UNIVERSIDADE FEDERAL DE SANTA MARIA
CENTRO DE CIÊNCIAS DA SAÚDE
PROGRAMA DE PÓS-GRADUAÇÃO EM CIÊNCIAS ODONTOLÓGICAS

Ananda Barrachini Londero

EFICÁCIA DO USO DO FIO DENTAL PARA TRATAMENTO DA GENGIVITE PROXIMAL EM ADULTOS: RESULTADOS PARCIAIS DE UM ENSAIO CLÍNICO RANDOMIZADO CEGO

Santa Maria, RS
2019

Ananda Barrachini Londero

EFICÁCIA DO USO DO FIO DENTAL PARA TRATAMENTO DA GENGIVITE PROXIMAL EM ADULTOS: RESULTADOS PARCIAIS DE UM ENSAIO CLÍNICO RANDOMIZADO CEGO

Dissertação apresentada ao Curso de Mestrado do Programa de Pós-Graduação em Ciências Odontológicas, Área de concentração em Odontologia, ênfase em Periodontia da Universidade Federal de Santa Maria (UFSM, RS), como requisito parcial para obtenção do grau de **Mestre em Ciências Odontológicas**.

Orientador: Prof. Dr. Carlos Heitor Cunha Moreira

Santa Maria, RS
2019

Londero, Ananda
Eficácia do uso do fio dental para tratamento da gengivite proximal em adultos: resultados parciais de um ensaio clínico randomizado cego. / Ananda Londero.- 2019.
77 p.; 30 cm

Orientador: Carlos Heitor Cunha Moreira
Dissertação (mestrado) - Universidade Federal de Santa Maria, Centro de Ciências da Saúde, Programa de Pós Graduação em Ciências Odontológicas, RS, 2019

1. Biofilme 2. Escovação 3. Fio Dental 4. Doenças gengivais I. Cunha Moreira, Carlos Heitor II. Título.

Sistema de geração automática de ficha catalográfica da UFSM. Dados fornecidos pelo autor(a). Sob supervisão da Direção da Divisão de Processos Técnicos da Biblioteca Central. Bibliotecária responsável Paula Schoenfeldt Patta CRB 10/1728.

Ananda Barrachini Londero

EFICÁCIA DO USO DO FIO DENTAL PARA TRATAMENTO DA GENGIVITE PROXIMAL EM ADULTOS: RESULTADOS PARCIAIS DE UM ENSAIO CLÍNICO RANDOMIZADO CEGO

Dissertação apresentada ao Curso de Mestrado do Programa de Pós-Graduação em Ciências Odontológicas, Área de concentração em Odontologia, ênfase em Periodontia da Universidade Federal de Santa Maria (UFSM, RS), como requisito parcial para obtenção do grau de **Mestre em Ciências Odontológicas**.

Aprovado em 19 de julho de 2019:

Carlos Heitor Cunha Moreira, Dr. (UFSM)
(Presidente/Orientador)

Ticiane de Goés Mario, Dra. (IMED)
(Examinadora)

Camila Sfreddo, Dra. (UFN)
(Examinadora)

Santa Maria, RS, 2019

DEDICATÓRIA

Dedico este trabalho, em primeiro lugar à Deus, que sempre me guia , ilumina meu caminho e me presenteia com pessoas maravilhosas, permitindo que independente da situação, eu tenha força para realizar os meus sonhos.

À minha mãe, Claise Marta Barrachini, meu anjo da guarda aqui na terra, exemplo de mulher forte e determinada, que jamais mediu esforços para lutar por mim, fazendo dos meus sonhos os seus. Tenho muito orgulho da sua história e como construiu a sua vida. Orgulho de como conseguiu lidar com todas as adversidades dessa vida, sendo calmaria em meio ao caos. Obrigada por nunca ter desistido de mim. Obrigada pela dedicação incondicional, pelas noites em que deixou de dormir para segurar a minha mão quando eu não conseguia fechar os olhos de medo, pelos " Eu te amo" sempre antes de dormir, pelas jantas que me esperam sempre que retorno de viagem. Jamais esquecerei a frase que escreveu em minha agenda quando tinha seis anos: " É de tijolinho em tijolinho que se levanta uma parede". Contigo aprendi a ser determinada e a nunca desistir dos meus sonhos. Todas as minhas conquistas são dedicadas a ela, dona do melhor colo do mundo e minha certeza de que nunca estarei sozinha nessa jornada.

