forma rápida e precisa (31,38).

Alterações de esmalte nos dentes anteriores podem gerar um impacto negativo na autoestima, na percepção estética e nos aspectos psicossociais de crianças e adolescentes (39–41). O estudo de Sujak e colaboradores (42) utilizou questionário e realizou exame clínico em escolares de 16 anos para avaliar a prevalência e o impacto psicossocial de defeitos de esmalte e verificou que 85,5% apresentou opacidade de esmalte. Entre as crianças que demonstraram insatisfação 18,8% relataram que colocavam mão sobre a boca para esconderem sorriso e 8,75% evitavam sair com amigos.

Em uma revisão de literatura sobre percepção estética da fluorose e a relação com aspectos psicossociais relacionados a qualidade de vida publicada em 2010 (43) foram citados trabalhos que utilizaram questionários como *Child Perceptions Questionnaire* (CPQ), *Oral Impact in Daily Performance* (OIDP), *Parent Perception Questionnaire (*PPQ). O *Oral Health Impact Profile* (OHIP) foi usado para avaliar qualidade de vida. Este estudo concluiu que a fluorose leve e muito leve indicou ter pouco ou nenhum efeito sobre a qualidade de vida das crianças possivelmente devido ao efeito de dentes mais brancos.

Perspectivas de crianças do Reino Unido após tratamento estético de defeitos de esmalte visíveis nos incisivos foram avaliadas por meio de questionário e de uma escala visual analógica onde encontraram impacto psicossocial negativo em algumas crianças que foi melhorado com o tratamento estético. O efeito combinado da microabrasão e restaurações em resina levou a um efeito positivo na autoestima e na felicidade das crianças (44).

Um estudo caso-controle com pacientes com e sem HMI realizado no Brasil por Leal et al. (2016) (17) avaliou se responsáveis e crianças são capazes de perceber opacidades nos incisivos associadas à HMI como um problema de saúde bucal, utilizando *Child's and Parent's Questionnaire about Teeth Appearance*, instrumento validado no Brasil em 2012 por Furtado et al. (45). Originalmente este questionário foi desenvolvido por Martinez et al. (46) para avaliação da percepção de crianças e pais dos Estados Unidos e do México com relação à fluorose dental. Este instrumento se mostrou eficaz na avaliação de opacidades por HMI no estudo supracitado de Leal et al. e concluiu que estas alterações de esmalte são uma preocupação para as crianças e para as mães pois se mostraram insatisfeitas com relação a descoloração do esmalte dentário.

O estudo de Hasmun et al. 2018 (47) avaliou mudança na qualidade de vida de crianças com opacidades demarcadas nos incisivos devido a HMI após diferentes tratamentos estéticos, incluindo infiltrante resinoso, e verificou um aumento significativo da qualidade de vida auto relatada (*Oral Health Related Quality of Life* - OHRQoL) e no bem-estar das crianças.

Desta forma, destaca-se a necessidade de mais pesquisas que avaliem o impacto da HMI na percepção estética de crianças e responsáveis assim como a relevância do tratamento estético de opacidades em dentes anteriores para este grupo de pacientes. Até o presente, são poucos os estudos com infiltrante resinoso no mascaramento de opacidades de esmalte em dentes anteriores relacionadas à HMI. A escassez de estudos clínicos e a difícil previsibilidade dos resultados justificam a realização do presente estudo.

1 **DESENVOLVIMENTO**

1.1 **Proposição**

1.1.1 Objetivo Geral

Avaliar o efeito de estratégias minimamente invasivas no mascaramento de opacidades relacionadas a defeitos de desenvolvimento do esmalte dentário.

1.1.2 Objetivos específicos

a) Apresentar um caso clínico descrevendo a técnica de infiltração de resina de baixa viscosidade combinada ao uso de resina composta para o mascaramento de opacidade difusa e demarcada em incisivos permanentes;
b) Avaliar o impacto do tratamento de opacidades demarcadas combinando microabrasão infiltradas com resina de baixa viscosidade em incisivos permanentes na percepção estética de crianças com HMI e seus responsáveis;
c) Avaliar o potencial de mascaramento do tratamento de opacidades demarcadas combinando microabrasão com resina de baixa viscosidade em incisivos permanentes após diferentes tempos de aplicação do infiltrante;
d) Avaliar a aceitação do tratamento combinando microabrasão com resina de baixa viscosidade em incisivos permanentes pelas crianças.

1.2 **Metodologia**

A presente tese é composta por 2 artigos com desenhos metodológicos distintos, a fim de elucidar e responder cada um dos objetivos específicos.

1.2.1 Estudo 1

O primeiro estudo é um relato de caso clínico.

1.2.1.1 Aspectos éticos

Este trabalho teve aprovação do Comitê de Ética e Pesquisa sob número 07753213.0.0000.5259 (Plataforma Brasil) e uma emenda sob número 787.354. O Termo de Consentimento Livre e Esclarecido (TCLE) foi assinado pela responsável legal da paciente, autorizando o tratamento e o uso de imagens.

1.2.1.2 Informações do paciente

Paciente com 8 anos de idade, gênero feminino, sem comprometimento sistêmico, compareceu a clínica de Odontopediatria da UERJ com queixa estética do aspecto esbranquiçado dos dentes anteriores superiores.

1.2.1.3 Achados clínicos

Ao exame clínico verificou-se opacidade difusa nos dentes: 12,11,21 e 22 com diagnóstico de fluorose moderada, escore 5. Uma opacidade demarcada cor amarelada no dente 21 foi diagnosticada como HMI (Figura 1). O diagnóstico de fluorose foi baseado no Índice de Thylstrup e Fejerskov (48) e o de HMI de acordo com a Academia Europeia de Odontopediatria (49).

1.2.1.4 Intervenção terapêutica

A decisão de tratamento foi baseada na odontologia de mínima intervenção usando a técnica de microinfiltração com resina de baixa viscosidade (ICON®, DMG) e resina composta (TPH, Dentisply, São Paulo, Brazil) como uma tentativa de mascarar as descolorações do esmalte.

Os dentes foram limpos e isolados com lençol de borracha (Figura 2). A técnica de infiltração seguiu as instruções do fabricante. O esmalte dos elementos 11, 12, 21 e 22 foi atacado com gel de HCl 15% (ICON etch®, DMG) por 2 min (Figura 3), seguido de enxágue por 30s, secagem com ar comprimido (Figura 4) e desidratação com etanol 100% (ICON dry®, DMG) por 30s. Durante a aplicação do etanol, o aspecto visual do esmalte foi verificado e as opacidades não desapareceram. Assim, a etapa de condicionamento foi repetida. Após o segundo condicionamento ácido, as opacidades difusas foram mascaradas, mas a opacidade creme no MIH no dente 21 ainda era visível. Em seguida, retirou-se aproximadamente 0,2mm do esmalte com broca de diamante e aplicou-se novamente o gel de ácido clorídrico (ICON etch®, DMG) apenas na área da opacidade demarcada (Figuras 5 e 6). Quando o etanol foi aplicado, foi possível observar que a opacidade demarcada também estava camuflada (Figura 7). A resina de infiltração (ICON® Infiltrant, DMG) foi cuidadosamente aplicada na área condicionada por 3 minutos sem fricção (Figura 8), levemente seca com ar comprimido e, após remoção do excesso com ar comprimido, fotopolimerizada por 40s (Altlux, Ribeirão Preto, SP, Brasil) (Figura 9). Resina composta, cor A2, (TPH,

Dentsply, São Paulo, Brasil) foi usada para restaurar o esmalte gasto pela broca. As superfícies dos dentes foram polidas com discos de polimento de resina composta (Sof-Lex, 3M ESPE, St Paul, MN, EUA).

1.2.1.5 Desfechos

A estratégia minimamente invasiva baseada na microinfiltração de resina de baixa viscosidade e compósito, adotada neste caso clínico, resultou em excelentes resultados estéticos. Opacidades difusas e demarcadas foram mascaradas em uma única sessão, melhorando a autoestima da paciente.

1.2.1.6 Acompanhamento

A paciente compareceu em todas as consultas de retorno e não relatou nenhum efeito adverso durante o atendimento e no follow-up. O tratamento realizado mostrou estabilidade de cor ao longo dos 24 meses de acompanhamento. O aspecto clínico imediatamente após a infiltração e retirada do lençol de borracha, acompanhamentos de 12 e 24 meses, são apresentados nas figuras 10, 11, 12 e 13 respectivamente.

1.2.2 Estudo 2

O segundo estudo foi delineado como um ensaio clínico controlado randomizado.

1.2.2.1 Aspectos éticos

O protocolo de pesquisa do presente estudo foi aprovado no Comitê de Ética em Pesquisa do Hospital Universitário Pedro Ernesto da Universidade do Estado do Rio de Janeiro (18245719.8.0000.5259) (ANEXO A) e inscrito no Registro Brasileiro de Ensaios Clínicos (U1111-1240-5384) (ANEXO B) seguindo o checklist do CONSORT 2010. Os participantes da pesquisa e seus responsáveis foram informados sobre os riscos e benefícios da pesquisa e participaram da pesquisa somente após leitura e assinatura do Termos de Assentimento - TALE (APÊNDICE A) e TCLE (APÊNDICE B). Este ensaio clínico.

Nos casos onde o tratamento com infiltrante (grupo teste) foi superior ao controle, este foi oferecido também aos pacientes do grupo controle. Em ambos os grupos, para aqueles que não ficaram satisfeitos com a estética do tratamento recebido pela técnica do infiltrante, foi oferecido o tratamento com restauração em resina composta.

1.2.2.2 Local do estudo

O presente ensaio clínico foi realizado na Clínica de Odontopediatria da Faculdade de Odontologia da Universidade do Estado do Rio de Janeiro (UERJ) situada no bairro de Vila Isabel, zona norte da cidade do Rio de Janeiro.

1.2.2.3 Amostra

Critérios de elegibilidade

A amostra foi composta por crianças e adolescentes, com idade entre 8 e 18 anos, com HMI, apresentando opacidades em esmalte de coloração branco-creme em pelo menos um incisivo permanente segundo critério da EAPD (49).

Critérios de exclusão:

-Pacientes com outros defeitos de desenvolvimento do esmalte dentário como amelogênese, dentinogênese , hipoplasia ou fluorose;

-Pacientes com aparelho ortodôntico fixo;

-Pacientes com síndromes ou comprometimento crônico de saúde ou outras condições que determinaram a necessidade de cuidados especiais durante o atendimento odontológico;

-Dentes anteriores com lesões de cárie ou com opacidades demarcadas de outras origens, como sequelas de trauma no decíduo antecessor ou que tenham recebido tratamento estético prévio.

Cálculo da amostra

O cálculo amostral baseou-se na estimativa de diminuição do escore médio de 0,5 no grupo controle e 1,0 no grupo teste no domínio social do questionário. Com nível de significância de 5% e poder de 80%, foi necessário um tamanho de amostra de no mínimo 32 pacientes. Considerando a possibilidade de perda de 25% após o tratamento, 20 pacientes em cada grupo foram incluídos na amostra.

1.2.2.4 Randomização

O método de randomização em blocos seguindo uma tabela de números aleatórios gerada no Microsoft Excel® para Mac (versão 16.44) foi utilizado para alocar os pacientes em grupo teste ou controle. A tabela de números aleatórios foi gerada com um total de 40 números divididos em 10 blocos, cada bloco com 4 opções de tratamento (2 testes e 2 controle). Os números randomizados correspondentes ao tratamento teste ou controle foram transferidos para envelopes opacos antes do início do ensaio clínico por uma pessoa que não estava envolvida na pesquisa. Os envelopes foram organizados sequencialmente de acordo com a sequência aleatória. À medida que os pacientes chegavam à clínica para o tratamento, um auxiliar retirava um envelope no qual havia a letra T para o grupo

teste ou C para o grupo controle, conforme a sequência randomizada. Operadores, pacientes e pais desconheciam o tratamento atribuído. Os pacientes foram agendados por turno; quatro da manhã e quatro da tarde e cada operador atendia dois por turno respeitando a sequência aleatória.

Durante o tratamento, o cegamento dos pacientes e responsáveis foi garantido, pois foi utilizado um tratamento placebo, simulando todas as etapas do tratamento teste no tratamento controle. Os operadores, entretanto, não ficaram cegos durante todo o tratamento porque os produtos placebo não imitaram os efeitos clínicos como a dessecação causada pelo ataque ácido. Os examinadores que realizaram a análise quantitativa e qualitativa do efeito de mascaramento não realizaram os tratamentos e, portanto, estavam cegos quanto ao tratamento.

1.2.2.5 Treinamento e calibração

Os operadores possuíam experiência prévia com uso da técnica de micro infiltração e antes do início do estudo realizaram um piloto onde cada operador atendeu uma criança, com opacidades demarcadas por HMI em dentes anteriores, seguindo todas as etapas da intervenção teste e controle. O piloto permitiu checar o tempo de trabalho cronometrando o passo a passo, treinar o manuseio da câmera fotográfica e orientar as auxiliares no correto preenchimento dos questionários dos responsáveis e das crianças. O questionário foi preenchido em separado para responsáveis e crianças de modo que não houvesse interferência nas respostas e serviu de roteiro de entrevista tendo cuidado para que o entrevistador não fizesse comentários ou expressões que pudessem induzir a resposta. Para a análise qualitativa, dois examinadores foram treinados para a avaliação clínica inicial e final classificando cada dente em mascaramento total, parcial ou não mascaramento. O Kappa ponderado para intraexaminador foi de 0,98 e 0,88 e para interexaminadores foi de 0,84. Um terceiro examinador foi treinado para a análise quantitativa por meio do sistema CIELAB no Photoshop CC para Mac (Adobe, San Jose, EUA). Os dois casos tratados na fase piloto foram analisados como parte do treinamento. Em seguida, 10% do ΔE inicial foram reavaliados para testar a concordância intraexaminador. A correlação intraclasse foi de 0,97 (IC 95%: 0,83 - 0,99).

1.2.2.6 Intervenção

Procedimentos Clínicos

Dois operadores previamente treinados realizaram os tratamentos. O operador 1 tratou 20 pacientes e o operador 2 tratou 20. Todos os pacientes receberam profilaxia com micromotor, taça de borracha e água seguida de anestesia tópica com benzocaína gel 20% (Benzotop, DFL, Rio de Janeiro, Brasil) para melhor conforto durante o isolamento com lençol de borracha. O isolamento com lençol de borracha envolveu os dentes anteriores superiores ou inferiores. Na sequência, o paciente foi tratado de acordo com a randomização.

Possíveis efeitos adversos como dor pós-operatória no dente e tecidos circundantes, paladar ruim (gosto ácido, amargo ou salgado) e dor gengival foram avaliados perguntando a criança imediatamente após o tratamento. Dois números de celular foram disponibilizados caso o responsável tivesse alguma dúvida ou desejasse relatar algum desconforto.

Intervenção Teste

Técnica da infiltração com resina de baixa viscosidade modificada por microabrasão e aumento do tempo de aplicação:

a) Isolamento absoluto;
b) 1ª aplicação do gel de ácido clorídrico a 15% (ICON etch®, DMG) sobre a opacidade por 2 min; realizando fricção com a própria ponta aplicadora nos primeiros 10s;
c) Lavagem por 30s e secagem com ar comprimido por 30s;
d) Aplicação de solução de etanol 99% (ICON dry®, DMG) por 30s;
e) Secagem com ar comprimido por 30s;
f) Reaplicação do gel de ácido clorídrico a 15% por mais 2 vezes conforme a 1ª aplicação seguindo os passos da 1ª aplicação;
g) Aplicação do infiltrante resinoso (ICON® Infiltrant, DMG), aguardando 30 min sem incidência de luz do refletor ou do ambiente sobre o(s) dente(s);

h) Remoção do excesso do infiltrante resinoso com gaze e fio dental;
i) Fotopolimerização por 40s;
j) Reaplicação infiltrante resinoso por mais 1 vez durante 1 min;
k) Remoção do excesso do infiltrante resinoso com gaze e fio dental;
l) Fotopolimerização por 40 segundos;
m) Remoção do lençol de borracha e polimento com pontas especificas para resina;

Intervenção Controle

a) Isolamento absoluto;
b) 1ª aplicação do gel placebo equivalente ao gel de ácido clorídrico sobre a opacidade por 2 min; realizando fricção com a própria ponta aplicadora do kit nos primeiros 10s;
c) Lavagem por 30s e secagem com ar comprimido por 30s;
d) Aplicação de solução placebo, equivalente ao etanol, por 30s;
e) Secagem com ar comprimido por 30s;
f) Reaplicação do gel placebo, equivalente ao gel de ácido clorídrico, por mais 2 vezes conforme a 1ª aplicação, seguindo os passos da 1ª aplicação;
g) Aplicação do placebo, referente ao infiltrante resinoso, aguardando 30 min sem incidência de luz do refletor ou do ambiente sobre o(s) dente(s);
h) Remoção do excesso do placebo referente ao infiltrante resinoso com gaze e fio dental;
i) Fotopolimerização por 40s;
j) Reaplicação do infiltrante placebo por 1 min;
k) Remoção do excesso do infiltrante placebo com gaze e fio dental;
l) Fotopolimerização por 40 segundos;
m) Remoção do lençol de borracha e polimento com pontas especificas para resina;

Intervenção Controle – descrição do placebo

Para cada produto utilizado nas etapas da intervenção teste havia um produto correspondente no grupo controle. A descrição detalhada do placebo está descrita abaixo:

a) Teste: solução de etanol a 99% / controle: solução isotônica composta: 0,9% de cloreto de sódio em água destilada.
b) Teste: gel de ácido clorídrico a 15% / controle: gel oral na composição: gelatina 6%; carboximetilcelulose 4%, cloreto de sódio 0,25%, benzoato de sódio 0,1%, ácido cítrico 1%, água destilada qsp 30g.
c) Teste: infiltrante resinoso / controle: solução de óleo mineral (0,35ml) e azeite de oliva extravirgem (0,1ml)

1.2.2.7 Desfechos

Impacto na percepção estética

A avaliação da percepção sobre a aparência dos dentes foi realizada por meio da versão validada em português do questionário “Child’s and Parent’s Questionnaire about Teeth Appearance” (45). Os pacientes e seus pais responderam ao questionário antes e um mês após o tratamento.

O questionário é dividido em três partes, incluindo 12 itens e subitens. A primeira, com três questões, avalia os domínios físico, psicológico e social e as respostas, registradas e codificadas, variam de "nada" (0) a "muito" (3). A segunda parte contém quatro afirmações nas quais crianças e pais são questionados sobre sua percepção sobre a satisfação, alinhamento, cor e saúde dos dentes da criança e se algum desses itens traz preocupação. As respostas nesta seção variam de "muito bom, muito alinhado, muito branco e muito saudável" (0) a "muito desagradável, muito torto, muito manchado e muito doente" (4). Para cada afirmação, foi questionado se gera preocupação, com "sim" ou "não". A última parte contém a frase: “A cor dos meus dentes/a cor dos dentes do meu filho é agradável e bonita” com respostas variando de “concordo totalmente” (0) a “discordo totalmente” (4).

Análise do efeito de mascaramento

A análise quantitativa do efeito de mascaramento foi realizada usando fotografias clínicas tiradas com uma câmera digital (Nikon D90, Nikon, Tóquio), lente macro (100 mm Macro Rokkor-X, Minolta, Tóquio), flash circular (Sigma, Welwyn Garden City, UK), na mesma exposição (ISO 100, velocidade 1/160, abertura F/20) e distância aproximada de 30 cm do paciente. As fotografias foram tiradas no baseline, ao longo do tempo de aplicação da resina teste ou placebo aos 0, 3, 10, 15, 20, 25 e 30 minutos da aplicação, logo após a retirada do lençol de borracha e na consulta de acompanhamento um mês depois do tratamento. Para garantir o equilíbrio do branco na análise das fotografias, foi utilizado em todas as fotografias intraorais um cartão cinza 18% acromático, livre de reflexos, opaco e neutro (Flexipalette color match FP 3004, Smile Line, Suíça).

As fotografias foram salvas no formato JPEG e analisadas no Photoshop CC para Mac (Adobe, San Jose, EUA) para análise quantitativa no sistema CIELAB (International Commission on Illumination). Valores absolutos de luminosidade (L), cor vermelho-esverdeado (a) e cor amarelo-azul (b) foram avaliados na opacidade e em uma área sadia do esmalte antes e após o tratamento. Calculou-se a diferença de luminosidade (ΔL), vermelho-verde (Δa) e amarelo-azul (Δb) entre a opacidade e a área sadia do esmalte. Em seguida, foi calculada a diferença total de cor (ΔE) entre a opacidade e a área sadia do esmalte por meio da equação ΔE = (ΔL * ² + Δa * ² + Δb * ²) ½ (50,51). O efeito de mascaramento foi representado por uma redução do valor de ΔE após o tratamento em comparação com o valor de ΔE antes do tratamento.

A análise qualitativa do efeito de mascaramento foi feita por leitura aos pares. As fotos iniciais e de acompanhamento foram organizadas lado a lado no Microsoft Power Point® para Mac (versão 16.45). Dois examinadores cegos, odontopediatras experientes, avaliaram as fotografias e classificaram o resultado do tratamento em: 1) mascaramento total (a opacidade não é mais perceptível); 2) mascaramento parcial (a opacidade da cor se aproximou da cor do dente e/ou diminuiu de tamanho, mas ainda é aparente); ou 3) sem mascaramento (não houve mudança na cor ou tamanho da opacidade).

Efeitos colaterais e aceitação do tratamento

Possíveis efeitos adversos como: dor pós-operatória em dentes e gengivas, danos em tecidos moles e gosto amargo foram registrados perguntando-se à criança logo após o tratamento. Dois números de telefone celular foram disponibilizados caso o paciente sentisse algum desconforto e/ou o responsável tivesse alguma dúvida. A aceitação do tratamento foi avaliada pela escala de dor de Wong & Baker (52) logo após o término do tratamento.

Análise estatística

Para a análise estatística foi utilizado o SPSS versão 25.0 (IBM, Chicago, IL, EUA). A caracterização da amostra baseou-se na análise descritiva de idade, sexo, tipo e número de dentes para grupo teste e controle separadamente. Os dados sobre dor e efeitos colaterais foram apresentados como frequências absolutas e relativas. O teste exato de Fisher foi usado para testar a associação entre variáveis dicotômicas.

Os dados relacionados ao questionário e os valores de ΔE foram testados para normalidade por meio do teste de Shapiro-Wilk. Como os dados apresentaram distribuição não normal, testes não paramétricos foram utilizados na análise estatística. O impacto do teste e do tratamento com placebo na percepção sobre a aparência dos dentes foi analisado comparando a pontuação média obtida em cada uma das perguntas do questionário antes e depois do tratamento usando o teste de classificação sinalizada de Wilcoxon para amostras relacionadas. A análise qualitativa, baseada na classificação de cada dente em mascaramento total, mascaramento parcial ou sem mascaramento após o tratamento, foi comparada entre os grupos teste e controle por meio do teste Qui-quadrado. A concordância intra e interexaminadores foi avaliada pelo kappa ponderado linear. O teste não paramétrico de Mann-Whitney foi utilizado para testar a diferença entre os grupos quanto aos valores de ΔE nos diferentes momentos. Em seguida, duas medidas de resumo foram definidas como principais resultados da análise quantitativa do efeito de mascaramento do tratamento: diferença absoluta entre o ΔE inicial e o ΔE final e o de follow-up; e a variação percentual entre o ΔE inicial e o ΔE final e o de follow-up. O teste de Mann-Whitney também foi usado para testar a diferença entre os

grupos em relação às medidas resumidas. Os dados foram apresentados em tabelas e gráficos de box-plot. A associação entre os resultados qualitativos e quantitativos foi testada usando a correlação de Spearman. O nível de significância foi estabelecido em 0,05.

1.2.2.8 Acompanhamento

Após tratamento com o infiltrante tanto os pacientes do grupo teste quanto do grupo controle ficaram agendados para consulta de retorno para 1 mês. Nesta consulta de follow-up foram tiradas fotografias e reaplicados os questionários.

1.3 **Resultados**

1.3.1 Esthetic management of incisors with diffuse and demarcated opacities: 24-dw (Artigo cientifico)

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CLINICAL RELEVANCE

A minimally invasive esthetic treatment can provide longevity and color stability.

SUMMARY

This clinical case report describes a minimally invasive approach to mask diffuse and demarcated opacities in permanent anterior teeth in an eight-year-old child who was upset with the appearance of her incisors. Clinical examination showed diffuse opacities in teeth 7, 8, 9, and 10, diagnosed as dental fluorosis associated with yellow demarcated opacity in tooth 9 related to molar-incisor hypomineralization. The treatment was based on conservative dentistry using the low-viscosity resin infiltration technique and resin composite restoration in an attempt to mask the lesions. The follow-up time was 24 months.

KEY WORDS: Dental Enamel Hypoplasia; Esthetics, Dental; Fluorosis, Dental; Icon Infiltrant; Molar incisor hypomineralization

INTRODUCTION

Developmental Defects of Enamel in anterior teeth might have negative impact on patients' self steem and consequently on their quality of life (1,2). Developmental Defects of Enamel can affect both dentitions and all the teeth as a whole or be localized in a specific group of teeth as in Molar Incisor Hypomineralization (MIH) (3,4). MIH is characterized by the presence of demarcated opacities in at least one first permanent molar, generally associated with incisors also affected (6). Fluorosis presents diffuse opacities with chalky white appearance or in severe cases, with staining and pitting (5). A demarcated opacity in a single permanent tooth can be attributed to trauma to its predecessor (3,7). All these conditions come out from abnormality in the enamel mineralization phase, modifying the chemical composition and optical characteristics of the enamel (7).

The patient's expectations and the severity of the enamel opacities will guide the clinician in the treatment choice. Alternatives to achieve esthetic improvement of demarcated and diffuse opacities range from minimally invasive strategies such as dental bleaching (8,9) and microabrasion (9–11), to more invasive techniques such as composite resin restorations or porcelain veneers (12,13). Microabrasion is indicated for fluorotic opacities, however attention should be taken to avoid excessive removal of enamel during the clinical procedure (13). Among the minimally invasive methods, bleaching with hydrogen peroxide or carbamide peroxide has been used successfully (14). The use of composite resins and porcelain veneers provide good esthetic results, but invariably lead to greater wear of the tooth structure (12,13).

More recently, the use of infiltrant resin has been recommended as a minimally invasive approach to masking opacities in the enamel. The infiltrant agent was initially proposed for the treatment of white spots lesions caused by dental caries, but successful experiments have been reported for masking opacities related to fluorosis and opacities caused by trauma (15–18). The technique of infiltrating the opacity with low viscosity resin is based on the fact that the resin has a refractive index similar to that of sound enamel. Thus, when the resin penetrates and fills the porosities of the carious lesions, the refractive index returns to values very close to that of the sound enamel, masking the opacity (18).

This clinical case report aimed to describe a minimally invasive approach to mask diffuse and demarcated opacities in permanent anterior teeth using resin infiltrant (ICON®, DMG, Hamburg, Germany) and composite resin restoration.

CLINICAL CASE REPORT

An eight-year-old female patient with no systemic disease, attended the Pediatric Dentistry Clinic of Rio de Janeiro State University, Rio de Janeiro-Brazil, reporting to be upset with the whitish appearance of her maxillary permanent incisors. Clinical examination showed diffuse opacities in teeth 7, 8, 9, 10, diagnosed as moderate fluorosis (score 5), based on the Thylstrup and Fejerskov Index (TFI) for Dental Fluorosis (19). A yellow demarcated opacity in tooth 9 was diagnosed as MIH, according to the European Academy of Pediatric Dentistry (4) because first permanent molars were also affected (Figure 1).

The treatment decision was based on minimally invasive dentistry, using the infiltration technique with low-viscosity resin (Icon) and composite resin (TPH, Dentsply, São Paulo, Brazil) as an attempt to mask the discolorations. The parent signed an informed consent authorizing the treatment and the use of images.

The teeth were cleaned and isolated with rubber dam (Figure 2). The Infiltration technique followed manufacture's instructions. The enamel with was etched using 15% HCl gel (ICON etch®, DMG) for 2 min (Figure 3) followed by rinsing for 30s, drying with compressed air (Figure 4) and dehydration with 100% ethanol (ICON dry®, DMG) for 30s. During ethanol application the visual aspect of the enamel was checked and the opacities did not disappear. Thus, the etching step was repeated. After the second acid etching the diffuse opacities were masked but the MIH yellow opacity in the tooth 21 was still visible. Then, approximately 0,2mm of the enamel was removed with a diamond bur and the acid gel (ICON etch®, DMG) was applied again only in the area of the demarcated opacity (Figures 5 and 6). When ethanol was applied, it was possible to see that the demarcated opacity was also camouflaged (Figure 7). The infiltration resin (ICON® Infiltrant, DMG) was carefully applied onto the etched area for 3 minutes without rubbing (Figure 8), slightly dried with compressed air, and after removing the excess with gauze, light-cured for 40s (Altlux, Ribeirão Preto, SP, Brazil) (Figure 9). Composite resin, color A2, (TPH, Dentsply, São Paulo, Brazil) was used to restore the enamel worn by bur. The tooth surfaces were polished with composite resin polishing discs (Sof-Lex, 3M ESPE, St Paul, MN, USA). The clinical aspect immediately after infiltration and rubber dam removal, 12 and 24-month follow-up are shown in figures 10, 11, 12 and 13 respectively.

Figure 1 1: Baseline: diffuse opacities in the upper central and lateral incisors. Yellow demarcated opacity in tooth 9.

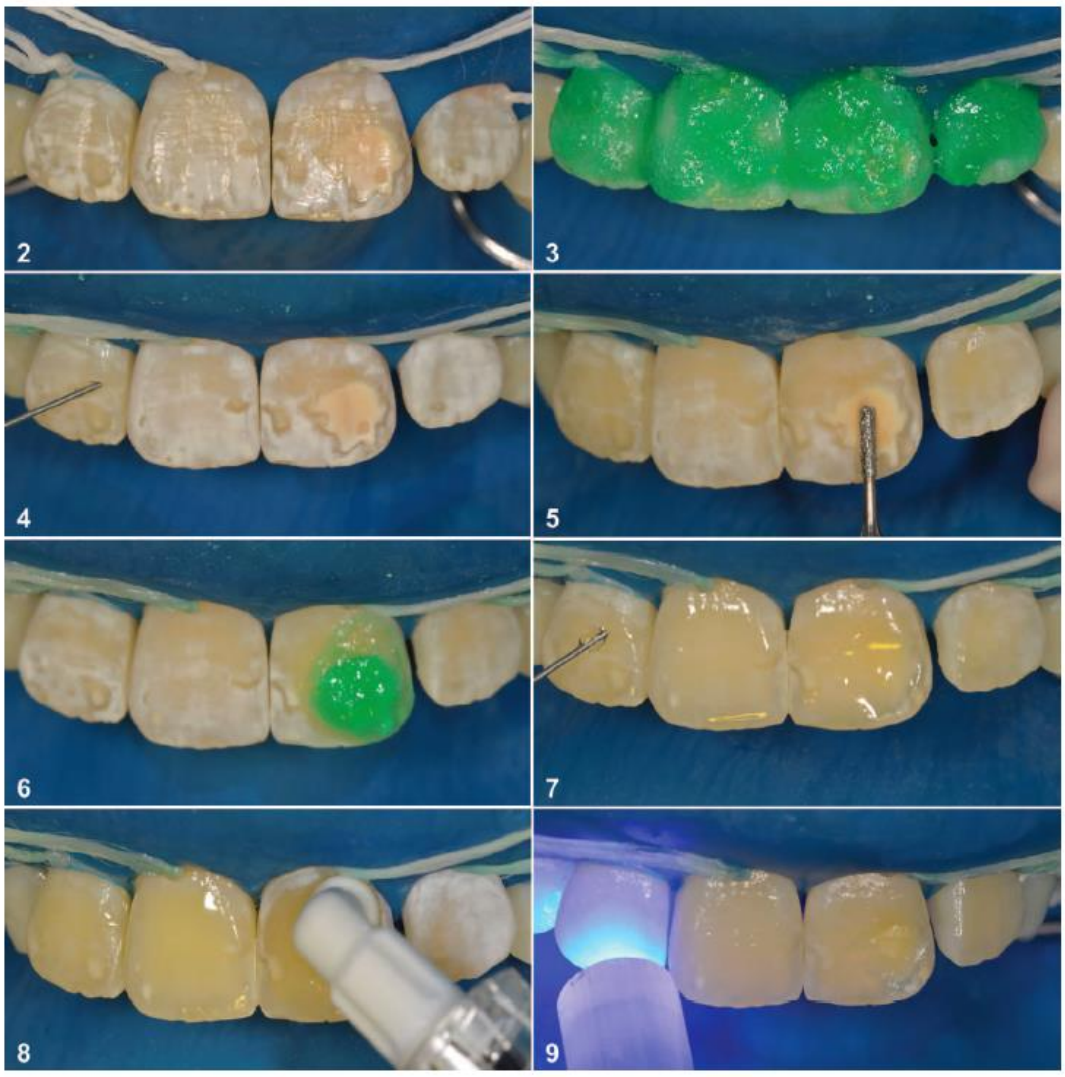

Figure 1 2: Rubber dam with ligatures.

Figure 1 3: 15% hydrochloric acid application (2min).

Figure 1 4: Aspect after hydrochloric acid application.

Figure 1 5: After ethanol application the diffuse white areas disappeared. The opacity did not change the aspect and 0.2mm enamel was removed (diamond burr - tooth 9).

Figure 1 6: 15% hydrochloric acid application in the opacity – tooth 9 for 15s.

Figure 1 7: Ethanol application to preview the masking effect.

Figure 1 8: Resin infiltration in teeth 7,8,9 and 10.

Figure 1 9: Light-cure for 40s.

Figure 1 10: Immediate aspect after resin infiltration and composite resin-teeth 7,8,9 and 10.

Figure 1 11: Immediate aspect after rubber dam removal

Figure 1 12: 6-month follow-up

Figure 1 13: 24-month follow-up

DISCUSSION

Resin infiltration is an approach that can be safely and effectively performed in a single session with optimal results (15–17,20). The diffuse opacities were completely masked by the infiltrant. Comparing to microabrasion, the resin infiltration technique removes considerably less enamel once the acid application is not combined with mechanical abrasion. The microabrasion technique with abrasive gel composed of a mixture of hydrochloric acid or phosphoric acid and pumice or silica carbide particles is widely used and referenced in the literature as a minimal intervention (21,22), although invariably results in considerable enamel reduction. The enamel loss after microabrasion ranges from around 100µm to over 250µm depending on the pressure, time of application and concentration of the acid (21,23–26). As mild to moderate fluorosis presents a porous subsurface zone of 80 to 100µm

in depth (5), microabrasion abrades the whole affected enamel. Hence, esthetics is improved because the fluorotic enamel is removed. Etching with 15% HCl for 120 s, according to the resin infiltration technique, removes between 30 and 40μm of surface layer enabling the resin to penetrate into the deeper affected enamel (27). The masking effect occurs due to the infiltration of the porous subsurface with resin. That is why the application of ethanol is used as a prognostic parameter of the final result. If the wetting effect of the ethanol masks the opacities partially or completely, it means that the infiltrant will penetrate resulting in the masking of the opacities. However, for a thicker surface zone additional etching might be necessary, as in the present case.

Home bleaching has been also recommended as an esthetic treatment for fluorosis. The modality that involves the use of a vacuum formed custom-fitted tray filled with carbamide peroxide (10−20%) or hydrogen peroxide (1−10%) and has been validated by several studies (14,28,29). For pediatric patients, the American Association of Pediatric Dentistry (AAPD) defined a strictly controlled use of bleaching techniques to choose the appropriate method and timing of the treatment (30). Taking into account that in young patient's dental pulp is wider than that of an adult patient, and that the diffusion of hydrogen peroxide at high concentrations into dental tissues is extensive, the risk of adverse effects such as sensitivity might be high. Additionally, in contrast to the bleaching therapy, which can reduce the microhardness of demineralized enamel surfaces (31), the infiltrant resin can strengthen the enamel structure mechanically (32). Therefore, for the current patient, bleaching was not considered.

Differently from the fluorotic opacities, the demarcated opacity localized in the right incisor did not show any improvement even after a second acid etching. It was decided to use a bur to remove a thin layer of opacity and repeat the acid etching. In this case, the treatment combining resin infiltration with composite can be considered a minimal invasive procedure because a very thin layer of enamel was removed restricted to the area of the demarcated opacity. Microabrasion was not used because of concerns about the risk of post-operative sensitivity considering the amount of enamel to be removed and the patient's young age. However, in a previous case report, a nine-year-old patient had a demarcated opacity treated with microabrasion repeated in three consecutive appointments followed by resin infiltration with no complains about sensitivity (33).

The combination of resin infiltration and composite was effective in improving esthetics with minimal loss of tooth structure. Besides, once the demarcated opacity was masked by the infiltrant, the restoration could be done with a single-color composite in a simple and practical procedure. No strategies combining opaque liner and different colors of composite were necessary to obtain the masking effect. Additionally, as bonding on a surface previously treated with Icon is possible (34), no prime or adhesive was used before inserting the composite resin. The esthetic result showed colour stability along 24-month follow up.

Molar incisor hypomineralization is relatively common worldwide with average prevalence of 11,24% (35) what means that both pediatric dentists and clinicians probably will have patients with esthetic issues related to this condition and should be aware of possible treatment options. Considering the importance of the smile during adolescence and implications for self-esteem and social wellbeing to a child, the treatment should consider a conservative and effective approach. In the current case, diffuse and demarcated opacities were masked by the combination of infiltrant with composite in a single session and a satisfactory outcome was achieved.

CONCLUSIONS

The esthetic treatment based on resin infiltration and composite resulted in excellent results with colour stability along 24-month follow up. Diffuse and demarcated opacities were masked in a single session, improving the patient's self-esteem.

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Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of the ethical committee from Universidade do Estado do Rio de Janeiro. The approval code issued for this study is 07753213.0.0000.5259.

Conflict of Interest

The authors of this manuscript certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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1.3.2 Impact of masking Molar Incisor Hypomineralization opacities in anterior teeth: a randomized controlled clinical trial (Artigo cientifico)

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ABSTRACT

Molar Incisor Hypomineralization (MIH) stands out as a prevalent condition worldwide, characterized by defects in the enamel mineralization of first permanent molars and incisors. Anterior teeth affected by demarcated opacities often demand treatment for aesthetic reasons. The aim of this blinded randomized controlled trial was to evaluate the impact of the treatment of demarcated opacities in anterior teeth on the aesthetic perception of children and their parents. As a secondary purpose, the masking effect of the treatment with resin infiltration was evaluated after different application times of the infiltrant. Thirty-nine patients, 8 to 18 years-old, presenting at least one permanent incisor with white-creamy opacity were randomly allocated to test (28 teeth) or control group (29 teeth). The test received microabrasion + resin infiltration and the control received a placebo treatment. Infiltrant and placebo were left on the teeth for 30 minutes before light curing. The perception about the teeth appearance was evaluated by the questionnaire Child's and Parent's Questionnaire about Teeth Appearance. The masking effect was quantitatively analyzed by digital

photography using the Lab System and ΔE between the opacity and the surrounding sound enamel was calculated in Photoshop. Two calibrated examiners based on pair wise reading of clinical photographs did the qualitative analysis. The impact of the test and placebo treatment on the perception about teeth appearance (mean score of the questionnaire) was compared using Wilcoxon test. The qualitative result (total, partial or no masking) was compared using Chi-square test. The examiners agreement was assessed using kappa coefficient. Mann-Whitney was used to test the difference in ΔE values in the different time points. Two summary measures were defined as the main outcomes: the absolute and the percentage difference between initial ΔE and final/ follow-up ΔE. The level of significance was set at 0.05. In the test group, it was observed a significant reduction in the questionnaire scores in the physical ($p = 0.01$), psychological ($p = 0.02$), and social ($p = 0.04$) domains in the parents' point of view. In the social domain, a significant reduction was also seen in the children's opinion ($p = 0.00$). After treatment, significantly less concern with tooth color was reported by parents ($p = 0.01$) and children ($p = 0.04$) from test group and with teeth pleasantness by parents from test group ($p = 0.01$). Before treatment, the mean ΔE was 6.45 ± 3.53 in the test and 5.98 ± 2.57 in the control group ($p = 0.88$). A significant difference between test and control groups was seen from 15 minutes of application onwards. Immediately after the treatment, the mean ΔE was 4.07 ± 3.07 in the test and 7.35 ± 3.54 in the control group ($p = 0.000$). In the follow up evaluation, one month after the treatment, the mean ΔE was 4.22 ± 2.96 in the test and 6.06 ± 2.52 in the control group ($p = 0.002$). As a conclusion, the present randomized controlled clinical trial observed a positive impact of resin infiltration as an aesthetic treatment for MIH opacities in anterior teeth on parents' and children's perception about teeth appearance. Resin infiltration was able to reduce de color difference between the MIH opacities and sound enamel significantly after an application time of at least fifteen minutes.

KEY WORDS: molar incisor hypomineralization; dental aesthetics; minimally invasive treatment; Icon infiltrant, children.

INTRODUCTION

Aesthetic procedures have attracted researcher's attention due to the increased demand for a more pleasant smile. Adolescents and children are forming their

personality and are under social judgment all the time. Opacities in anterior teeth are perceived by children and generate dissatisfaction both in parents as in children who sometimes try to hide their smile [1,2].

Studies involving developmental defects of dental enamel (DDE) are valuable due to the significant impact of these defects on oral health with several clinical and aesthetic consequences [3]. Molar-Incisor-Hypomineralization (MIH) stands out as a prevalent condition in the world population, characterized by disturbance of enamel mineralization that results in demarcated opacities affecting first permanent molars and incisors [4,5]. Recently, it has been observed that individuals with MIH may present other permanent teeth also affected by hypomineralization [6]. The defective enamel presents clinically as a demarcated opacity that can vary in color, from white-creamy to yellow-brownish [7]. Negative impacted of MIH on the oral health related quality of life has been reported in the literature [8–10].

Patients with anterior teeth affected by demarcated opacities often seek treatment for aesthetic reasons. Resin infiltration has shown excellent results on masking white spot lesions caused by caries as a proposal for a minimally invasive treatment [11,12]. The reason why the whitish appearance is camouflaged by the infiltrant is related to the modification of light scattering. Sound enamel has a refractive index of 1.62. In an initial caries lesion, the porous enamel is either filled with water (refractive index of 1.33) or air (refractive index of 1.0). The difference in the refractive indices is the cause of the whitish appearance of such lesions. Once the porosities of the caries lesions are filled by the infiltrant, the light refraction within the enamel returns close to normal, around 1.52. Hence, the white spot becomes less perceptible by naked eyes [13].

The same effect has been achieved with diffuse opacities typical from dental fluorosis that were successfully masked by resin infiltration [14–17] However, no effect or only partial camouflage was reached when demarcated opacities associated with MIH or trauma to the predecessor tooth were treated [15,18–22]. The combination of microabrasion or the removal of a thin layer of enamel with burr followed by resin infiltration resulted in better masking of demarcated opacities in incisors [17,23–25]. More invasive techniques such as restorations with composite restorations or veneers provide good aesthetic appearance [26,27]. However, they result in greater wear of the tooth structure and initiate a restorative cycle prematurely, which should be avoided or postponed in young permanent teeth as maximum as possible.