Ao meu pai Sergio Sanzovo, que sempre me cuidou e protegeu como se fosse sua filha, demonstrando que não são os laços de sangue que determinam o valor de uma família, mas sim, laços de amor, respeito e cumplicidade. Obrigada por todas as oportunidades de estudo e por todos os ensinamentos. Com ele aprendi a ter responsabilidade,

organização e que não devemos fazer o mais fácil, mas sim o que é certo. Obrigada por tudo.

À minha vó Darcília Barrachini, que me cuiudou inúmeras vezes quando era pequena. Exemplo de mulher forte e guerreira. Admiro muito a sua história

Ao meu namorado, Alexandre Macagnan, que sempre esteve do meu lado ao longo desses anos. Diariamente me mostra que independente do lugar onde estiver morando, sempre estará do meu lado. Com ele tenho a certeza de que tenho um porto seguro para os momentos de angústia. Muito obrigada por tornar minha vida mais leve e alegre. Muito obrigada por sempre ser meu companheiro e compreender os meus ausências. Muito obrigada por se preocupar comigo e levar calzones em dias em que ficava até tarde na antiga reitoria por causa do projeto. Obrigada por me ajudar na formatação deste trabalho inúmeras vezes. Eu te amo.

AGRADECIMENTOS

Um agradecimento especial ao meu orientador, Carlos Heitor Cunha Moreira, exemplo de pessoa e profissional. Tive muita sorte de poder trabalhar com o senhor ao longo desses anos. Agradeço por todas as oportunidades, ensinamentos e paciência em me ensinar. Obrigada por acreditar em mim para ser tua orientada. Muito obrigada por sempre motivar a nossa curiosidade e constante busca pelo conhecimento. Com certeza aprendi muito mais do que periodontia e odontologia com o senhor. Aprendi sobre ética, humildade, dedicação e amor ao que se faz. O mundo precisa de mais pessoas e profissionais assim. Com muito orgulho fui orientada de mestrado do professor Carlos Heitor.

Agradeço à minha família por sempre me apoiar e incentivar meus sonhos. Um agradecimento especial à minha prima Ana Luiza Barrachini, quase uma irmã para mim. Obrigada por sempre estar do meu lado e ser minha companheira. Muito obrigada por participar deste projeto também. Eu te amo e te admiro muito.

Agradeço aos meus companheiros de sempre neste projeto e na pós-graduação, Ana Paula Reininger e Rodrigo Tavares. Muito obrigada por tudo, tenho certeza que a minha jornada é muito mais fácil com vocês do meu lado. Não consigo mencionar minha gratidão pelas horas que dedicaram a este trabalho e momentos de lazer que abriram mão para examinarmos pacientes. Obrigada por aguentarem meus desabafos a cada mensagem de whastapp que recebia dos pacientes. Muito obrigada por cada noite de Otão, de antiga reitoria, de convites em salas de aula e RU. Com vocês sempre tive a certeza de que iremos conseguir finalizar, por mais difícil que pareça. Muito Obrigada à Ana Carolina, que mesmo com várias atividades relacionadas ao seu

projeto, nos acompanhava durante alguns exames no Otão e antiga reitoria. Juntos vamos mais longe.

Agradeço também as mais recentes integrantes do projeto, Ciandra Ferreira e Gabriela Ortigara. Muito obrigada meninas por toda ajuda e comprometimento com este projeto. Vocês são fundamentais para que a gente consiga continuar.

Agradeço às professoras Tíciane Mário, Camila Sfreddo e Raquel Antoniazzi por aceitarem participar da banca examinadora desta dissertação. Tenho muito orgulho das mulheres e pesquisadoras que estarão presentes neste dia tão importante para mim. Tenho certeza que as contribuições de vocês serão essenciais neste trabalho.

Agradeço aos professores da periodontia, Karla Kantorski, Fabrício Zanatta e Raquel Antoniazzi. Tenho muito orgulho dos professores que contribuem para a minha formação. Vocês formam um time e tanto, com muito conhecimento, mas acima de tudo, didática. Acredito que seja resultado do amor que vocês têm pela periodontia e pela profissão. Muito obrigada por todas as atividades propostas. Tenho a certeza que o objetivo é sempre nos capacitar a sermos profissionais melhores Vocês são um exemplo para mim. Muito obrigada por tudo.