Minimally invasive approach should be the first option for the treatment of enamel opacities in anterior teeth and the importance of a pleasant smile for children and adolescents justifies clinical studies evaluating different strategies to improve the aesthetic of MIH opacities. The purpose of this study was to evaluate the impact of the treatment of demarcated opacities in anterior teeth with the combination of microabrasion and low viscosity resin infiltration on the aesthetic perception of children with MIH and their parents. As a secondary purpose, the masking effect of the treatment with resin infiltration was evaluated after different application times of the infiltrant.

MATERIALS AND METHODS

This clinical trial was approved by the local Ethics and Research Committee (3,621,870) and registered in the Brazilian Registry of Clinical Trials (U1111-1240-5384; https://ensaiosclinicos.gov.br/). The participants and their parents were informed about the risks and benefits of the research and signed an informed consent. This clinical trial followed the CONSORT guide (Consolidated Standards for Reporting Trials).

Clinical trial and sample design

This randomized controlled clinical trial was carried out at the Pediatric Dental Clinic at the University of the State of Rio de Janeiro. Health children presenting MIH [28] with white-creamy demarcated opacity in at least one permanent incisor, which caused aesthetic discomfort to the child and/or his/her guardian were eligible for the study. Other developmental defects of dental enamel *(i.e.* hypoplasia or fluorosis) and previous restorative, infiltration, microabrasion and/or whitening treatment were reasons for exclusion.

The sample calculation was based on the estimative of a decrease in the mean score of 0.5 in the control group and 1.0 in the test group in the social domain of the questionnaire. With a significance level of 5% and power of 80%, a sample size of at least 32 patients was required. Considering the possibility of 25% loss after treatment, 20 patients in each group were included in the sample.

Randomization and Intervention

The method of block randomization following a random number table generated in Microsoft Excel® for Mac (version 16.44) was used to allocate the patients into test or

control group. The random number table was generated with a total of 40 numbers divided in 10 blocks, each block with 4 treatment options (2 tests and 2 control). The randomized numbers corresponding to test or control treatment were transferred to opaque envelopes before the beginning of the clinical trial by a person who was not involved in the research. The envelopes were organized sequentially according to the random sequence. As the patients arrived at the clinic for the treatment, an assistant picked an envelope in which there was a letter T for test group or C for control group, according to the randomized sequence. Operators, patients and parents were blind regarding the assigned treatment. Patients were scheduled per shift; four in the morning and four in the afternoon and each operator treated two per shift respecting the random sequence.

During the treatment, blinding of the patients and guardians was guaranteed because a placebo treatment was used, simulating all the steps of the test treatment in the control treatment. The operators, however, were not blind during the whole treatment because the placebo products did not mimic clinical effects like the desiccation caused by the acid etching. The examiners who performed the quantitative and qualitative analysis of the masking effect did not perform the treatments and therefore were blind regarding the treatment.

Two previously trained operators performed the treatments. Operator 1 treated 20 patients and operator 2 treated 20. Tooth prophylaxis with a rubber cup and water was followed by local topical anesthesia with benzocaine gel 20% (Benzotop, DFL, Rio de Janeiro, Brazil), for better comfort during rubber dam isolation. Table 1 presents the test and control treatment steps as well as the detailed descriptions of the test and placebo products.

Table 1: Description of the test and control interventions (detailed description of the composition of the products are presented as notes).

Intervention steps	**Test**	**Control**
Tooth prophylaxis	Rubber cup/water	Rubber cup/water
Topical anesthesia	Benzocaine 20% gel	Benzocaine 20% gel
Isolation	Rubber dam	Rubber dam
Etching step (was done 3 times)		
Etching 2 min + Microabrasion 10s	Icon Etch[a]	Placebo etching gel[b]
Rinsing 30 s	Water	0.9% saline solution
Drying 30 s	Compressed air	Compressed air
Desiccation 30 s	99% Ethanol	0.9% saline solution
Drying 30 s	Compressed air	Compressed air
1st Infiltration		
Resin application 30 min	Icon Infiltrant[c]	Placebo infiltrant[d]
Excess removal	Gauze and dental floss	Gauze and dental floss
Light curing	Light curing 40 s	Light curing 40 s

2nd Infiltration		
Resin application 1 min	Icon Infiltrant[c]	Placebo infiltrant[d]
Excess removal	Gauze and dental floss	Gauze and dental floss
Light curing	Light curing[e] 40 s	Light curing[e] 40 s
Polishing (after rubber dam removal)	Polishing and finishing cups	Polishing and finishing cups

[a] 15% hydrochloric acid gel, pyrogenic silicic acid, surface-active substances.
[b] Oral gel: gelly 6%, carboxymethilcellulose 4%, sodium chloride 0,25, sodium benzoate 0,1%, citric acid 1%, distilled water 30g, 18 drops of food coloring liquid (blue) and 10 drops of green food coloring (green).
[c] Methacrylate-based resin matrix, initiators and additives.
[d] Mineral oil solution (0,35ml) and olive oil (0,1ml).

Impact on aesthetic perception

The Portuguese validated version of the Child's and Parent's Questionnaire about Teeth Appearance [29] was used to evaluate the impact of the treatment on the perception about teeth appearance. The questionnaire comprises three sections, including 12 items and sub-items. The first, with three questions, assesses the physical, psychological and social domains and the answers range from "nothing" (0) to "very" (3). The second part contains four statements in which children and parents are asked about their perception of the satisfaction, alignment, colour and health of the child's teeth and whether any of these items are of concern. The responses in this section range from "very good, very aligned, very white and very healthy" (0) to "very unpleasant, very crooked, very stained and very sick" (4). For each statement, it was asked whether it generates concern, with "yes" or "no". The last part contains the sentence: "The color of my teeth/ the color of my child's teeth is pleasant and beautiful" with answers ranging from "I totally agree" (0) to "I totally disagree" (4).

Analysis of opacity masking effect

Quantitative analysis of the masking effect was performed using clinical photographs taken with a digital camera (Nikon D90, Nikon, Tokyo), macro lens (100-mm Macro Rokkor-X, Minolta, Tokyo), circular flash (Sigma, Welwyn Garden City, UK), in the same exhibition (ISO 100, 1 / 160 speed, F / 20 aperture) and approximate 30 cm of distance of the patient. The photographs were taken in baseline, over the application time of the test or placebo resin at 0, 3, 10, 15, 20, 25 and 30 minutes of application, right after removing the rubber dam and in the follow-up appointment one month after treatment. In order, to ensure the white balance in the analysis of the photographs, a gray card 18% achromatic, free of reflection, opaque and neutral (Flexipalette color match FP 3004, Smile Line, Swiss) was used in every intraoral photograph.

Photographs were saved in JPEG format and analyzed using Photoshop CC for Mac (Adobe, San Jose, USA) for quantitative analysis using the CIELAB (International Commission on Illumination) system. Absolute values of luminosity (L), red-green color (a) and yellow-blue color (b) were assessed in the opacity and in a sound area of the enamel before and after treatment. The difference in luminosity (ΔL), red-green (Δa) and yellow-blue (Δb) between the opacity and the sound area of the enamel were calculated. Then, the total color difference (ΔE) between the opacity and the sound area of the enamel was calculated using the equation ΔE = (ΔL * ² + Δa * ² + Δb * ²) ½ (31). The masking effect was represented by a reduction of the ΔE value after the treatment in comparison with the ΔE value before the treatment.

The qualitative analysis of the masking effect was done by pair-wise reading. The initial and the follow-up photographs were organized side by side in Microsoft Power Point® for Mac (version 16.45). Two blinded examiners, experienced pediatric dentists, evaluated the photographs and classified the result of the treatment as: 1) total masking (the opacity is no longer noticeable); 2) partial masking (the opacity color approached the tooth color and / or reduced in size, but it is still apparent); or 3) no masking (there was no change in color or opacity size).

Training and Calibration

Prior to the study, test and control interventions was discussed with the two operators in detail. In a pilot phase, each of the operators treated one patient following all the steps of the intervention protocol. For the qualitative analysis, two examiners were trained for the assessment of initial and final clinical pictures classifying each tooth as complete, partial, or no masking. Linear weighted kappa for intra-examiner was 0.98 and 0.88 and for inter-examiners it was 0.84. A third examiner was trained for the quantitative analysis using the CIELAB system in Photoshop CC for Mac (Adobe, San Jose, USA). The two cases treated in the pilot phase were analyzed as part of the training. Then, 10% of the initial ΔE were reassessed to test intra-examiner agreement. Intraclass correlation was 0.97 (95% CI: 0.83 – 0.99).

Side effects and acceptance of the treatment

Possible adverse effects such as: postoperative pain in teeth and gums, damage in soft tissues and bitter taste were recorded by asking the child right after

treatment. Two cell phone numbers were made available if the patient had any discomfort and/or the guardian has any questions. Treatment acceptance was assessed by Wong & Baker [30] pain scale right after the end of treatment.

Statistical analysis

SPSS version 25.0 (IBM, Chicago, IL, USA) was used for statistical analysis. The characterization of the sample was based on the descriptive analysis of age, gender, type and number of teeth for test and control group separately. Data about pain and side effects were presented as absolute and relative frequencies. Fisher's Exact Test was used to test the association between dichotomic variables.

Data related to the questionnaire and ΔE values were tested for normality using Shapiro-Wilk test. As the data showed a non-normal distribution, non-parametric tests were used in the statistical analysis. The impact of the test and placebo treatment on the perception about teeth appearance was analyzed comparing the mean score obtained in each of the questionnaire's domains before and after treatment using the Wilcoxon signed rank test for related samples. The qualitative analysis, based on the classification of each tooth as total masking, partial masking or no masking after treatment was compared between test and control groups using Chi-square test. The intra and inter-examiners agreement was assessed kappa with linear weighting. The non-parametric test Mann-Whitney was used to test difference between groups regarding the ΔE values in the different time points. Then, two summary measures were defined as the main outcomes of the quantitative analysis of the masking effect of the treatment: the absolute difference between the initial ΔE and the final and follow-up ΔE; and the percentage change between the initial ΔE and the final and follow-up ΔE. Mann-Whitney test was also used to test the difference between groups regarding the summary measures. Data were presented in tables and box-plot charts. The association between the qualitative and the quantitative results was tested using Spearman's correlation. The level of significance was set at 0.05.

RESULTS

Sample description

The sample characteristics are presented in Table 2. One patient missed the follow-up appointment and was considered as a dropout. Interventions (test and placebo treatments) and follow-up appointments took place between February 2020 and January 2021. Clinical trial flow diagram is shown in figure 1.

Table 2: Characterization of the sample regarding age, gender, number and type of treated teeth. The characteristics of the dropout are given as notes.

Variables	**Test Group** (n = 19)	**Control Group** (n = 20)	**p-value**
Age			
range	8 – 18 years	8 – 16 years	0.166[a]
mean	11.2 (SD = 2.79)	10.1 (SD = 2.20)	
median	10.0	9.0	
Gender			
male	8 (42.1%)	9 (45.0%)	0.556[b]
female	11 (57.9%)	11 (55.0%)	
Number of treated incisors			
range	1 – 3 teeth	1 – 3 teeth	0.923[a]
mean	1.47 (SD = 0.61)	1.45 (SD = 0.61)	
median	1.0	1.0	
Type of treated incisors			
only upper	15 (78.9%)	14 (70.0%)	0.571[c]
only lower	4 (21.1%)	5 (25.0%)	
upper and lower	0 (0%)	1 (5.0%)	

Dropout: there was one dropout from the Test group; a girl, 14 years old who had two lower incisors treated.
[a] Mann Whitney Test; [b] Fisher's Exact Test; [c] Pearson Chi-Square Test.

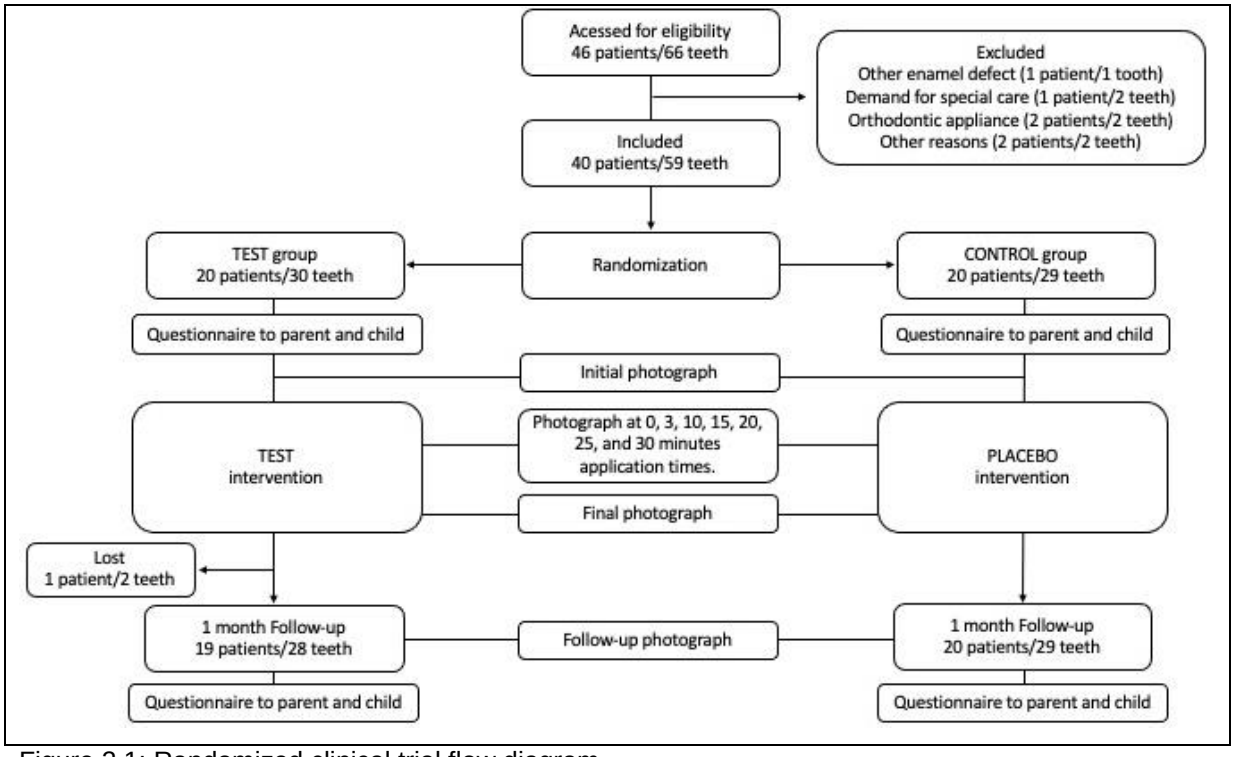

Figure 2 1: Randomized clinical trial flow diagram.

Impact on parents' and children's aesthetic perception

In the test group, it was observed a significant reduction in the questionnaire scores in relation to physical (p = 0.01), psychological (p = 0.02), and social (p = 0.04) domains in the parents' point of view after treatment. In the social domain a significant reduction was also seen in the children's opinion (p = 0.00). In the control group, a significant reduction was seen only in the physical domain reported by parents (p = 0.02) (Table 3).

In the second part of the questionnaire (Table 4), parents from the test group reported significantly less dissatisfaction with their child's teeth regarding pleasantness (p = 0.01) and both parents (p = 0.01) and children (p = 0.04) from the control group reported less dissatisfaction about tooth colour after treatment. In the control group, parents also perceived fewer discolourations in their child's teeth after treatment (p = 0.04). Children from the test group (p = 0.04) and parents from both test (p = 0.01) and control (p = 0.04) groups perceived more tooth misalignment after treatment. When questioned about how concerned they were with tooth pleasantness, tooth alignment, tooth colour and tooth health, parents from test group reported significantly less concern with tooth colour after treatment (Table 4). No other significant difference was observed.

In the third part of the questionnaire, regarding the affirmative "the color of my teeth / my child's teeth is pleasant and beautiful", no significant difference was observed in the mean score given by parents or children before and after treatment in both groups (Table 4).

Table 3: Mean values and standard deviation of the scores given by parents and children regarding physical, psychological and social domains of the Child's and Parent's Questionnaire about Teeth Appearance before and after TEST and CONTROL treatments.

Questions	Respondent	Test			Control		
		Before treatment	After treatment	p-value	Before treatment	After treatment	p-value
Physical							
How much has the appearance of your teeth/your child's teeth upset you?	Parent	2.11 (0.88)	1.26 (0.99)	0.01*	1.90 (0.85)	1.35 (1.09)	0.02*
	Child	1.47 (1.12)	1.00 (1.10)	0.16	1.05 (1.05)	0.65 (1.04)	0.31
Psychological							
How much has the appearance of your teeth/your child's teeth worried you?	Parent	2.05 (0.91)	1.32 (1.10)	0.02*	1.90 (1.07)	1.60 (1.09)	0.38
	Child	1.32 (1.25)	1.21 (1.13)	0.76	1.05 (1.14)	1.15 (1.04)	0.69
Social							
How much has the appearance of your teeth/your child's teeth kept you/your child from smiling?	Parent	1.42 (1.08)	0.79 (1.27)	0.04*	0.45 (0.94)	0.35 (0.67)	0.70
	Child	1.42 (1.35)	0.53 (0.84)	0.00*	0.50 (1.00)	0.35 (0.74)	0.68

Related samples Wilcoxon Rank Test.
*significant difference

Table 4: Mean values and standard deviations (SD) of the scores given by children and parents regarding their perception about the pleasantness, alignment, color and health of the child's teeth before and after TEST and CONTROL treatments.

Questions	Respondent	Test			Control		
		Before treatment	After treatment	p-value	Before treatment	After treatment	p-value
Perception of the child's teeth pleasantness.	Parent	1.84 (1.17)	1.00 (1.00)	0.01*	1.75 (1.02)	1.30 (0.80)	0.12
	Child	1.58 (1.35)	1.11 (1.33)	0.12	1.45 (1.50)	1.30 (1.13)	0.58
Perception of the child's teeth alignment.	Parent	2.16 (1.02)	3.16 (1.07)	0.00*	2.35 (1.14)	3.45 (0.76)	0.00*
	Child	2.00 (1.20)	1.89 (0.99)	0.75	2.40 (1.10)	2.20 (0.89)	0.33
Perception of the child's teeth color.	Parent	3.16 (0.38)	2.32 (1.16)	0.01*	3.10 (0.45)	2.60 (1.05)	0.04*
	Child	2.47 (1.22)	1.95 (1.22)	0.04*	2.40 (1.23)	2.45 (0.95)	0.77
Perception of the child's teeth health.	Parent	1.47 (0.96)	1.11 (0.94)	0.25	1.70 (0.98)	1.20 (0.70)	0.06
	Child	1.16 (1.12)	0.68 (0.58)	0.07	1.05 (0.83)	1.35 (1.14)	0.32
How much do you agree that the color of your teeth / your child's teeth is pleasant and beautiful?	Parent	2.42 (1.17)	1.74 (0.93)	0.06	2.45 (0.76)	1.95 (1.10)	0.13
	Child	1.89 (1.10)	1.32 (1.06)	0.09	1.40 (1.05)	1.55 (1.36)	0.56

Related samples Wilcoxon Rank Test.
*significant difference

Quantitative Analysis

Before treatment, the mean ΔE was 6.45 ± 3.53 in the test and 5.98 ± 2.57 in the control group (p=0.88). A significant difference between test and control groups was seen from 15 minutes of application onwards. Immediately after the treatment, the mean ΔE was 4.07 ± 3.07 in the test and 7.35 ± 3.54 in the control group (p=0.000). In the follow up evaluation, one month after the treatment, the mean ΔE was 4.22 ± 2.96 in the test and 6.06 ± 2.52 in the control group (p=0.002). Figure 2 shows the ΔE values in relation to the different application time points in the test and control groups.

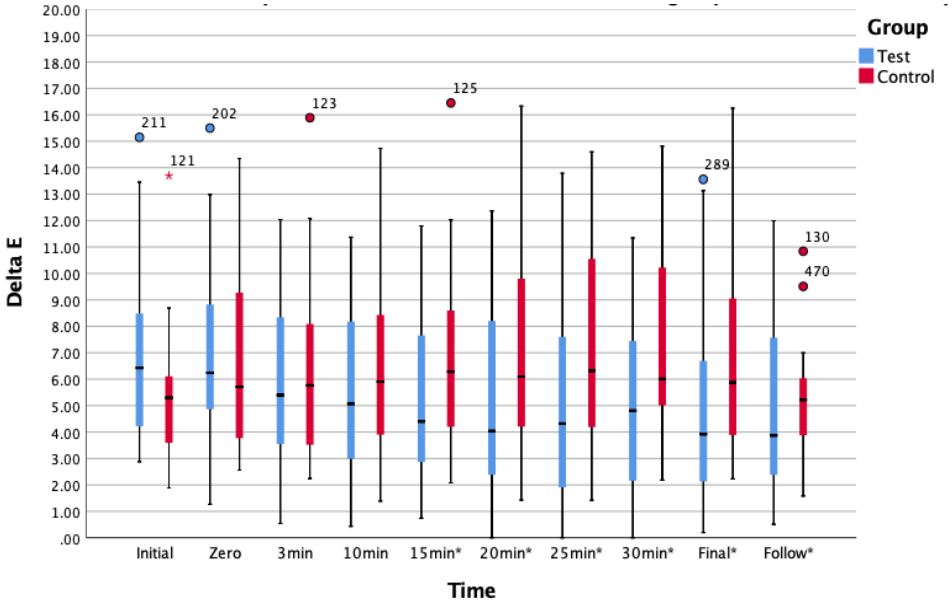

Figure 2 2: Clustered boxplot showing ΔE values for test and control groups for the different application time points. * Significant difference between groups (Mann-Whitney Test).

Figure 3A illustrates the absolute difference between the initial ΔE and the final ΔE. In the test group, the mean difference between initial and final ΔE was 2.50 ± 4.28 with a median of 1.97. In the control group, the mean difference between initial and final ΔE was –1.20 ± 2.38 with a median of –1.10, indicating that the final ΔE was greater than the initial ΔE in at least 50% of the teeth. Figure 3B illustrates the absolute difference between the initial ΔE and the follow-up ΔE. In the test group, the mean difference between initial and follow-up ΔE was 2.42 ± 2.93 with a median of 2.12. In the control group, the mean difference between initial and final ΔE was –0.003 ± 1.59 with a median of –0.000, indicating that the follow-up ΔE was close to the initial ΔE.

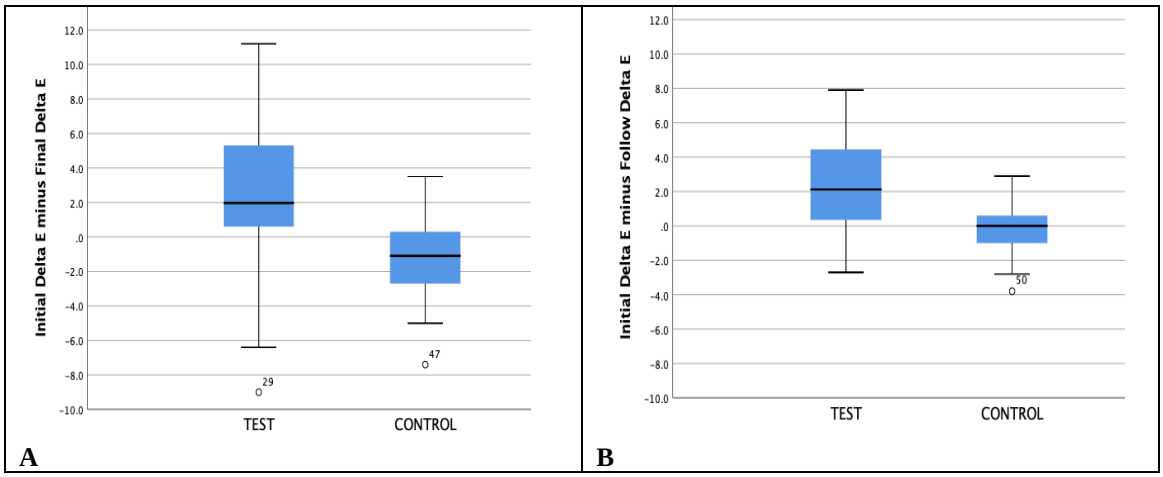

Figure 2 3: Absolute difference between the initial ΔE and the final ΔE for test and control groups **(A)** (Mann-Whitney Test; p = 0.000); absolute difference between the initial ΔE and the follow-up ΔE for test and control groups **(B)** (Mann-Whitney Test; p = 0.001).

Figure 4A and 4B present the percentage change between the initial ΔE and the final and follow-up ΔE, respectively. In the test group, the mean final ΔE was 73.5% ± 71.0% of the initial ΔE with a median of 50.4%. In the control group the mean final ΔE was 124.4% ± 46.6% of the initial ΔE with a median of 116.2%. The data indicate that the reduction of the ΔE that was seen in the test group after treatment was not observed in the control group. On the contrary, in the control group, the final ΔE tended to be greater than the initial ΔE. In the follow up appointment, the mean ΔE in the test group was 66.7% ± 39.8% of the initial ΔE and in the control group it was 102.8% ± 25.6% of the initial ΔE. The median values were 62.7% and 100% for test and control group, respectively.

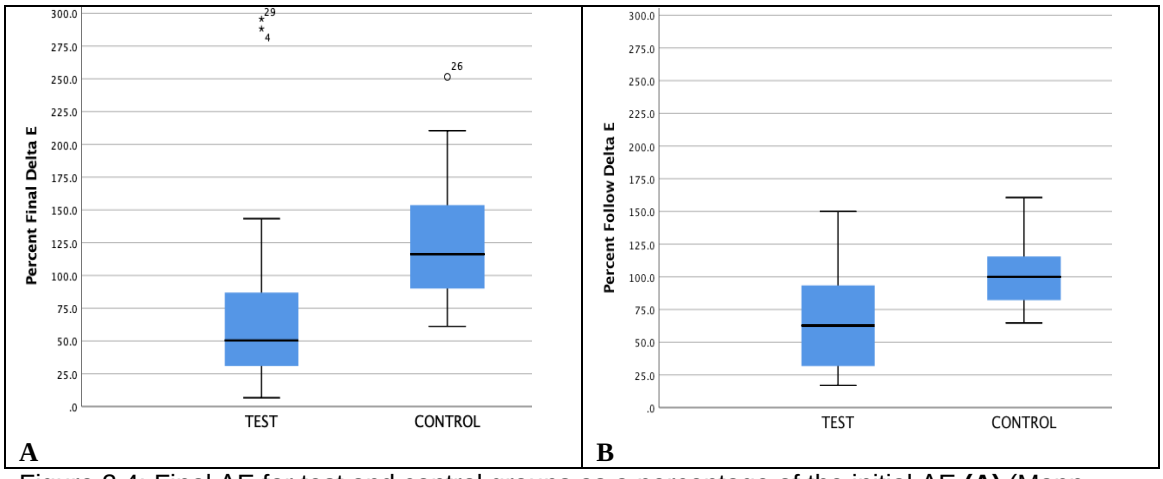

Figure 2 4: Final ΔE for test and control groups as a percentage of the initial ΔE **(A)** (Mann-Whitney Test; p = 0.000); Follow-up ΔE for test and control groups as a percentage of the initial ΔE **(B)** (Mann-Whitney Test; p = 0.001).

Qualitative Analysis

The results of the qualitative analysis, done by two blinded examiners independently, are shown in Table 5. The masking effect was significantly more frequent in the test group when compared with the control group (p = 0.000). A total masking was achieved in 16 (57.1%) and 13 (46.4%) teeth of the test group, according to the examiner 1 and 2, respectively. None of the teeth from the control group was classified as total masking. Inter-examiners agreement was substantially high. The examiners agreed in 86% of the cases resulting in weighted kappa coefficient of 0.84. The evaluations were repeated within an interval of 10 days and the intra-examiner weighted kappa coefficient was 0.98 e 0.88 for examiner 1 and 2, respectively.

Table 5: Treatment effect according to the qualitative analysis done by two blinded examiners for test (n = 28) and control (n = 29) groups.

Treatment effect	Examiner 1			Examiner 2		
	Test n (%)	Control n (%)	p-value*	Test n (%)	Control n (%)	p-value*
Total masking	16 (57.1)	0 (0)		13 (46.4)	0 (0)	
Partial masking	9 (32.1)	0 (0)	0.000	14 (50.0)	1 (3.4)	0.000
No masking	3 (10.7)	29 (0)		1 (3.6)	28 (96.6)	

*Chi-square test

Qualitative Analysis X Quantitative Analysis

The absolute difference and the percentage change between the initial ΔE and the follow-up ΔE were significantly correlated to the qualitative assessment of the treatment effect (Figures 5A-B and 6A-B). As greater was the reduction of the absolute value of the ΔE and as lower was the follow-up percentage of the initial ΔE, more apparent was the masking effect.

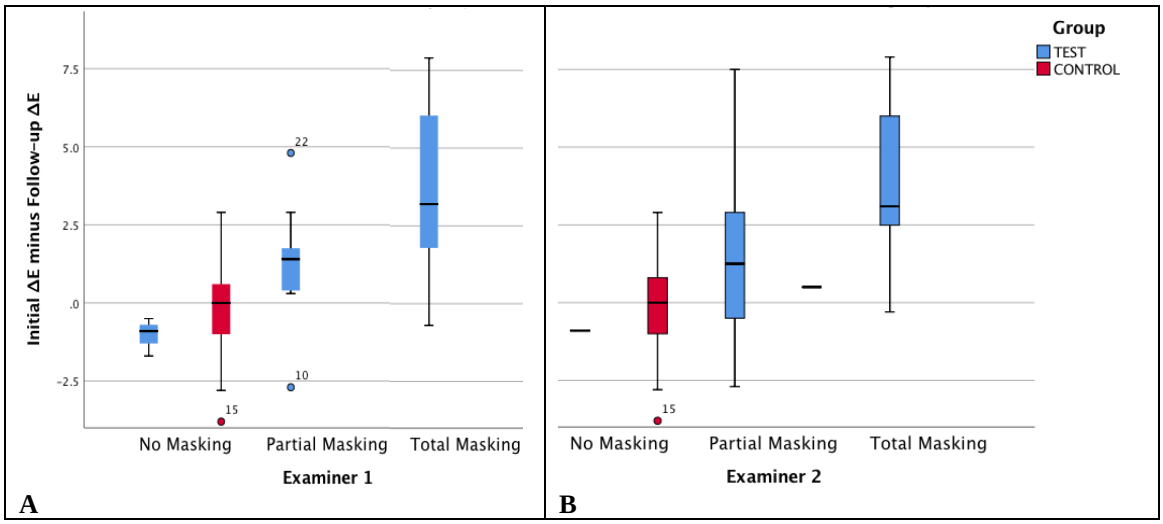

Figure 2 5: Correlation between the absolute difference between the initial ΔE and the follow-up ΔE and the qualitative assessment of the treatment effect for examiner 1 (r = 0.60) **(A)** and examiner 2 (r = 0.54) **(B)**.

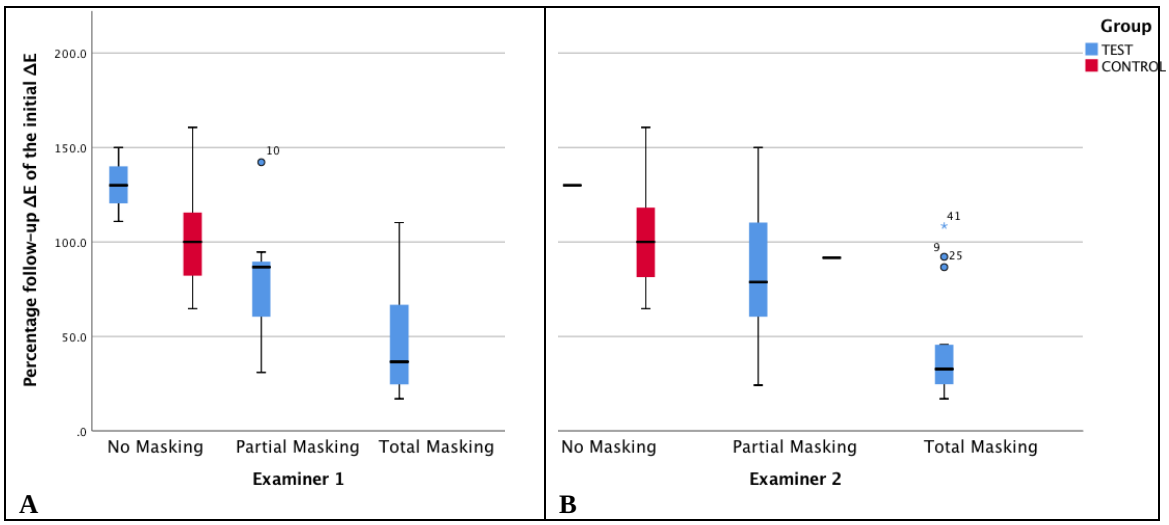

Figure 2 6: Correlation between the percentage difference between the initial ΔE and the follow-up ΔE and the qualitative assessment of the treatment effect for examiner 1 (r = −0.61) **(A)** and examiner 2 (r = −0.55) **(B)**.

Side effects and acceptance

No unwanted relevant side effects, like pain, vitality loss, or gingival damage were reported. The majority of patients did not report any adverse effect after treatment (59.04%; n = 23). Immediately after removing the rubber dam, 11 patients (28.2%) reported bitter taste and 5 (12.8%) reported postoperative pain/discomfort in the area of the treated tooth. These symptoms disappeared within the next hours after the procedure.

Regarding the Wong-Baker facial pain scale [30], most of the children (69.5%; n = 27) pointed out the first and happiest face indicating no pain during the treatment. Nine patients (23.1%) selected the second face indicating "a little pain", two (5.1%) children selected the third face indicating "a little more pain" and one child (2.6%) selected the last face indicating the highest score of pain ("hurts worst").

DISCUSSION

The present study demonstrated that resin infiltration was able to reduce the color difference between the demarcated opacities and the surrounding normal enamel significantly. The masking effect was observed both qualitatively, by visual evaluation, and quantitatively, by the calculation of the difference between the initial and final ΔE, with a relevant impact on the perception about tooth appearance for both parents and children.

Factors expected to influence the aesthetic result of resin infiltration are the thickness of the surface layer, the depth of the lesion, and the histological organization of the subsurface [31]. The enamel affected by initial caries lesions and mild/moderate fluorosis show similar histological features. The more porous enamel, the so-called body of lesion, is underneath a hypermineralized surface and the shape of the lesion forms an obtuse angle with the surface. In a histological section it is possible to see that the extension of the surface layer is wider than the subsurface [32]. Once the acid etching erodes the surface layer, the infiltrant gains access to the complete subsurface extension and is able to fill the porosities into the enamel [31,33]. For both fluorosis and caries, the aesthetic outcome is quite predictable. However, while fluorosis is limited to the external thickness of the enamel [34], caries lesions varies widely in depth and may reach the internal third of the enamel. Moreover, inactive caries lesions might present a surface layer even more mineralized. Hence, deeper and inactive enamel caries might be more difficult to mask [35]. In order to obtain enhanced aesthetic results, longer etching time than the original manufacture’s recommendation for the infiltration of proximal caries lesions were reported both for caries lesions and fluorosis [11,14].

Demarcated opacities associated with MIH differ from enamel caries and fluorosis. Firstly, they start from the enamel-dentine junction toward to the enamel surface and, secondly, they differ in shape [26,36,37]. Most of the lesions extend to

the whole enamel thickness, but some can be confined to the inner half of enamel [37,38]. Not rarely, a demarcated opacity has a narrower surface layer and a broader subsurface, forming an acute angle with the enamel surface [26]. In these cases, the acid etching of the surface layer gives access only to the central part of the lesion. In caries lesions, once the access is gained, the infiltrant flows in the direction of the deepest parts of the lesion and may infiltrate it completely or almost completely. In a demarcated opacity, if the edges of the lesion are underneath sound enamel, they may not be properly filled [26]. Thus, the result of treatment might be quite unpredictable [39].

Trying to overcome this difficulty and optimize access to the infiltrant, in the present study, the resin infiltration protocol was based not only on longer acid etching, like previous studies on caries and fluorosis [11,14], but also on a modification of the application of the etching gel. In each of the etching steps, the applicator tip was used to rub the etching gel on the enamel surface during the first 10 seconds, what we called microabrasion although no abrasives were added to the gel. Rubbing the etching gel, we avoided that air bubbles prevented the contact between the etching gel and the enamel surface. Moreover, using light pressure, we aimed to optimize the erosive effect of the HCl gel on the enamel surface. The use of a brush to apply the etching gel in occlusal fissure improved the contact between the gel and the enamel surface in a previous study [40].

Previous studies on caries showed that the application time also influences in the depth and homogeneity of the infiltration. Longer application time, of five minutes, resulted in deeper penetration of the infiltrant, but three minutes application was considered an adequate amount of time for the infiltrant to penetrate the caries lesions deep enough to hamper caries progression [41]. However, even longer application (30 minutes) was more effective in masking natural proximal caries lesions in a vitro study [42]. When liquid contacts a porous solid, it penetrates into the porous structure by capillary forces. The geometrical shape of the porous solid and properties of the liquid are factors that influence the flow behavior of the liquid and, consequently, the amount of time needed to fill the porosities completely [43]. In a uniform porous medium, it is possible to calculate the depth of penetration in relation to time of a liquid with known penetration coefficient [44]. Although the infiltrant resin has a very high penetration coefficient, being able to penetrate several hundred micrometers into porous enamel [45], the structure of caries lesions and

hypomineralized enamel do not follow a standard pattern. Therefore, it is expected that different lesions take different time to be infiltrated.

Then, in the present study, we decided to observe the masking effect along 30 minutes application of the infiltrant. The fifteenth minute represented a kind of turning point, when a significant difference started to be seen in the values of ΔE between test and control groups. After 30 minutes application, around half of the opacities in the test group were considered totally masked. Including those considered partially masked, around 90% of the opacities had their appearance improved by the test treatment. This result was considerably more favorable than those reported by studies that followed the standard original manufacturer's instructions for resin infiltration of proximal caries, *i.e.* 2 minutes etching and 3 minutes infiltration [18,20,22]. Kim et al. (2011) [20] reported only 25% of complete masking and 35% of partial masking. Bandhari et al. (2018) [18] reported a reduction in the whitish color of the opacities, but no complete masking and Khanna et al (2020) [22] reported no masking effect at all. Using a longer etching time, as recommended by the manufacture for buccal lesions, Gençer et al. (2019) [46] observed that resin infiltration resulted in greater difference in ΔE value and more effective results in comparison with microabrasion followed by remineralizing agents, although the difference in the ΔE was not statistically significant in relation to microabrasion followed by fluoride varnish.

Predictability is still a matter of concern. Although a considerable change in the initial and final ΔE was observed and a considerable proportion of the opacities were totally masked in the present study, it was not possible to predict this result. The color changes observed during re-wetting with ethanol worked as a good predictor of the masking result of caries lesions [47]. Interestingly, authors mention that the final aesthetic result might be even better than the aspect observed after the re-wetting with ethanol. In the present study, we observed that if the color difference was attenuated by the ethanol application, it was a sign that a good result could be expected. However, the opposite was not always true. In many cases, we saw no change after re-wetting with ethanol and only after 15 or 20 minutes of the infiltrant application, the color changing was noticeable. A possible reason might be that the alcohol starts evaporating before it is able to reach a substantial area of the porosities of MIH opacities that might be broader in the subsurface [26]. For caries lesions, attempts to find a threshold in the level of fluorescence or color difference

between the lesion and the surrounding sound enamel, or in the diameter of the superficial extension of the lesion as a predictor of the visual result of infiltration did not succeed [48]. Transillumination has been indicated to estimate the depth and to better visualize the area of the opacities. Comparing transilluminated with reflected photography, it was possible to see that transillumination allowed better detection of the peripheral extension at the margins of the opacities [49,50]. Hence, it might assist the clinician at each step of the procedure identifying areas on the enamel surface that will need more etching or maybe indicated to be removed with a burr. It worked successfully in a case report [25], but no clinical studies have been conducted so far to confirm this result in a larger scale. Therefore, there are still open questions, which answers will be certainly useful to improve the infiltration protocol for MIH opacities and further studies are required.

In hypomineralized enamel, it has been argued that the pattern of infiltration may not be explained only by porosity variation, but the protein content in the enamel may also interfere with the penetrability of the resin [39]. As in the present study only white opacities with intact enamel surface were included, we believe that it was not a matter of major concern because the protein content in white opacities is consistently lower than in yellow or brown ones [37]. Moreover, it has been reported that integrity of the enamel surface influences the protein profile of MIH lesions. Differences in the protein-banding pattern between intact and broken lesions indicate that proteins from oral fluids are present in broken but not in intact lesion [51]. The benefit of strategies to remove proteins from the enamel prior to infiltration is controversial. Irrigation with sodium hypochlorite did not enhance the depth or the percentage area infiltrated [39]. Similarly, no significant impact on enamel bonding performance was seen after pre-treatment with sodium hypochlorite [52] in MIH molars. Contrarily, the bond strength to adhesives was significantly increased in white-creamy and yellow-brownish opacities treated with sodium hypochlorite or papain-based gel [53] and the infiltration of brown opacities seemed to be more consistent after pre-treatment with hydrogen peroxide [54]. More studies are still necessary to better understand if the application deproteinization substances improves infiltration and, consequently, the masking effect of MIH opacities.

In the present study, the positive impact of the test treatment on the perception about tooth appearance was represented by a significant decrease in the mean scores of the three questions of the first part (physical, psychological and social

domains) and in two questions of the second part of the Child's and Parent's Questionnaire about Teeth Appearance. In the question about how much the appearance of the teeth kept the child from smiling and in the question about the perception about teeth color, the significant reduction was observed on both parents' and children's perception. In the other questions, only parents reported significant less concern after the treatment. We wonder if some of the words used in these questions like "upset", "worry", and "pleasantness" might be quite abstract for children justifying the difference between children's and parents' answers. In a study that used the Child Oral Health Impact Profile Questionnaire, a positive impact was also seen after masking MIH opacities with different aesthetic treatments, including resin infiltration [24].

Surprisingly, in the present study, parents from the control group also showed a significant reduction in the mean score of two questions, related to how much their child's teeth upset them and their perception about their child's teeth color. We infer that this result is possibly related to the fact that parents felt confident about having their child's teeth improved after being included in the study. When invited to participate in the study, they were informed about the possibility of an alternative treatment if the one being tested did not satisfy them. Also interesting was the fact that parents from both groups reported increased concerns about tooth alignment after treatment. We speculate if the participation in the study either improved the aesthetic appearance of their child's teeth or made them more relaxed about this matter opening room for other concerns, *e.g.* tooth alignment.