Um agradecimento especial à Tíciane Mário, que me incentivou a seguir na pós-graduação em periodontia. Te admiro muito, como pesquisadora e clínica. Tu és um exemplo de pessoa determinada, organizada e ética. Muito obrigada pelas oportunidades às quais me apresentou e por sempre estar disponível para ajudar com o que puderes.

Aos meus colegas da periodontia, agradeço pela amizade e apoio que sempre damos uns aos outros. Vocês tornam a pós-graduação mais leve e divertida.

Agradeço à Jéssica Dalcin, por ser sempre tão disponível. Muito obrigada pela paciência que tens em resolver todas as questões da pós-graduação. Muito obrigada por sempre lidar com muito carinho com todos, mesmo em momentos de caos. Tu és fundamental ao nosso programa.

Aos funcionários da Universidade, que sempre tiveram paciência conosco durante a realização deste projeto. Muito Obrigada.

Aos pacientes que aceitaram participar deste Ensaio clínico. Muito obrigada pelo comparecimento semanal de vocês em cada consulta. Sem vocês este trabalho não existiria.

Agradeço às minhas amigas de infância, Bruna, Débora e Franciele. Muito obrigada por todos os momentos e por permitirem que a nossa amizade continue, mesmo que a gente cresça e as responsabilidades aumentem. Muito obrigada por estarem ao meu lado em momentos de alegria e aqueles mais difíceis. Sou muito grata pela nossa amizade e união. Sou muito feliz em nossas jantas, tudo fica mais leve e todas as preocupações ficam em segundo plano. Bruna e Franciele, muito obrigada também por estarem disponíveis e participarem deste projeto, mesmo com inúmeras atividades. Débora muito obrigada por incentivar o teu namorado a participar também.

“A estratégia sem tática é o caminho mais lento para a vitória. Tática sem estratégia é o ruído antes da derrota.”

SunTzu

RESUMO

EFICÁCIA DO USO DO FIO DENTAL PARA TRATAMENTO DA GENGIVITE PROXIMAL EM ADULTOS: RESULTADOS PARCIAIS DE UM ENSAIO CLÍNICO RANDOMIZADO CEGO.

AUTORA: Ananda Barrachini Londero
ORIENTADOR: Carlos Heitor Cunha Moreira

Este ensaio clínico randomizado cego avaliou a eficácia do fio dental adjunto a escovação dental, comparado com a escovação sozinha, no tratamento da gengivite proximal em adultos. Quarenta e nove indivíduos adultos, sistemicamente saudáveis, sem perda de inserção proximal e com gengivite generalizada em sítios proximais foram incluídos no estudo. No *baseline*, os indivíduos foram randomizados em dois grupos de acordo com o uso de fio dental: Grupo escovação dental manual sem o uso de fio dental (sem fio) e Grupo escovação dental manual e uso de fio dental (fio). Durante dois meses, os sujeitos compareceram em uma consulta semanal para deplacagem profissional e orientação de higiene. Índice de Sangramento Gengival (IG) e Índice de Placa (IPl) no *baseline*, 30 e 60 dias foram medidos por um avaliador cegado. Modelos Lineares Mistos foram utilizados para comparar as médias de IPI e IG nas faces proximais entre os grupos. A diferença nos parâmetros IPI (p= 0,718) e IG (p= 0,612) entre os grupos não foi estatisticamente significante. As médias de IPI e IG reduziram nos dois grupos ao longo do tempo. Apenas entre o período *baseline* e 30 dias a redução de IG foi estatisticamente significante. As reduções nas médias de IPl e IG foram observadas nos dois grupos. A desorganização dos biofilmes pela escova multicerdas quando realizada de forma eficaz alcança resultados semelhantes aos observados quando além da escovação os indivíduos também utilizaram fio dental.

Palavras-chave: Biofilme. Escovação. Fio Dental. Doenças Gengivais. Ensaio Clínico

ABSTRACT

EFFICACY OF DENTAL FLOSS FOR GINGIVITIS TREATMENT IN ADULTS: A RANDOMIZED CLINICAL TRIAL.