To the best of our knowledge, this is the first randomized controlled trial evaluating the impact of aesthetic treatment of MIH opacities with resin infiltration on children's and parents' perception about teeth appearance. A particular strength of the present study was the use of placebo treatment mimicking the test treatment and guaranteeing blindness of the participants and their parents. Moreover, two examiners did the qualitative analysis with no access to the results of the quantitative analysis and a third examiner did the quantitative analyses with no access to the results of the qualitative analysis. None of them participated in the intervention procedures and therefore were also blind in relation to the treatment groups. Noteworthy was the correlation observed between the qualitative and the quantitative analyses.

We may consider that a limitation of the present study was not including a group without the microabrasion step in treatment protocol. However, based on previous attempts to mask MIH opacities without microabrasion [17,23–25], we assumed that no satisfactory results would be achieved. Once the infiltrant is applied and light cured it is not possible to try a second infiltration to improve the result because part of the pores in the subsurface are already blocked by the resin. Thus, due to ethical reasons, we decided not having a group without microabrasion. Future studies could evaluate if modifications in the microabrasion procedure, e.g., using abrasives or rotating instruments, may improve the infiltration favoring a complete masking of a higher proportion of MIH opacities. As resin infiltration may have additional other benefits for the hypomineralized enamel such as reducing permeability and increasing hardness and strength [37], further studies also testing the protocol with modified etching and longer application time also in posterior teeth are desirable.

CONCLUSIONS

The present randomized controlled clinical trial observed a positive impact of resin infiltration as an aesthetic treatment for MIH opacities in anterior teeth on parents' and children's perception about teeth appearance. Resin infiltration was able to reduce de color difference between the MIH opacities and sound enamel significantly after an application time of at least fifteen minutes with a masking effect.

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Conflict of interest

The authors declare no conflict of interest.

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CONCLUSÃO

a) O tratamento estético baseado na infiltração de resina de baixa viscosidade combinada à resina composta resultou em excelentes resultados com estabilidade de cor ao longo de 24 meses de acompanhamento. Opacidades difusas e demarcadas foram mascaradas em uma única sessão, melhorando a autoestima da paciente.
b) O ensaio clínico controlado randomizado observou um impacto positivo da técnica de infiltração de resina de baixa viscosidade nas opacidades por HMI em dentes anteriores na percepção estética dos pais e das crianças.
c) A técnica de infiltração de resina de baixa viscosidade, utilizando um tempo prolongado de aplicação do infiltrante, precedida de microabrasão, diminuiu significativamente os valores de ΔE no grupo teste, mostrando que o infiltrante foi capaz de reduzir a diferença de cor entre as opacidades por HMI e o esmalte sadio.

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APÊNDICE A - Termo de consentimento livre e esclarecido

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO (TCLE)

Eu,_____,
identidade nº _____, órgão emissor _____, idade____, sexo (M) (F),
residente à **(Rua,Av.)**_____,
nº_____, bairro _____, cidade_____,
UF _____, CEP _____, telefone ( )_____,
e-mail_____, autorizo
meu(minha) filho(a) _____,
a participar da pesquisa cujo título é" Mascaramento **de opacidades demarcadas em dentes anteriores em pacientes com HMI – ensaio clínico controlado randomizado**".

Declaro que fui informado e estou ciente de que:

1) Minha identidade será preservada;
2) O objetivo desta pesquisa será avaliar o **impacto do tratamento das manchas de esmalte** dos dentes permanentes anteriores superiores do meu(minha) filho(a) na **percepção estética** dele(dela) e também na minha **percepção estética**;
3) A fim de cobrir as manchas meu(minha) filho(a) será utilizado o produto odontológico ICON® (DMG), uma resina líquida que é aplicada sobre o esmalte do dente.
4) O risco que esse tratamento oferece pode ser considerado mínimo porque é um material autorizado para uso clínico e todo cuidado para este uso (manuseio) será tomado;
5) Caso eu e/ou meu(minha) filho(a) não fique(m) satisfeito com o resultado outro tratamento estético será oferecido;
6) Existem dois grupos nesta pesquisa: um que receberá tratamento com o produto (ICON®, DMG) chamado de **grupo teste** e outro que receberá o tratamento placebo simulando o tratamento com o Icon® (DMG) chamado de **grupo placebo**. Meu(minha) filho(a) poderá entrar em qualquer um dos grupos;
7) Qualquer informação adicional poderá ser fornecida pela pesquisadora responsável, Profa. Dra. Vera Soviero, sempre que solicitada pelo tel: (21) 2868-8272 (Faculdade de Odontologia – UERJ). Os dados pessoais dos voluntários serão mantidos sob sigilo, sendo manipulados apenas pelos responsáveis pela pesquisa e arquivados

por um período de 5 anos. No entanto, o resultado final do trabalho, bem como a sua análise, será publicado em literatura especializada e estarão disponíveis no banco de Teses da UERJ.

8) Posso retirar meu consentimento a qualquer momento sem quaisquer ônus ou prejuízos. Devo fazer isso por escrito, valendo a desistência a partir da data da formalização do pedido;
9) O pesquisador responsável por esta pesquisa é a Profa. Dra. Vera Mendes Soviero, e-mail: verasoviero@gmail.com, endereço Boulevard Vinte e Oito de Setembro, 157, Vila Isabel, Vila Isabel, Rio de Janeiro, RJ.

Rio de Janeiro, _____de _____de_____.

_____
_____
ASSINATURA DO(A) RESPONSÁVEL **ASSINATURA DE QUEM RECOLHEU O TCLE**

APÊNDICE B - Termo de assentimento para menores de idade alfabetizados

TERMO DE ASSENTIMENTO PARA MASCARAMENTO OPACIDADES POR INDIVÍDUOS MENORES DE IDADE ALFABETIZADOS

Meu NOME é _____ e eu tenho ___ anos de idade.

A pessoa que perguntou se eu queria cobrir a mancha branca do meu(s) dente(s) me disse que:

1) Um material usado para cobrir manchas de dentes será utilizado no meu(s) dente(s) para saber se é realmente bom.

2) meu nome não vai aparecer em nenhum lugar, vai ficar guardado com as pessoas desta pesquisa.

3) posso desistir e pedir para interromper o tratamento a qualquer momento da pesquisa.

4) a utilização deste produto em meu dente não oferece risco para a minha saúde.

5) o meu pai ou a minha mãe podem perguntar sobre o tratamento do meu(s) dente(s) a qualquer momento entrando em contato com o responsável pela pesquisa.

Como eu já sei ler e escrever, vou fazer um "X" no quadrado ao lado do que eu quero fazer e vou assinar, escrevendo meu nome embaixo.

☐ Eu **CONCORDO** em deixar usar um material para cobrir manchas no(s) meu(s) dentes.

☐ Eu **NÃO CONCORDO** em deixar usar um material para cobrir manchas no(s) meu(s) dentes.

_____

Minha assinatura

APÊNDICE C - Questionário das crianças e adolescentes sobre a aparência de seus dentes

Instruções de preenchimento:

- Isto não é uma prova. Não existem respostas certas ou erradas, pois este questionário pergunta a sua OPINIÃO a respeito dos seus próprios dentes;
- Tudo que precisa fazer é marcar apenas uma alternativa (aquela com a qual você mais concorda), não deixando nenhuma questão em branco.

1-Durante os últimos dois meses o quanto a aparência dos seus dentes incomodou você?

□ Muito □ Um pouco □ Muito pouco □ Nada □ Não sei

2-Durante os últimos dois meses o quanto a aparência dos seus dentes deixou você preocupado(a)?

□ Muito □ Um pouco □ Muito pouco □ Nada □ Não sei

3-Durante os últimos dois meses o quanto a aparência dos dentes impediu que você de sorrir espontaneamente?

□ Muito □ Um pouco □ Muito pouco □ Nada □ Não sei

4-Por favor, classifique os dentes de acordo com a descrição abaixo e indique se a situação preocupa você:		
A	Meus dentes estão:	
	□ Muito bons □ Levemente bons □ Nem bons nem desagradáveis □ Levemente desagradáveis □ Muito desagradáveis	Estou preocupado(a) por causa disso: □ Sim □ Não
B	Meus dentes estão: □ Muito alinhados □ Levemente alinhados □ Nem alinhados nem tortos □ Levemente tortos □ Muito tortos	Estou preocupado(a) por causa disso: □ Sim □ Não
C	Meus dentes estão: □ Muito brancos □ Levemente brancos □ Nem brancos nem manchados □ Levemente manchados □ Muito manchados	Estou preocupado(a) por causa disso: □ Sim □ Não
D	Meus dentes estão: □ Muito saudáveis □ Levemente saudáveis □ Nem saudáveis nem doentes □ Levemente doentes □ Muito doentes	Estou preocupado(a) por causa disso: □ Sim □ Não

5-Por favor diga o quanto você concorda com a frase: “a cor dos meus dentes é agradável e bonita”:				
□ Concordo totalmente	□ Concordo	□ Nem concordo nem discordo	□ Discordo	□ Discordo totalmente

APÊNDICE D - Questionário dos responsáveis sobre a aparência do dente do seu/sua filho(a)

Instruções de preenchimento:

- Não existem respostas certas ou erradas, pois este questionário pergunta a sua opinião a respeito do dente do seu/sua filho(a);
- Por favor não mostre as questões a seu/sua filho(a), neste momento, estamos interessados apenas na SUA opinião e a entrevista dele será realizada na clínica;
- Tudo que precisa fazer é marcar apenas uma alternativa (aquela com a qual você mais concorda, não deixando nenhuma questão em branco.

1-Durante os últimos 2 meses o quanto a aparência dos dentes do seu/sua filho(a) incomodou você?

□ Muito □ Um pouco □ Muito pouco □ Nada □ Não sei

2-Durante os últimos dois meses o quanto a aparência dos dentes do seu/sua filho(a) deixou você preocupado?

□ Muito □ Um pouco □ Muito pouco □ Nada □ Não sei

3-Durante os últimos dois meses o quanto a aparência dos dentes do seu/sua filho/filha impediu que ele/ela sorrisse espontaneamente?

□ Muito □ Um pouco □ Muito pouco □ Nada □ Não sei

<table>
<tr><td colspan="6">4-Por favor, classifique os dentes de acordo com a descrição abaixo e indique se a situação preocupa você:</td></tr>
<tr><td rowspan="2">A</td><td colspan="3">Os dentes do meu/minha filho(a) estão:</td><td colspan="2"></td></tr>
<tr><td colspan="3">□ Muito bons
□ Levemente bons
□ Nem bons nem desagradáveis
□ Levemente desagradáveis
□ Muito desagradáveis</td><td colspan="2">Estou preocupado(a) por causa disso:
□ Sim
□ Não</td></tr>
<tr><td>B</td><td colspan="3">□ Os dentes do meu/minha filho(a) estão:
□ Muito alinhados
□ Levemente alinhados
□ Nem alinhados nem tortos
□ Levemente tortos
□ Muito tortos</td><td colspan="2">Estou preocupado(a) por causa disso:
□ Sim
□ Não</td></tr>
<tr><td>C</td><td colspan="3">□ Os dentes do(a) meu/minha filho(a) estão:
□ Muito brancos
□ Levemente brancos
□ Nem brancos nem manchados
□ Levemente manchados
□ Muito manchados</td><td colspan="2">Estou preocupado(a) por causa disso:
□ Sim
□ Não</td></tr>
<tr><td>D</td><td colspan="3">□ Os dentes do(a) meu/minha filho(a) estão:
□ Muito saudáveis
□ Levemente saudáveis
□ Nem saudáveis nem doentes
□ Levemente doentes
□ Muito doentes</td><td colspan="2">Estou preocupado(a) por causa disso:
□ Sim
□ Não</td></tr>
<tr><td colspan="6">5-Por favor diga o quanto você concorda com a frase: “a cor dos dentes do(a) meu/minha filho(a) é agradável e bonita”:</td></tr>
<tr><td>□ Concordo totalmente</td><td>□ Concordo</td><td colspan="2">□ Nem concordo nem discordo</td><td>□ Discordo</td><td>□ Discordo totalmente</td></tr>
</table>

APÊNDICE E - Questionário das crianças e adolescentes sobre a aparência de seus dentes follow-up

Instruções de preenchimento:

- Isto não é uma prova. Não existem respostas certas ou erradas, pois este questionário pergunta a sua OPINIÃO a respeito dos seus próprios dentes;
- Tudo que precisa fazer é marcar apenas uma alternativa (aquela com a qual você mais concorda), não deixando nenhuma questão em branco.

1-Durante o último mês o quanto a aparência dos seus dentes incomodou você?

□ Muito □ Um pouco □ Muito pouco □ Nada □ Não sei

2-Durante o último mês o quanto a aparência dos seus dentes deixou você preocupado(a)?

□ Muito □ Um pouco □ Muito pouco □ Nada □ Não sei

3-Durante o último mês o quanto a aparência dos dentes impediu você de sorrir espontaneamente?

□ Muito □ Um pouco □ Muito pouco □ Nada □ Não sei

<table>
<tr><td colspan="3">4-Por favor, classifique os dentes de acordo com a descrição abaixo e indique se a situação preocupa você:</td></tr>
<tr><td>A</td><td>Meus dentes estão:</td><td></td></tr>
<tr><td></td><td>□ Muito bons
□ Levemente bons
□ Nem bons nem desagradáveis
□ Levemente desagradáveis
□ Muito desagradáveis</td><td>Estou preocupado(a) por causa disso:
□ Sim
□ Não</td></tr>
<tr><td>B</td><td>Meus dentes estão:
□ Muito alinhados
□ Levemente alinhados
□ Nem alinhados nem tortos
□ Levemente tortos
□ Muito tortos</td><td>Estou preocupado(a) por causa disso:
□ Sim
□ Não</td></tr>
<tr><td>C</td><td>Meus dentes estão:
□ Muito brancos
□ Levemente brancos
□ Nem brancos nem manchados
□ Levemente manchados
□ Muito manchados</td><td>Estou preocupado(a) por causa disso:
□ Sim
□ Não</td></tr>
<tr><td>D</td><td>Meus dentes estão:
□ Muito saudáveis
□ Levemente saudáveis
□ Nem saudáveis nem doentes
□ Levemente doentes
□ Muito doentes</td><td>Estou preocupado(a) por causa disso:
□ Sim
□ Não</td></tr>
<tr><td colspan="3">5-Por favor diga o quanto você concorda com a frase: “a cor dos meus dentes é agradável e bonita”:</td></tr>
<tr><td>□ Concordo totalmente</td><td>□ Concordo</td><td>□ Nem concordo nem discordo</td><td>□ Discordo</td><td>□ Discordo totalmente</td></tr>
</table>

APÊNDICE F – Questionário dos pais sobre a aparência dos dentes de seu/sua filho(a) - follow-up

Instruções de preenchimento:

- Não existem respostas certas ou erradas, pois este questionário pergunta a sua opinião a respeito do dente do seu/sua filho(a);
- Por favor não mostre as questões a seu/sua filho(a), neste momento, estamos interessados apenas na SUA opinião e a entrevista dele será realizada na clínica;
- Tudo que precisa fazer é marcar apenas uma alternativa (aquela com a qual você mais concorda, não deixando nenhuma questão em branco.

1-Durante o último mês o quanto a aparência dos dentes do seu/sua filho(a) incomodou você?

□ Muito □ Um pouco □ Muito pouco □ Nada □ Não sei

2-Durante o último mês o quanto a aparência dos dentes do seu/sua filho(a) deixou você preocupado?

□ Muito □ Um pouco □ Muito pouco □ Nada □ Não sei

3-Durante o último mês o quanto a aparência dos dentes do seu/sua filho/filha impediu que ele/ela sorrisse espontaneamente?

□ Muito □ Um pouco □ Muito pouco □ Nada □ Não sei

<table>
<tr><td colspan="5">4-Por favor, classifique os dentes de acordo com a descrição abaixo e indique se a situação preocupa você:</td></tr>
<tr><td>A</td><td colspan="2">Os dentes do meu/minha filho(a) estão:</td><td colspan="2"></td></tr>
<tr><td></td><td colspan="2">□ Muito bons
□ Levemente bons
□ Nem bons nem desagradáveis
□ Levemente desagradáveis
□ Muito desagradáveis</td><td colspan="2">Estou preocupado(a) por causa disso:
□ Sim
□ Não</td></tr>
<tr><td>B</td><td colspan="2">□ Os dentes do meu/minha filho(a) estão:
□ Muito alinhados
□ Levemente alinhados
□ Nem alinhados nem tortos
□ Levemente tortos
□ Muito tortos</td><td colspan="2">Estou preocupado(a) por causa disso:
□ Sim
□ Não</td></tr>
<tr><td>C</td><td colspan="2">□ Os dentes do(a) meu/minha filho(a) estão:
□ Muito brancos
□ Levemente brancos
□ Nem brancos nem manchados
□ Levemente manchados
□ Muito manchados</td><td colspan="2">Estou preocupado(a) por causa disso:
□ Sim
□ Não</td></tr>
<tr><td>D</td><td colspan="2">□ Os dentes do(a) meu/minha filho(a) estão:
□ Muito saudáveis
□ Levemente saudáveis
□ Nem saudáveis nem doentes
□ Levemente doentes
□ Muito doentes</td><td colspan="2">Estou preocupado(a) por causa disso:
□ Sim
□ Não</td></tr>
<tr><td colspan="5">5-Por favor diga o quanto você concorda com a frase: “a cor dos dentes do(a) meu/minha filho(a) é agradável e bonita”:</td></tr>
<tr><td>□ Concordo totalmente</td><td>□ Concordo</td><td>□ Nem concordo nem discordo</td><td>□ Discordo</td><td>□ Discordo totalmente</td></tr>
</table>

APÊNDICE G – Artigos da tese publicados – versões originais

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Esthetic Management of Incisors with Diffuse and Demarcated Opacities: 24 Month Follow-up Case Report

GS Athayde • RC Jorge • GCA Americano • F Barja-Fidalgo • VM Soviero

Clinical Relevance

A minimally invasive esthetic treatment can provide longevity and color stability.

SUMMARY

This clinical case report describes a minimally invasive approach to mask diffuse and demarcated opacities in permanent anterior teeth in an eight-year-old child who was upset with the appearance of her incisors. Clinical examination showed diffuse opacities in teeth 7, 8, 9, and 10, diagnosed as dental fluorosis associated with yellow demarcated opacity in tooth 9 related to molar-incisor hypomineralization. The treatment was based on conservative dentistry using the low-viscosity resin infiltration technique and resin composite restoration in an attempt to mask the lesions. The follow-up time was 24 months.

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INTRODUCTION

Developmental defects of enamel in anterior teeth might have negative impact on patient self-esteem and consequently quality of life.[1,2] Developmental defects of enamel can affect all the teeth as a whole or can be localized in a specific group of teeth, as in molar incisor hypomineralization (MIH).[3,4] MIH is characterized by the presence of demarcated opacities in at least one first permanent molar, generally associated with incisors also affected.[5] Fluorosis presents diffuse opacities with a chalky white appearance or, in severe cases, with staining and pitting.[6] A demarcated opacity in a single permanent tooth can be attributed to trauma to its predeces-

sor.[3,7] All these conditions come from abnormality in the enamel mineralization phase, modifying the chemical composition and optical characteristics of the enamel.[7]

The patient's expectations and the severity of the enamel opacities will guide the clinician's treatment choice. Alternatives to achieve esthetic improvement of demarcated and diffuse opacities range from minimally invasive strategies, such as dental bleaching[8,9] and microabrasion,[9-11] to more invasive techniques, such as composite resin restorations or porcelain veneers.[12,13] Microabrasion is indicated for fluorotic opacities; however, care should be taken to avoid excessive removal of enamel during the clinical procedure.[13] Among the minimally invasive methods, bleaching with hydrogen peroxide or carbamide peroxide has been used successfully.[14] Composite resins and porcelain veneers have been used to provide good esthetic results but invariably cause greater loss of tooth structure due to tooth preparation.[12,13]

More recently, the use of an infiltrant resin has been recommended as a minimally invasive approach to masking opacities in the enamel. The infiltrant agent was initially proposed for the treatment of white spot lesions caused by dental caries, but successful experiments have been reported for masking opacities related to fluorosis and opacities caused by trauma.[15-18] The technique of infiltrating the opacity with low-viscosity resin is based on the fact that the resin has a refractive index similar to that of sound enamel. Thus, when the resin penetrates and fills the porosities of the carious lesions, the refractive index returns to values very close to those of the sound enamel, masking the opacity.[18]

This clinical case report describes a minimally invasive approach to mask diffuse and demarcated opacities in permanent anterior teeth using a resin infiltrant (Icon, DMG, Hamburg, Germany) and composite resin restoration.

CLINICAL CASE REPORT

An eight-year-old female patient with no systemic disease attended the Pediatric Dentistry Clinic of Rio de Janeiro State University, Rio de Janeiro, Brazil. She was upset with the whitish appearance of her maxillary permanent incisors. Clinical examination showed diffuse opacities in teeth 7, 8, 9, and 10, which was diagnosed as moderate fluorosis (score 5) based on the Thylstrup and Fejerskov Index for Dental Fluorosis.[19] A yellow demarcated opacity in tooth 9 was diagnosed as MIH, according to the European Academy of Pediatric Dentistry[4] because the first permanent molars were also affected (Figure 1).

Figure 1. *Baseline: diffuse opacities in the upper central and lateral incisors. Yellow demarcated opacity in tooth 9.*

The treatment decision was based on minimally invasive dentistry, using the infiltration technique with low-viscosity resin (Icon) and composite resin (TPH, Dentsply, São Paulo, Brazil) in an attempt to mask the discolorations. The parent signed an informed consent form authorizing the treatment and the use of images.

The teeth were cleaned and isolated with a rubber dam (Figure 2). The infiltration technique followed was per the manufacturer's instructions. The enamel was etched using 15% HCl gel (Icon etch, DMG) for 2 minutes (Figure 3) followed by rinsing for 30 seconds, drying with compressed air (Figure 4) and dehydration with 100% ethanol (Icon dry, DMG) for 30 seconds. During ethanol application the visual aspect of the enamel was checked and the opacities had not disappeared. Thus, the etching step was repeated. After the second acid etching the diffuse opacities were masked, but the MIH yellow opacity in tooth 9 was still visible. Then, approximately 0.2 mm of the enamel was removed with a diamond bur and the acid gel (Icon etch) was reapplied only in the area of the demarcated opacity (Figures 5 and 6). When ethanol was applied, it was possible to see that the demarcated opacity was also camouflaged (Figure 7). The infiltration resin (Icon Infiltrant, DMG) was carefully applied onto the etched area for 3 minutes without rubbing (Figure 8); slightly dried with compressed air; and, after removing the excess with gauze, light-cured for 40 seconds (Altlux, Ribeirão Preto, São Paulo, Brazil) (Figure 9). Composite resin, color A2, (TPH) was used to restore the enamel removed by the bur. The tooth surfaces were polished with composite resin polishing discs (Sof-Lex, 3M ESPE, St Paul, MN, USA). The clinical

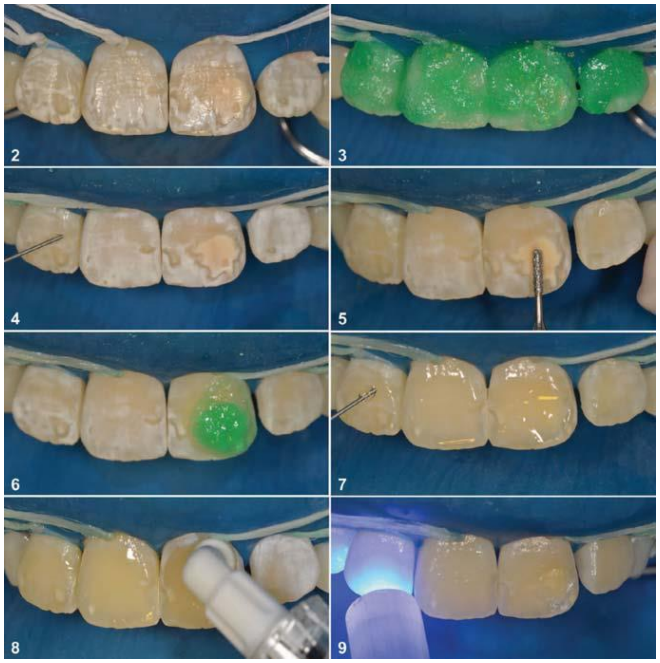

Figure 2. *Rubber dam with ligatures.*

Figure 3. *15% hydrochloric acid application (2 min).*

Figure 4. *Aspect after hydrochloric acid application. Ready for ethanol application.*

Figure 5. *After ethanol application, the diffuse white areas disappeared. The opacity did not change the aspect and 0.2mm enamel was removed (diamond bur-tooth 9).*

Figure 6. *15% hydrochloric acid application in the opacity – tooth 9 for 15s.*

Figure 7. *Ethanol application to preview the masking effect.*

Figure 8. *Resin infiltration in teeth 7,8,9 and 10.*

Figure 9. *Light-cure for 40s.*

aspect immediately after infiltration and rubber dam removal and at the 12-month and 24-month follow-up are shown in Figures 10, 11, 12, and 13 respectively.

DISCUSSION

Resin infiltration is an approach that can be safely and effectively performed in a single session with optimal results.[15-17,20] The diffuse opacities were completely masked by the infiltrant. Compared with microabrasion, the resin infiltration technique removes considerably less enamel as the acid application is not combined with mechanical abrasion. The microabrasion technique with abrasive gel composed of a mixture of hydrochloric acid or phosphoric acid and pumice or silica carbide particles is widely used as a minimal intervention,[21,22] although it invariably results in considerable enamel reduction. The enamel loss after microabrasion ranges from around 100 μm to more than 250 μm depending on the pressure, time of application, and concentration of the acid.[21,23-26] As mild to moderate fluorosis presents a porous subsurface zone of 80 to 100 μm in depth,[5] microabrasion abrades the whole affected enamel. Hence, the esthetic appearance is improved because the fluorotic enamel is removed. Etching with 15% HCl for 120 seconds, according to the resin infiltration technique, removes between 30 and 40 μm of surface layer, thus enabling the resin to penetrate into the deeper affected enamel.[27] The masking effect occurs due to the resin infiltrating the porous subsurface. That is why the application of ethanol is used as a prognostic parameter of the final result. If the wetting effect of the ethanol masks the opacities partially or completely, it means that the infiltrant will penetrate and mask the opacities. For a thicker surface zone additional etching may be necessary, as in the present case.

Home bleaching has also been recommended as an esthetic treatment for fluorosis. The modality that involves the use of a vacuum-formed custom-fitted tray filled with carbamide peroxide (10%-20%) or hydrogen peroxide (1%-10%) and has been validated by several studies.[14,28,29] For pediatric patients, the

Figure 10. *Immediate aspect after resin infiltration and composite resin - teeth 7,8,9 and 10.*

Figure 11. *Immediate aspect after rubber dam removal.*

Figure 12. *6-month follow-up.*

Figure 13. *24-month follow-up.*

American Association of Pediatric Dentistry recommends caution in the use of bleaching techniques.[30] Taking into account that in young patients dental pulp is wider than in adult patients and that the diffusion of hydrogen peroxide at high concentrations into dental tissues is extensive, the risk of adverse effects such as sensitivity might be high. Additionally, in contrast to bleaching therapy, which can reduce the microhardness of demineralized enamel surfaces,[31] the infiltrant resin can strengthen the enamel structure mechanically.[32] Therefore, for the current patient, bleaching was not considered.

In contrast to the fluorotic opacities, the demarcated opacity localized in the left incisor did not show any improvement even after a second acid etching. It was decided to use a bur to remove the superficial layer of the opacity and repeat the acid etching. In this case, treatment combining resin infiltration with composite can be considered a minimally invasive procedure because a very thin layer of enamel was removed that was restricted to the area of the demarcated opacity. Microabrasion was not used because of concerns about the risk of postoperative sensitivity considering the amount of enamel that would need to be removed and the patient's young age. However, in a previous case report, a nine-year-old patient had a demarcated opacity that was treated with microabrasion repeated in three consecutive appointments followed by resin infiltration; the patient had no complaints about sensitivity.[33]

The combination of resin infiltration and composite was effective in improving esthetics with minimal loss of tooth structure. Once the demarcated opacity was masked by the infiltrant, the restoration could be done with a single-color composite in a simple and practical procedure. No strategies combining opaque liner and different colors of composite were necessary to obtain the masking effect. Additionally, as bonding on a surface previously treated with Icon is possible,[34] no primer or adhesive was used before inserting the composite resin. The esthetic result showed color stability at the 24-month follow-up.

MIH is relatively common worldwide with an average prevalence of 11.24%,[35] which means pediatric dentists and clinicians will probably have patients with esthetic issues related to this condition and should be aware of possible treatment options. Considering the importance of the smile during adolescence and implications for self-esteem and social well-being to a child, clinicians should consider a conservative and effective approach. In the current case, diffuse and demarcated opacities were masked by the combination of infiltrant with composite in a single session, and a satisfactory outcome was achieved.

CONCLUSIONS

The esthetic treatment based on resin infiltration and composite achieved excellent results with color stability at the 24-month follow-up. Diffuse and demarcated opacities were masked in a single session that improved the patient's self-esteem.

Acknowledgements

Special thanks to DMG (Hamburg, Germany) for providing Icon.

Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of the ethical committee from Universidade do Estado do Rio de Janeiro. The approval code issued for this study is 07753213.0.0000.5259.

Conflict of Interest

The authors of this manuscript certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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Impact of masking hypomineralization opacities in anterior teeth on the esthetic perception of children and parents: A randomized controlled clinical trial

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ABSTRACT

Objectives: The aim of this study was to evaluate the impact of treating demarcated opacities in anterior teeth on the esthetic perception of children and their parents. Additionally, the masking effect was evaluated quantitively and qualitatively. Methods: Thirty-nine patients, 8–18 years-old, presenting white-creamy opacity in permanent incisors were randomly allocated to test or control group. Test received resin infiltration and control received a placebo. The questionnaire Child's and Parent's Questionnaire about Teeth Appearance was used. The masking effect was quantitatively analyzed using the Lab System to calculate the color difference (ΔE) between the opacity and the surrounding enamel in Photoshop. Fisher's, Chi-square, Wilcoxon, Mann-Whitney tests and Spearman's correlation were applied to data analysis. Results: In the test group, a significant impact on physical and psychological domains in parents' and in social domain in parents' and children's perception was observed ($p<0.05$). Significant difference in ΔE between test and control groups was seen from 15 min of application onwards ($p<0.05$). After treatment, the mean ΔE was 4.07 (SD=3.07) in the test and 7.35 (SD=3.54) in the control group ($p<0.01$). One month later, the mean ΔE was 4.22 (SD=2.96) in the test and 6.06 (SD=2.52) in the control group ($p<0.01$). Total masking was seen only in the test group ($p<0.01$). Conclusion: Aesthetic treatment of hypomineralization opacities in anterior teeth with resin infiltration impacted positively on parents and children. Resin infiltration reduced the color difference between opacities and sound enamel significantly after an application time of at least fifteen minutes.

Clinical significance: Opacities in anterior teeth impact the self-image of children and parents negatively. This study demonstrated that 15 min resin infiltration can mask opacities in permanent incisors and recover social wellbeing. This minimally invasive approach can be offered to MIH children who report dissatisfaction with their incisors.

1. Introduction

Dental esthetic treatments have attracted researcher's attention due to the increased demand for a more pleasant smile. Adolescents and children are forming their personality and are under social judgment all the time. Opacities in anterior teeth are perceived by children and generate dissatisfaction both in parents as in children who sometimes try to hide their smile [1,2].

Molar-Incisor-Hypomineralization (MIH) stands out as a prevalent condition worldwide, characterized by disturbance of enamel mineralization that results in demarcated opacities affecting first permanent molars and incisors [3]. The defective enamel presents clinically as a demarcated opacity that can vary in color, from white-creamy to yellow-brownish [4]. The negative impact of MIH on the oral health

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related quality of life has been reported in the literature [5–7].

Patients with anterior teeth affected by demarcated opacities often seek treatment for esthetic reasons. Resin infiltration has shown excellent results on masking white spot lesions caused by caries as a proposal for a minimally invasive treatment [8,9]. The reason why the whitish appearance is camouflaged by the infiltrant is related to the modification of light scattering. Sound enamel has a refractive index of 1.62. In an initial caries lesion, the porous enamel is either filled with water (refractive index of 1.33) or air (refractive index of 1.0). The difference in the refractive indices is the cause of the whitish appearance of such lesions. Once the porosities of the caries lesions are filled by the infiltrant, the light refraction within the enamel returns close to normal, around 1.52. Hence, the white spot becomes less perceptible by naked eyes [10].

The same effect has been achieved with diffuse opacities typical from dental fluorosis that were successfully masked by resin infiltration [11–14] However, no effect or only partial coverage was reached when demarcated opacities were treated [12,15–19]. The combination of microabrasion or the removal of a thin layer of enamel with burr followed by resin infiltration resulted in better masking of demarcated opacities in incisors [14,20–22]. More invasive techniques such as restorations with composite restorations or veneers provide good esthetic appearance [23,24]. However, they result in removal of some structure and initiate a restorative cycle prematurely, which should be avoided or postponed in young permanent teeth as maximum as possible.

Minimally invasive treatments to mask opacities in permanent incisors of children with MIH improved their socio-emotional wellbeing [21]. This approach is the first option for the treatment of enamel opacities in anterior teeth and the importance of a pleasant smile for children and adolescents justifies clinical studies evaluating different strategies to improve the esthetic of MIH opacities. The purpose of this study was to evaluate the impact of the treatment of demarcated opacities in anterior teeth with resin infiltration on the esthetic perception of children with MIH and their parents. As a secondary purpose, the masking effect of the treatment was evaluated after infiltrant application over the time.

2. Materials and methods

This clinical trial was approved by the local Ethics and Research Committee (3621,870) and registered in the Brazilian Registry of Clinical Trials (U1111–1240–5384; https://ensaiosclinicos.gov.br/). The participants and their parents were informed about the risks and benefits of the research and signed an informed consent. This clinical trial followed the CONSORT guide (Consolidated Standards for Reporting Trials).

2.1. Clinical trial and sample design

This randomized controlled clinical trial was carried out at the Pediatric Dental Clinic of the university. Healthy children presenting MIH [25] with intact white-creamy demarcated opacity in at least one permanent incisor, that caused esthetic discomfort to them and their guardian were eligible for the study. Other developmental defects of dental enamel (i.e. hypoplasia or fluorosis) and previous restorative, infiltration, microabrasion and/or whitening treatment were reasons for exclusion. Yellow-brownish opacities and post-eruptive enamel breakdown were also reasons for exclusion. All the inclusions were confirmed by the most experienced author (VMS).

The sample calculation was based on the estimative of a decrease in the mean score of 0.5 in the control group and 1.0 in the test group in the social domain of the questionnaire. With a significance level of 5% and power of 80%, a sample size of at least 32 patients was required. Considering the possibility of 25% loss after treatment, 20 patients in each group were included in the sample.

3. Randomization and intervention

The method of block randomization following a random number table generated in Microsoft Excel® for Mac (version 16.44) was used to allocate the patients into test or control group. The random number table was generated with a total of 40 numbers divided in 10 blocks, each block with 4 treatment options (2 tests and 2 control). The randomized numbers corresponding to test or control treatment were transferred to opaque envelopes before the beginning of the clinical trial by a person who was not involved in the research. The envelopes were organized sequentially according to the random sequence. As the patients arrived at the clinic for the treatment, an assistant picked an envelope in which there was a letter T for test group or C for control group, according to the randomized sequence. If the patient presented more than one eligible tooth, the same treatment (T or C) was performed. Operators, patients and parents were blind regarding the assigned treatment. Patients were scheduled per shift; four in the morning and four in the afternoon and each operator treated two per shift respecting the random sequence.

During the treatment, blinding of the patients and guardians was guaranteed because a placebo treatment was used, simulating all the steps of the test treatment in the control treatment. The operators, however, were not blind during the whole treatment because the placebo products did not mimic clinical effects like the desiccation caused by the acid etching. The examiners who performed the quantitative and qualitative analysis of the masking effect did not perform the treatments and therefore were blind regarding the treatment.

Two operators (GSA and PPGR) treated 20 patients each. Tooth prophylaxis with a rubber cup and water was followed by local topical anesthesia with benzocaine gel 20% (Benzotop, DFL, Rio de Janeiro, Brazil), for better comfort during rubber dam isolation. Table 1 presents

Table 1
Description of the test and control interventions (detailed description of the composition of the products are presented as notes).

Intervention steps	Test	Control
Tooth prophylaxis	Rubber cup/water	Rubber cup/water
Topical anesthesia	Benzocaine 20% gel	Benzocaine 20% gel
Isolation	Rubber dam	Rubber dam
Etching step (was done 3 times)		
Etching 2 min + Microabrasion[a]	Icon Etch[b]	Placebo etching gel[c]
Rinsing 30 s	Water	Water
Drying 30 s	Compressed air	Compressed air
Desiccation 30 s	Icon Dry[d]	0.9% saline solution
Drying 30 s	Compressed air	Compressed air
1st Infiltration		
Resin application 30 min[e]	Icon Infiltrant[f]	Placebo infiltrant[g]
Excess removal	Gauze and dental floss	Gauze and dental floss
Light curing	Light curing 40 s	Light curing 40 s
2nd Infiltration		
Resin application 1 min	Icon Infiltrant[f]	Placebo infiltrant[g]
Excess removal	Gauze and dental floss	Gauze and dental floss
Light curing	Light curing 40 s	Light curing 40 s
Polishing (after rubber dam removal)	Polishing and finishing cups	Polishing and finishing cups

aMicroabrasion: the applicator tip was used to rub the etching gel on the enamel surface in the first 10 s of the etching time.
b 15% hydrochloric acid gel, pyrogenic silicic acid, surface-active substances.
c Oral gel: gelly 6%, carboxymethilcellulose 4%, sodium chloride 0,25, sodium benzoate 0,1%, citric acid 1%, distilled water 30 g, 18 drops of food coloring liquid (blue) and 10 drops of green food coloring (green).
d 99% ethanol.
e An opaque protector barrier was placed in parallel few mm away from the tooth to block light and avoid infiltrant polymerization.
fMethacrylate-based resin matrix, initiators and additives. Methacrylate refraction index ~ 1.48[27].
g Mineral oil solution (0,35 ml) and olive oil (0,1 ml). Mineral oil refraction index ~1.48 and olive oil ~1.47[28].

the test and control treatment steps as well as the detailed descriptions of the test and placebo products. The operators worked in the same room under the same operating and lighting conditions. One of the authors (RCJ) was in charge of taking the initial, intermediate, and final photographs.

3.1. Impact on esthetic perception

The Portuguese validated version of the Child's and Parent's Questionnaire about Teeth Appearance [26] was used to evaluate the impact of the treatment on the perception about teeth appearance. The questionnaire comprises three sections, including 12 items and sub-items. The first, with three questions, assesses the physical, psychological and social domains and the answers range from "nothing" (0) to "very" (3). The second part contains four statements in which children and parents are asked about their perception of the satisfaction, alignment, color and health of the child's teeth and whether any of these items are of concern. The responses in this section range from "very good, very aligned, very white and very healthy" (0) to "very unpleasant, very crooked, very stained and very sick" (4). For each statement, a second question was asked whether it generates concern, with "yes" or "no". The last part contains the sentence: "The color of my teeth/ the color of my child's teeth is pleasant and beautiful" with answers ranging from "I totally agree" (0) to "I totally disagree" (4). The child and his/her parent were asked to complete the questionnaire before each session. It was a requirement that the same parent complete the questionnaire before and after the treatment.

3.2. Analysis of opacity masking effect

Quantitative analysis of the masking effect was performed blindly by one examiner (VMS). Clinical photographs were taken with a digital camera (Nikon D90, Nikon, Tokyo), macro lens (100-mm Macro Rokkor-X, Minolta, Tokyo), circular flash (Sigma, Welwyn Garden City, UK), using the same exposure (ISO 100, 1 / 160 speed, F / 20 aperture), with the patient and digital camera at the same vertical plane, dental clinic illuminated evenly, and approximate 30 cm of distance of the patient. The photographs were taken in baseline, during the application time of the test or placebo resin at 0, 3, 10, 15, 20, 25 and 30 min, immediately after removing the rubber dam and in the follow-up appointment one month after treatment. In order, to ensure the white balance in the analysis of the photographs, a gray card 18% achromatic, free of reflection, opaque and neutral (Flexipalette color match FP 3004, Smile Line, Swiss) was used in every intraoral photograph [27].

Photographs were saved in JPEG format and analyzed using Photoshop CC for Mac (Adobe, San Jose, USA) for quantitative analysis using the CIELAB (International Commission on Illumination) system. Absolute values of luminosity (L), red-green color (a) and yellow-blue color (b) were assessed in the opacity and in a sound area of the enamel before and after treatment. The difference in luminosity (ΔL), red-green (Δa) and yellow-blue (Δb) between the opacity and the sound area of the enamel were calculated. Then, the total color difference (ΔE) between the opacity and the sound area of the enamel was calculated using the equation $\Delta E = (\Delta L^{*2} + \Delta a^{*2} + \Delta b^{*2})$ ½ (31). The masking effect was represented by a reduction of the ΔE value after the treatment (final ΔE) in comparison with the ΔE value before the treatment (initial ΔE). Initial ΔE and final ΔE were calculated between a sound and an affected area of the enamel in the initial and final clinical pictures, respectively. For the analysis of ΔE, first, in the initial clinical picture, an area in the opacity was selected and saved. Then the same selection, with the same size and shape, was transferred to a sound area of the enamel and saved. For the definition of the area, the following criteria were used: (1) it should cover the opacity as much as possible; (2) the same area in size and shape should be applicable to the opacity and to the surrounding sound enamel. The same selected areas were applied in the final clinical picture.

The qualitative analysis of the masking effect was performed by pairwise reading. The initial and the follow-up photographs were organized side by side in Microsoft Power Point® for Mac (version 16.45). Two blinded examiners (GCAA and TKSF), experienced pediatric dentists, independently evaluated the photographs and classified the result of the treatment as: (1) total masking (the opacity is no longer noticeable); (2) partial masking (the opacity color approached the tooth color and / or reduced in size, but it is still apparent); or (3) no masking (there was no change in color or opacity size).

3.3. Training and calibration

Prior to the study, the two operators (GSA and PPGR) who performed the treatments were trained by an experienced clinician on resin infiltration (VMS). In the first phase, the operators received a theoretical training about the physical and mechanical properties of the infiltrant resin. In the second phase, test and control interventions protocols were discussed in detail and each of the operators treated one patient following all the steps of the intervention protocol. For the qualitative analysis, two examiners were trained for the assessment of initial and final clinical pictures classifying each tooth as complete, partial, or no masking. Linear weighted kappa for intra-examiner was 0.98 and 0.88 and for inter-examiners it was 0.84. A third examiner was trained for the quantitative analysis using the CIELAB system in Photoshop CC for Mac (Adobe, San Jose, USA). The two cases treated in the pilot phase were analyzed as part of the training. Then, 10% of the initial ΔE were reassessed to test intra-examiner agreement. Intraclass correlation was 0.97 (95% CI: 0.83 – 0.99).

3.4. Side effects and report of pain/discomfort during the procedure

Possible adverse effects, such as postoperative pain in teeth and gums, damage in soft tissues and bitter taste were recorded by asking the child right after treatment. Two cell phone numbers were made available 24 h a day if the patient had any discomfort and/or the guardian has any questions. The report of pain/discomfort during the procedure was assessed by Wong and Baker [28] pain scale right after the end of treatment.

3.5. Statistical analysis

SPSS version 25.0 (IBM, Chicago, IL, USA) was used for statistical analysis. The characterization of the sample was based on the descriptive analysis of age, gender, type and number of teeth for test and control group separately. Data about pain and side effects were presented as absolute and relative frequencies. Fisher's Exact test was used to test the association between dichotomic variables.

Data related to the questionnaire and ΔE values were tested for normality using Shapiro-Wilk test. As the data showed a non-normal distribution, non-parametric tests were used in the statistical analysis. The impact of the test and placebo treatment on the perception about teeth appearance was analyzed comparing the mean score obtained in each of the questionnaire's domains before and after treatment using the Wilcoxon signed rank test for related samples. The qualitative analysis, based on the classification of each tooth as total masking, partial masking or no masking after treatment, was compared between test and control groups using Chi-square test. The intra and inter-examiners agreement was assessed kappa with linear weighting for qualitative analysis and Intraclass correlation for quantitative analysis. The Mann-Whitney non-parametric test was used to test difference between groups regarding the ΔE values in the different time points. Then, two summary measures were defined as the main outcomes of the quantitative analysis of the masking effect of the treatment: the absolute difference between the initial ΔE and the final and follow-up ΔE; and the percentage change between the initial ΔE and the final and follow-up ΔE. Mann-Whitney test was also used to test the difference between

groups regarding the summary measures. The association between the qualitative and the quantitative results was tested using Spearman's correlation. The level of significance was set at 0.05.

4. Results

4.1. Sample description

Clinical trial flowchart is shown in Fig. 1. One patient missed the follow-up appointment and was considered as a dropout. The sample characteristics are presented in Table 2. Interventions (test and placebo treatments) and follow-up appointments took place between February 2020 and January 2021.

4.2. Impact on parents' and children's esthetic perception

In the test group, a significant reduction in the questionnaire scores related to physical ($p = 0.01$), psychological ($p = 0.02$), and social ($p = 0.04$) domains in the parents' point of view after treatment was observed. In the social domain a significant reduction was also seen in the children's opinion ($p < 0.01$). In the control group, a significant reduction was seen in the physical domain reported by parents ($p = 0.02$) (Table 3).

In the second part of the questionnaire, parents from the test group reported significantly less dissatisfaction with their child's teeth regarding pleasantness ($p = 0.01$) and both parents ($p = 0.01$) and children ($p = 0.04$) from the test group reported less dissatisfaction about tooth color after treatment. In the control group, parents also perceived fewer discolorations in their child's teeth after treatment ($p = 0.04$). Children from the test group ($p = 0.04$) and parents from both test ($p = 0.01$) and control ($p = 0.04$) groups perceived more tooth misalignment after treatment. When questioned about how concerned they were with tooth pleasantness, tooth alignment, tooth color and tooth health, parents from test group reported significantly less concern with tooth color after treatment (Table 4).

In the third part of the questionnaire, regarding the affirmative "the color of my teeth / my child's teeth is pleasant and beautiful", no significant difference was observed in the mean score given by parents or children before and after treatment in both groups (Table 4).

Table 2
Characterization of the sample regarding age, gender, number and type of treated teeth. The characteristics of the dropout are given as notes.

Variables	Test Group (n = 19)	Control Group (n = 20)	p-value
Age			
Range	8 – 18 years	8 – 16 years	0.166[a]
Mean (SD)	11.2 (2.79)	10.1 (2.20)	
Median	10.0	9.0	
Gender			
Male	8 (42.1%)	9 (45.0%)	0.556[b]
Female	11 (57.9%)	11 (55.0%)	
Number of treated incisors			
Range	1 – 3 teeth	1 – 3 teeth	0.923[a]
mean (SD)	1.47 (0.61)	1.45 (0.61)	
Median	1.0	1.0	
Type of treated incisors			
only upper	15 (78.9%)	14 (70.0%)	0.571[c]
only lower	4 (21.1%)	5 (25.0%)	
upper and lower	0 (0%)	1 (5.0%)	

Dropout: there was one dropout from the Test group; a girl, 14 years old who had two lower incisors treated.
a Mann Whitney Test; b Fisher's Exact Test; c Pearson Chi-Square Test.

4.3. Quantitative analysis

Before treatment, the mean ΔE was 6.45 (SD = 3.53) in the test and 5.98 (SD = 2.57) in the control group ($p = 0.88$). A significant difference between test and control groups was seen from 15 min of infiltrant application onwards. Immediately after the treatment, the mean ΔE was 4.07 (SD = 3.07) in the test and 7.35 (SD = 3.54) in the control group ($p < 0.01$). In the follow up evaluation, one month after the treatment, the mean ΔE was 4.22 (SD = 2.96) in the test and 6.06 (SD = 2.52) in the control group ($p = 0.002$). Fig. 2 shows the ΔE values related to the different application time points in the test and control groups.

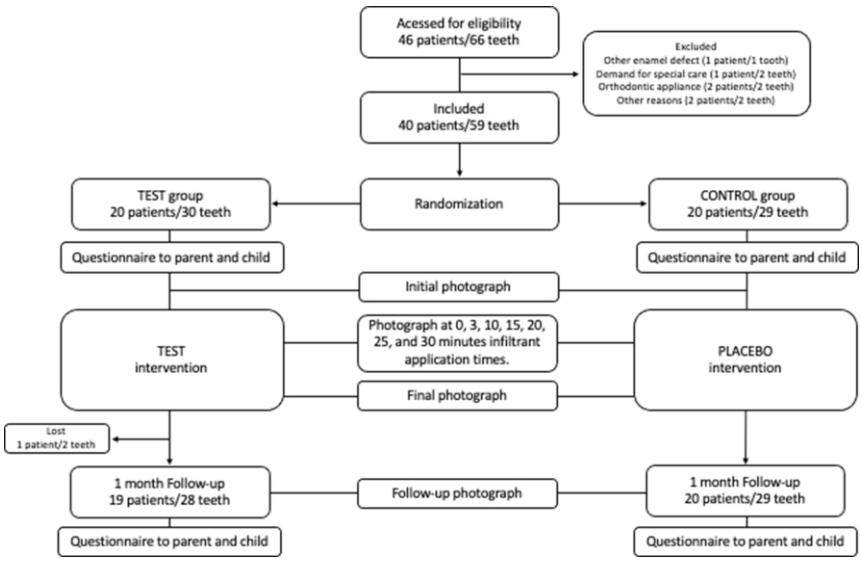

Fig. 1. Flowchart of the study.

Table 3
Mean values and standard deviation (SD) of the scores given by parents and children regarding physical, psychological and social domains of the Child's and Parent's Questionnaire about Teeth Appearance before and after TEST and CONTROL treatments.

Questions	Respondent	Test			Control		
		Before treatment Mean (SD)	After treatment Mean (SD)	*p*-value	Before treatment Mean (SD)	After treatment Mean (SD)	*p*-value
Physical							
How much has the appearance of your teeth/your child's teeth upset you?	Parent	2.11 (0.88)	1.26 (0.99)	0.01*	1.90 (0.85)	1.35 (1.09)	0.02*
	Child	1.47 (1.12)	1.00 (1.10)	0.16	1.05 (1.05)	0.65 (1.04)	0.31
Psychological							
How much has the appearance of your teeth/your child's teeth worried you?	Parent	2.05 (0.91)	1.32 (1.10)	0.02*	1.90 (1.07)	1.60 (1.09)	0.38
	Child	1.32 (1.25)	1.21 (1.13)	0.76	1.05 (1.14)	1.15 (1.04)	0.69
Social							
How much has the appearance of your teeth/your child's teeth kept you/your child from smiling?	Parent	1.42 (1.08)	0.79 (1.27)	0.04*	0.45 (0.94)	0.35 (0.67)	0.70
	Child	1.42 (1.35)	0.53 (0.84)	0.00*	0.50 (±1.00)	0.35 (±0.74)	0.68

Related samples Wilcoxon Rank Test.
*significant difference.

Table 4
Mean values and standard deviations (SD) of the scores given by children and parents regarding their perception about the pleasantness, alignment, color and health of the child's teeth before and after TEST and CONTROL treatments.

Questions	Respondent	Test			Control		
		Before treatment Mean (SD)	After treatment Mean (SD)	*p*-value	Before treatment Mean (SD)	After treatment Mean (SD)	*p*-value
Perception of the child's teeth pleasantness.	Parent	1.84 (1.17)	1.00 (1.00)	0.01*	1.75 (1.02)	1.30 (0.80)	0.12
	Child	1.58 (1.35)	1.11 (1.33)	0.12	1.45 (1.50)	1.30 (1.13)	0.58
Perception of the child's teeth alignment.	Parent	2.16 (1.02)	3.16 (1.07)	0.00*	2.35 (1.14)	3.45 (0.76)	0.00*
	Child	2.00 (1.20)	1.89 (0.99)	0.75	2.40 (1.10)	2.20 (0.89)	0.33
Perception of the child's teeth color.	Parent	3.16 (0.38)	2.32 (1.16)	0.01*	3.10 (0.45)	2.60 (1.05)	0.04*
	Child	2.47 (1.22)	1.95 (1.22)	0.04*	2.40 (1.23)	2.45 (0.95)	0.77
Perception of the child's teeth health.	Parent	1.47 (0.96)	1.11 (0.94)	0.25	1.70 (0.98)	1.20 (0.70)	0.06
	Child	1.16 (1.12)	0.68 (0.58)	0.07	1.05 (0.83)	1.35 (1.14)	0.32
How much do you agree that the color of your teeth / your child's teeth is pleasant and beautiful?	Parent	2.42 (1.17)	1.74 (0.93)	0.06	2.45 (0.76)	1.95 (1.10)	0.13
	Child	1.89 (1.10)	1.32 (1.06)	0.09	1.40 (1.05)	1.55 (1.36)	0.56

Related samples Wilcoxon Rank Test.
*significant difference.

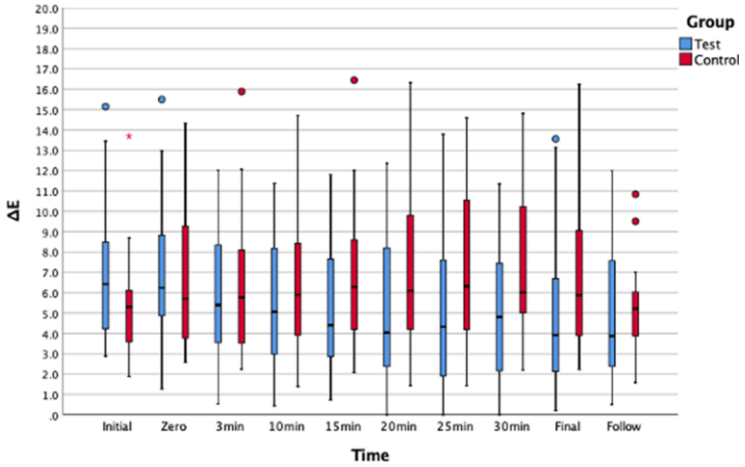

Fig. 2. Clustered boxplot showing ΔE values for test and control groups for the different infiltrant application time points. ✧Significant difference between groups (Mann-Whitney Test).

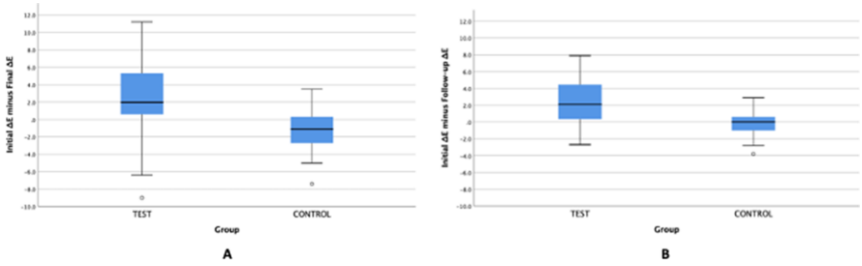

Fig. 3. Absolute differences of initial and final ΔE. (A) Comparison between the initial ΔE and the final ΔE for test and control groups (Mann-Whitney Test; $p < 0.01$); (B) Comparison between the initial and the 1-month follow-up ΔE for test and control groups (Mann-Whitney Test; $p = 0.001$).

Fig. 3A illustrates the absolute difference between the initial ΔE and the final ΔE. In the test group, the mean difference between initial and final ΔE was 2.50 (SD = 4.28) with a median of 1.97 (min: –9.0; max: 11.2). In the control group, the mean difference between initial and final ΔE was –1.20 (SD = 2.38) with a median of –1.10 (min: –7.4; max: 3.5), indicating that the final ΔE was greater than the initial ΔE in at least 50% of the teeth. Fig. 3B illustrates the absolute difference between the initial ΔE and the follow-up ΔE. In the test group, the mean difference between initial and follow-up ΔE was 2.42 (SD = 2.93) with a median of 2.12 (min: –2.7; max: 7.9). In the control group, the mean difference between initial and final ΔE was –0.003 (SD = 1.59) with a median of –0.000 (min: –3.8; max: 2.9), indicating that the follow-up ΔE was close to the initial ΔE.

Fig. 4A and B present the percentage change between the initial ΔE and the final and follow-up ΔE, respectively. In the test group, the mean final ΔE was 73.5% (SD = 71.0%) of the initial ΔE with a median of 50.4% (min: 6.7; max: 295.7). In the control group the mean final ΔE was 124.4% (SD = 46.6%) of the initial ΔE with a median of 116.2% (min: 61.1; max: 251.5). The data indicate that the reduction of the ΔE that was seen in the test group after treatment was not observed in the control group. However, in the control group, the final ΔE tended to be greater than the initial ΔE. In the follow up appointment, the mean ΔE in the test group was 66.7% (SD = 39.8%) of the initial ΔE and in the control group it was 102.8% (SD = 25.6%) of the initial ΔE. The median values were 62.7% (min: 17.0; max: 150.0) and 100% (min: 64.7; max: 160.6) for test and control group, respectively.

4.4. Qualitative analysis

The results of the qualitative analysis, done by two blinded examiners independently, are shown in Table 5. The masking effect was significantly more frequent in the test group when compared with the control group ($p < 0.001$). A total masking was achieved in 16 (57.1%) and 13 (46.4%) teeth of the test group, according to the examiner 1 and 2, respectively. No teeth from the control group were classified as total masking. Inter-examiners agreement was substantially high. The examiners agreed in 86% of the cases resulting in weighted kappa coefficient of 0.84. The evaluations were repeated within an interval of 15 days and the intra-examiner weighted kappa coefficient was 0.98 e 0.88 for examiner 1 and 2, respectively.

Table 5
Qualitative analysis of clinical treatment effect for test ($n = 28$) and control ($n = 29$) groups.

Treatment effect	Examiner 1			Examiner 2		
	Test	Control	*p*-value*	Test	Control	*p*-value*
	n (%)	n (%)		n (%)	n (%)	
Total masking	16 (57.1)	0 (0)		13 (46.4)	0 (0)	
Partial masking	9 (32.1)	0 (0)	< 0.001	14 (50.0)	1 (3.4)	< 0.001
No masking	3 (10.7)	29 (100)		1 (3.6)	28 (96.6)	

*Chi-square test.

4.5. Qualitative analysis X quantitative analysis

The absolute difference and the percentage change between the initial ΔE and the follow-up ΔE were significantly correlated to the qualitative assessment of the treatment effect (Figs. 5A, B and 6A, B are available as supplementary material). As greater was the reduction of the absolute value of the ΔE and as lower was the follow-up percentage of the initial ΔE, more apparent was the masking effect. Values of Spearman's correlation were 0.614 ($p<0.01$) and 0.540 ($p<0.01$) for examiner 1 and 2, respectively.

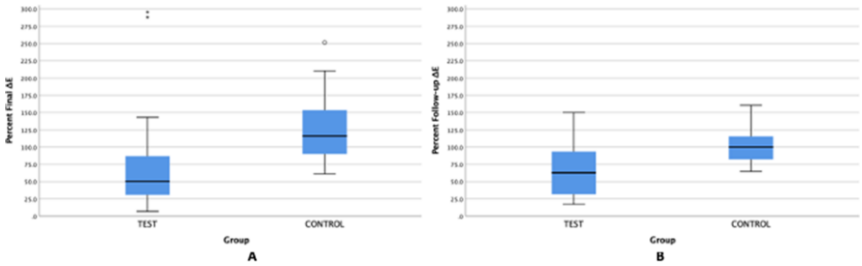

Fig. 4. Differences of initial and final ΔE percentages. (A) Comparison between the initial ΔE and the final ΔE as a percentage for test and control groups (Mann-Whitney Test; $p < 0.01$); (B) Comparison between the initial and after the 1-month follow-up ΔE as a percentage for test and control groups (Mann-Whitney Test; $p = 0.001$).

4.6. Side effects and report of pain/discomfort during the procedure

No major side effects, like pain, vitality loss, or gingival damage were reported. Most patients did not report any adverse effect after treatment (11 (57.9%) from the test and 12 (60%) from the placebo group). Immediately after removing the rubber dam, 6 (31.6%) children from the test and 5 (25%) from the placebo group reported bitter taste. Two (10.5%) children from the test and 3 (15%) from the control group reported postoperative pain/discomfort in the area of the treated tooth. These symptoms disappeared within the next hours after the procedure. No significant difference between groups was observed ($p = 0.77$).

Regarding the Wong-Baker facial pain scale [28], most of the children in both groups, 12 (63.2%) and 15 (75%) from test and placebo, respectively, pointed out the first and happiest face indicating no pain during the treatment. The second face, indicating "a little pain", was selected by 4 (21.1%) children from the test and 5 (25%) from the placebo group. Only 2 (10.5%) children from the test group selected the third face indicating "a little more pain" and one child (5.3%) also from the test group selected the last face indicating the highest score of pain ("hurts worst"). There was no significant difference between groups regarding the report of pain during the treatment ($p = 0.33$).

5. Discussion

The present study demonstrated that resin infiltration was able to reduce the color difference between demarcated opacities and the surrounding normal enamel significantly in patients with MIH. The masking effect was observed both qualitatively, by visual evaluation, and quantitatively, by the calculation of the difference between the initial and final ΔE, with a relevant impact on the perception about tooth appearance for both parents and children.

Nowadays, patient-reported outcomes have gaining space in dental research scenario. In the present study, the primary outcome was the impact of the treatment on the esthetic perception of children and their parents. The positive impact of the test treatment on the perception about tooth appearance was represented by a significant decrease in the mean scores of the three questions of the first domain and in two questions of the second domain of the Child's and Parent's Questionnaire about Teeth Appearance. In the question about how much the appearance of the teeth kept the child from smiling and in the question about the perception about teeth color, the significant reduction was observed on both parents' and children's perception. In the other questions, only parents reported significant less concern after the treatment. We wonder if some of the words used in these questions like "upset", "worry", and "pleasantness" might be quite abstract for children justifying the difference between children's and parents' answers. It is worth mentioning that although a significant decrease in the mean scores of the questionnaire was seen in the test group, it did not represent a change from a total dissatisfaction to a complete satisfaction considering the 5-Likert scale used to indicate the child/parent's answers. Nonetheless, the positive impact on the esthetic perception perceived in the test group is supported by the quantitative and qualitative analyses of the color change. In a study that used the Child Oral Health Impact Profile Questionnaire, a positive impact was also seen after masking MIH opacities with different esthetic treatments, including resin infiltration [21].

Surprisingly, in the present study, parents from the control group also showed a significant reduction in the mean score of two questions, related to how much their child's teeth upset them and their perception about their child's teeth color. We infer that this result is possibly related to the placebo effect. Moreover, parents felt confident about having their child's teeth improved after being included in the study. When invited to participate in the study, they were informed about the possibility of an alternative treatment if the one being tested did not satisfy them. Also interesting was the fact that parents from both groups reported increased concerns about tooth alignment after treatment. We speculate whether the participation in the study either improved the esthetic appearance of their child's teeth or made them more relaxed about this matter opening room for other concerns, e.g. tooth alignment.

To the best of our knowledge, this is the first randomized controlled trial evaluating the impact of esthetic treatment of MIH opacities with resin infiltration on children's and parents' perception about teeth appearance. A particular strength of the present study was the use of placebo treatment mimicking the test treatment and guaranteeing blindness of the participants and their parents. Moreover, two examiners performed the qualitative analysis with no access to the results of the quantitative analysis and a third examiner did the quantitative analyses with no access to the results of the qualitative analysis. None of them participated in the intervention procedures and therefore were also blind in relation to the treatment groups. Noteworthy was the correlation observed between the qualitative and the quantitative analyses. For the quantitative analysis, we used the color difference between the opacity and the sound area of the enamel calculated in clinical pictures before and after treatment. Due to the irregular shape of the opacities, we did not consider using a spectrophotometer because the probe tip of the device has a fixed round shape of 5 mm diameter. Therefore, in many cases, it would not be possible to keep the probe tip positioned in the opacity without touching a sound area and vice-versa.

Factors expected to influence the esthetic result of resin infiltration are the thickness of the enamel surface layer, the depth of the lesion, and the histological organization of the subsurface [29]. The enamel affected by initial caries lesions and mild/moderate fluorosis show similar histological features. The more porous enamel, the so-called body of lesion, is underneath a hypermineralized surface and the shape of the lesion forms an obtuse angle with the surface. In a histological section it is possible to see that the extension of the surface layer is wider than the subsurface [30]. Once the acid etching erodes the surface layer, the infiltrant gains access to the complete subsurface extension and is able to fill the porosities into the enamel [29]. For both fluorosis and caries, the esthetic outcome is quite predictable. However, while fluorosis is limited to the external thickness of the enamel, caries lesions vary widely in depth and may reach the internal third of the enamel [31]. Microabrasion alone might be able to improve aesthetics in cases of fluorosis or shallow caries lesions if the outer defective enamel layer is completely abraded [32]. Nonetheless, deeper and inactive enamel caries might be more difficult to mask. In order to obtain enhanced esthetic results, longer etching time than the original manufacture's recommendation for the infiltration of proximal caries lesions were reported both for caries lesions and fluorosis [8,11].

Demarcated opacities associated with MIH differ from enamel caries and fluorosis. Firstly, they start from the enamel-dentine junction toward to the enamel surface and, secondly, they differ in shape [23]. Not rarely, a demarcated opacity has a narrower surface layer and a broader subsurface, forming an acute angle with the enamel surface [23]. In these cases, the acid etching of the surface layer gives access only to the central part of the lesion. In caries lesions, once the access is gained, the infiltrant flows in the direction of the deepest parts of the lesion and may infiltrate it completely or almost completely. In a demarcated opacity, if the edges of the lesion are underneath sound enamel, they may not be properly filled [23]. Thus, the result of treatment might be quite unpredictable.

Trying to overcome this difficulty and optimize access to the infiltrant, in the present study, the resin infiltration protocol was based not only on longer acid etching, like previous studies on caries and fluorosis [8,11], but also on a modification of the application of the etching gel. In each of the etching steps, the applicator tip was used to rub the etching gel on the enamel surface during the first 10 s, but no abrasives were added to the gel. Using light pressure, we aimed to optimize the erosive effect of the HCl gel on the enamel surface. The use of a brush to apply the etching gel in occlusal fissure improved the contact between the gel and the enamel surface in a previous study [33].

Previous studies on caries showed that the application time

influences in the depth and homogeneity of the infiltration. Longer application time resulted in deeper penetration of the infiltrant, but three minutes was considered adequate to penetrate caries lesions deep enough to hamper their progression [34]. However, longer application was more effective in masking natural proximal caries lesions in an *in vitro* study [35] and demarcated opacities *in vivo* [36]. When liquid contacts a porous solid, it penetrates into the porous structure by capillary forces. The geometrical shape of the porous solid and properties of the liquid are factors that influence the flow behavior of the liquid and, consequently, the amount of time needed to fill the porosities completely [37]. As the structure of caries lesions and hypomineralized enamel do not follow a standard pattern, it is expected that different lesions take different time to be infiltrated.

Then, in the present study, we decided to observe the masking effect along 30 min application of the infiltrant. The fifteenth minute represented a kind of turning point, when a significant difference started to be seen in the values of ΔE between test and control groups. After 30 min application, around half of the opacities in the test group were considered totally masked. Including those considered partially masked, around 90% of the opacities had their appearance improved by the test treatment. This result was considerably more favorable than those reported by studies that followed the standard original manufacturer's instructions for resin infiltration of proximal caries, i.e. 2 min etching and 3 min infiltration [15,17,19]. Kim et al. [17] reported only 25% of complete masking and 35% of partial masking. Bandhari et al. [15] reported a reduction in the whitish color of the opacities, but no complete masking and Khanna et al. [19] reported no masking effect at all. Using a longer etching time, as recommended by the manufacture for buccal lesions, Gençer et al. [38] observed that resin infiltration resulted in greater difference in ΔE value and more effective results in comparison with microabrasion followed by remineralizing agents, although the difference in the ΔE was not statistically significant in relation to microabrasion followed by fluoride varnish.

Predictability of the treatment is still a matter of concern. The color changes observed during re-wetting with ethanol worked as a good predictor of the masking result of caries lesions [39]. In the present study, we observed that if the color difference was attenuated by the ethanol application, it was a sign that a good result could be expected. However, the opposite was not always true. In many cases, we saw no change after re-wetting with ethanol and only after 15 or 20 min of the infiltrant application, the color changing was noticeable. A possible reason might be that the alcohol starts evaporating before it is able to reach a substantial area of the porosities of MIH opacities that might be broader in the subsurface [23]. Transillumination has been indicated to estimate the depth and to better visualize the area of the opacities. Comparing transilluminated with reflected photography, it was possible to see that transillumination allowed better detection of the peripheral extension at the margins of the opacities [40,41]. Hence, it might assist the clinician at each step of the procedure identifying areas on the enamel surface that will need more etching or maybe indicated to be removed with a burr. It worked successfully in a case report [22], but no clinical studies have been conducted so far to confirm this result in a larger scale.

In hypomineralized enamel, it has been argued that the pattern of infiltration may not be explained only by porosity variation, but the protein content in the enamel may also interfere with the penetrability of the resin [42]. As in the present study only white opacities with intact enamel surface were included, we believe that it was not a matter of major concern because the protein content in white opacities is consistently lower than in yellow or brown ones [43]. Moreover, it has been reported that integrity of the enamel surface influences the protein profile of MIH lesions. Differences in the protein-banding pattern between intact and broken lesions indicate that proteins from oral fluids are present in broken but not in intact lesion [44]. The benefit of strategies to remove proteins from the enamel prior to infiltration is controversial [42,45]. More studies are still necessary to better understand if the application deproteinization substances improves infiltration and, consequently, the masking effect of MIH opacities.

We may consider that a limitation of the present study was not including a group where the acid-etching was applied on the enamel surface without the scrubbing step in the treatment protocol. However, based on previous attempts to mask MIH opacities without any microabrasion [14,20–22], we assumed that no satisfactory results would be achieved. Once the infiltrant is applied and light cured it is not possible to try a second infiltration to improve the result because part of the pores in the subsurface are already blocked by the resin. Thus, due to ethical reasons, we decided not having a group without the acid scrubbing step. Future studies could evaluate if other modifications in the etching step, using abrasives and/or rotating instruments, may improve the infiltration favoring a complete masking of a higher proportion of MIH opacities. Another limitation of the present study was the fact that the size of the opacities was not measured. Although the opacities varied in size and shape in both groups, small opacities may be camouflaged more easily than large opacities. Future studies should consider size as a variable of interest and analyze if the size of the opacity influences the outcome. Other additional variables such malocclusion and gingival disease that might interfere with the esthetic perception should be controlled in further studies. Moreover, although the randomization generated two similar groups regarding age, gender, number/type of teeth, and mean scores of the physical and psychological domains of the questionnaire, the mean score of the social domain was lower in the control group. However, the initial ΔE was not significantly different between groups and the masking effect of the test treatment was seen not only by the reduction in the mean scores of the questionnaire but was confirmed by the quantitative and qualitative analyses.

As resin infiltration may have other additional benefits for the hypomineralized enamel such as reducing permeability and increasing hardness and strength [43], further studies also testing the protocol with modified etching and longer application time also in posterior teeth are desirable.

6. Conclusions

The present randomized controlled clinical trial observed a positive impact of resin infiltration as an esthetic treatment for MIH opacities in anterior teeth on parents' and children's perception about teeth appearance. Resin infiltration was able to reduce de color difference between the MIH opacities and sound enamel significantly after an application time of at least fifteen minutes.

Authors contributions

V.M.S. conceived the idea. V.M.S. and G.S.A. designed the study. G.S.A., P.P.G.R., and R.C.J. performed the clinical treatments and documentation. V.M.S., T.K.S.F., and G.C.A.A. analysed the data. V.M.S. and G.S.A. wrote the paper with input from all authors.

Declaration of Competing Interest

The authors declare no conflict of interest.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jdent.2022.104168.

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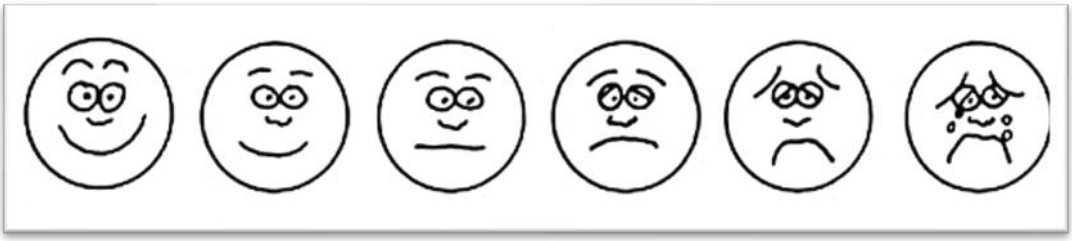
ANEXO A - Escala facial de dor Wong & Baker



Legenda

FACE 0: Muito feliz porque não tem dor;

FACE 1: Dói um pouco;

FACE 2: Dói um pouco mais;

FACE 3: Dói mais ainda;

FACE 4: Dói bastante;

FACE 5: Dói tanto quanto você pode imaginar.

ANEXO B - Aprovação do Comitê de Ética em Pesquisa - Ensaio Clínico

UERJ - HOSPITAL UNIVERSITÁRIO PEDRO ERNESTO/
UNIVERSIDADE DO ESTADO DO RIO DE JANEIRO

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: MASCARAMENTO DE OPACIDADES DEMARCADAS EM DENTES ANTERIORES EM PACIENTES COM HMI:ENSAIO CLÍNICO CONTROLADO RANDOMIZADO

Pesquisador: VERA LIGIA VIEIRA MENDES SOVIERO

Área Temática:
Versão: 1

CAAE: 18245719.8.0000.5259

Instituição Proponente: Hospital Universitário Pedro Ernesto/UERJ

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 3.621.870

O projeto pode ser realizado da forma como está apresentado. Diante do exposto e à luz da Resolução CNS no466/2012, o projeto pode ser enquadrado na categoria – APROVADO.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

ANEXO C - Aprovação do Comitê de Ética em Pesquisa - Caso Clínico

UERJ - HOSPITAL UNIVERSITÁRIO PEDRO ERNESTO/ UNIVERSIDADE DO ESTADO DO RIO DE JANEIRO

PARECER CONSUBSTANCIADO DO CEP

Título da Pesquisa: Hipomineralização de molares e incisivos

Pesquisador: VERA LIGIA VIEIRA MENDES SOVIERO

Área Temática:

Versão: 1

CAAE: 07753213.0.0000.5259

Instituição Proponente: Hospital Universitário Pedro Ernesto/UERJ

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 195.230

Data da Relatoria: 07/02/2013

Apresentação do Projeto:

O projeto está apresentado corretamente

Objetivo da Pesquisa:

Avaliar se crianças que possuam hipomineralização de molares e de incisivos apresentam maiornecessidade de restauração dos dentes do que os não portadores

Avaliação dos Riscos e Benefícios:

Não há riscos

Comentários e Considerações sobre a Pesquisa:

A pesquisa aborda assunto atual e está bem estruturada

Considerações sobre os Termos de apresentação obrigatória:

Toda a documentação pertinente foi apresentada

Recomendações:

Não há

Conclusões ou Pendências e Lista de Inadequações:

O trabalho pode ser realizado da forma como foi apresentado a este CEP

Situação do Parecer:

Aprovado

ANEXO D - Aprovação do Comitê de Ética em Pesquisa Caso Clínico – emenda

UERJ - HOSPITAL UNIVERSITÁRIO PEDRO ERNESTO/
UNIVERSIDADE DO ESTADO DO RIO DE JANEIRO

PARECER CONSUBSTANCIADO DO CEP

Título da Pesquisa: Hipomineralização de molares e incisivos

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Hipomineralização de molares e incisivos
Pesquisador: VERA LIGIA VIEIRA MENDES SOVIERO
Área Temática:
Versão: 2
CAAE: 07753213.0.0000.5259
Instituição Proponente: Hospital Universitário Pedro Ernesto/UERJ
Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 787.354
Data da Relatoria: 10/09/2014

Apresentação do Projeto:
Emenda para aprovação de documentação e alterações no protocolo

Objetivo da Pesquisa:
Emenda para aprovação de documentação e alterações no protocolo

Avaliação dos Riscos e Benefícios:

Emenda para aprovação de documentação e alterações no protocolo

Comentários e Considerações sobre a Pesquisa:

Justificativa da Emenda:

Pretende-se ampliar o estudo, aumentando a amostra e realizando uma avaliação longitudinal dos pacientesincluídos no projeto.

Considerações sobre os Termos de apresentação obrigatória:

Todos os documentos de apresentação obrigatória foram encaminhados a este Comitê.

Recomendações:

Conclusões ou Pendências e Lista de Inadequações:

Foram analisados as documentações e as mesmas se encontram dentro das normas.

Situação do Parecer:

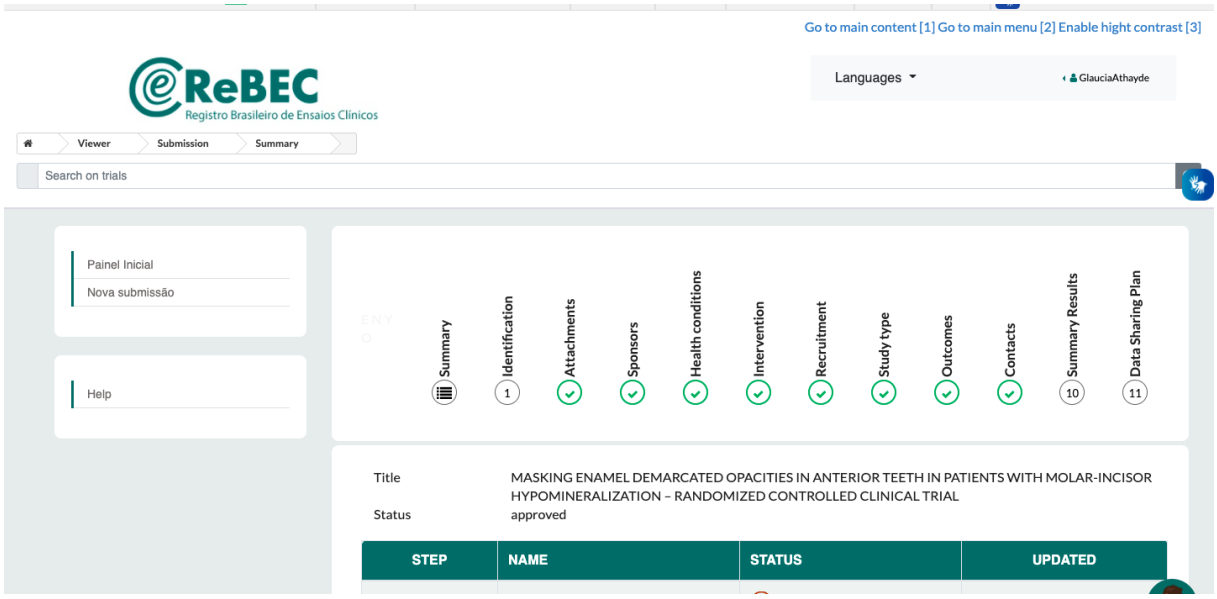
Aprovado

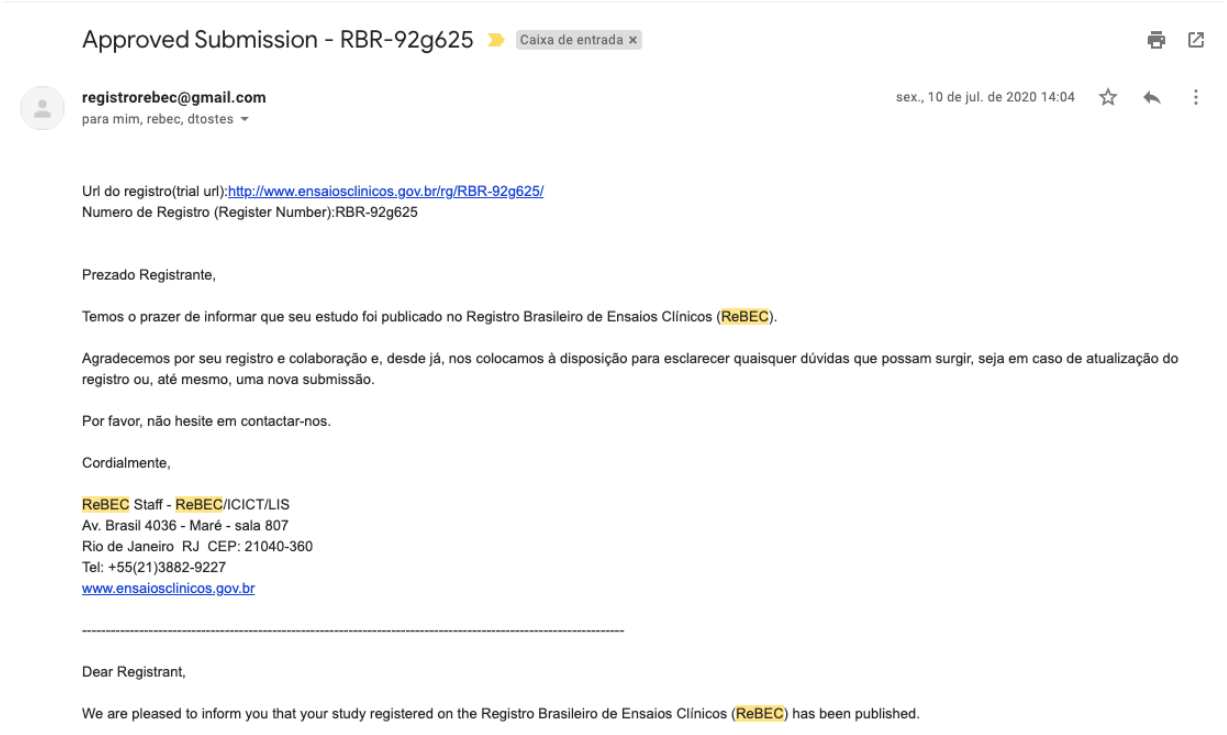
Necessita Apreciação da CONEP:

Não

Considerações Finais a critério do CEP:

ANEXO E – Publicação no Registro Brasileiro de Ensaios Clínicos





Approved Submission - RBR-92g625 Caixa de entrada ×

registrorebec@gmail.com
para mim, rebec, dtostes

sex., 10 de jul. de 2020 14:04

Url do registro(trial url):http://www.ensaiosclinicos.gov.br/rg/RBR-92g625/
Numero de Registro (Register Number):RBR-92g625

Prezado Registrante,

Temos o prazer de informar que seu estudo foi publicado no Registro Brasileiro de Ensaios Clínicos (ReBEC).

Agradecemos por seu registro e colaboração e, desde já, nos colocamos à disposição para esclarecer quaisquer dúvidas que possam surgir, seja em caso de atualização do registro ou, até mesmo, uma nova submissão.

Por favor, não hesite em contactar-nos.

Cordialmente,

ReBEC Staff - ReBEC/ICICT/LIS
Av. Brasil 4036 - Maré - sala 807
Rio de Janeiro RJ CEP: 21040-360
Tel: +55(21)3882-9227
www.ensaiosclinicos.gov.br

Dear Registrant,

We are pleased to inform you that your study registered on the Registro Brasileiro de Ensaios Clínicos (ReBEC) has been published.

ANEXO F – Termo de Autorização das Editoras e Autorização dos demais autores dos artigos

editor@jopdent.org 10/02/2020
Para: verasoviero@gmail.c... e mais 4 >

Operative Dentistry Manuscript #19-206-SR

December 19, 2019

Dear Vera Soviero,

The referees' comments regarding your manuscript, "ESTHETIC MANAGEMENT OF INCISORS WITH DIFFUSE AND DEMARCATED OPACITIES: 24 MONTHS FOLLOW-UP CASE REPORT", have been received. On the basis of these reviews I am pleased to inform you that your paper is accepted for publication in Operative Dentistry. We will begin our initial editing of the paper within one month of this email. The authors will be asked to proof the copy (text) first, and will have a chance to edit the final typeset version before it is published online early. The paper will be first published electronically on our online journal site at www.jopdentonline.org and then assigned to a specific issue in the Journal as determined

Rights and Access

Impact of masking hypomineralization opacities in anterior teeth on the aesthetic perception of children and parents: a randomized controlled clinical trial

Corresponding author	Professor Vera Mendes Soviero
E-mail address	verasoviero@gmail.com

Journal	Journal of Dentistry
Article number	104168
Our reference	JJOD_104168
PII	S0300-5712(22)00224-X

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Universidade do Estado do Rio de Janeiro
Faculdade de Odontologia
Departamento de Odontologia Preventiva e Comunitária

TERMO DE AUTORIZAÇÃO

Nós, abaixo-assinados, autorizamos a publicação do manuscrito intitulado *Esthetic Managment of Incisors with Diffuse and Demarcated Opacities: 24 Month Follow-up Case Report* na Biblioteca Digital de Teses e Dissertações.

Rio de Janeiro, 22 de dezembro de 2022.

Dra. Glaucia dos Santos Athayde Gonçalves

Dra. Roberta Costa Jorge

Dra. Gabriela Caldeira Andrade Americano

Dra. Fernanda Barja-Fidalgo

Dra. Vera Mendes Soviero

Universidade do Estado do Rio de Janeiro
Faculdade de Odontologia
Departamento de Odontologia Preventiva e Comunitária

TERMO DE AUTORIZAÇÃO

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Rio de Janeiro, 22 de dezembro de 2022.

Dra. Glaucia dos Santos Athayde Gonçalves

Dra. Patrícia Papoula Gorni do Reis

Dra. Roberta Costa Jorge

Dra. Gabriela Caldeira Andrade Americano

Dra. Tatiana Kelly da Silva Fidalgo

Dra. Vera Mendes Soviero