AUTHOR: Ananda Barrachini Londero
ADVISOR: Carlos Heitor Cunha Moreira

This blinded randomized clinicaltrial evaluated the efficacy of dental floss plus toothbrush, compared to toothbrushing alone, in the treatment of proximal gingivitis in adults. Forty-nine subjects, systemically healthy, without loss of proximal attachment and with generalized gingivitis at proximal sites were included in the study. Smoking subjects with fixed orthodontic braces or restraint and pregnant women were not eligible. At baseline, subjects were randomized into two groups according to the use of dental floss: Manual toothbrushing group without the use of dental floss (TB) and Group dental toothbrushing manual and dental floss (DF). For two months, the subjects attended a weekly consultation for professional plaque removal and buccal hygiene orientation. Index of Gingival Bleeding (GI) and Plaque Index (PII) at baseline, 30 and 60 days were measured by a blinded evaluator. Linear Mixed Models were used to compare the means of IPI and GI between groups. The difference in PII ($p = 0.718$) and GI ($p = 0.612$) between the groups was not significant. The means of PII and IG decreased in both groups over time. Only between the baseline period and 30 days the GI reduction was significant statistically. The reductions in PII and GI averages were observed in both groups. The disorganization of biofilms by the multitufde toothbrush when performed efficiently achieves results similar to those observed when in addition to brushing individuals also used dental floss.

Keywords: Dental Floss. Dental Plaque. Gingivitis. Toothbrushing. Randomized Clinical Trial

SUMÁRIO

1 INTRODUÇÃO

Gengivite induzida por biofilme resulta da resposta inflamatória dos tecidos gengivais devido ao acúmulo de placa localizado no terço cervical dos dentes (MURAKAMI et al., 2018). De acordo com dados epidemiológicos recentes, a gengivite afeta 95% da população (LANG & BARTOLD, 2018), além de ser o tipo mais frequente de doença periodontal (PAGE; BAAB, 1985). Se não tratada, em indivíduos suscetíveis, a gengivite pode evoluir para periodontite, caracterizada pela destruição dos tecidos de sustentação dos dentes (TONETTI et al., 2018). O estágio final desta doença é a perda do dente.

A etiologia bacteriana da gengivite foi estabelecida por Löe e colaboradores (1965). Neste estudo, indivíduos com adequado controle de placa e com gengiva clinicamente saudável, suspenderam os procedimentos de higiene bucal permitindo o acúmulo de placa, inflamação gengival foi observada após um período entre 10 a 21 dias. Após restituição dos procedimentos a saúde gengival foi restabelecida (7-10 dias). A partir desse estudo, foi estabelecido de uma maneira clara a causalidade entre o acúmulo de bactérias nas superfícies dentárias e a consequente inflamação gengival. Os principais desfechos da gengivite incluem sinais e sintomas de inflamação. Os pacientes podem relatar sinais como sangramento durante a escovação, sangue na saliva, vermelhidão, edema e halitose (MURAKAMI et al., 2018). Os sinais clínicos são restritos à gengiva livre e inserida e são reversíveis com a desorganização do biofilme sem qualquer prejuízo ao periodonto de suporte (MURAKAMI et al., 2018).

A inflamação gengival tem sido associada com o desenvolvimento de periodontite (KINANE et al., 2005). Portanto, o tratamento da gengivite é uma estratégia essencial para prevenção de periodontite (MARIOTTI, 1999). Lang et al. (2009) observaram que os dentes associados com gengiva inflamada tiveram um risco significativamente maior de perda dentária do que dentes com gengiva saudável ou levemente inflamada. Hugoson et al. (2008) mostraram que melhorias no controle de placa reduziram a prevalência de gengivite e periodontite moderada em quatro estudos transversais realizados ao longo de 30 anos na Suécia. Dessa forma, prevenção e tratamento da gengivite podem reduzir indiretamente a perda dentária.

O controle mecânico da placa supragengival é o principal mecanismo de prevenção e tratamento da gengivite (PINTO et al., 2013; POKLEPOVI et al., 2012). Os benefícios de um adequado controle de placa incluem manutenção de uma dentição funcional, otimização de valores estéticos, como aparência e bom hálito, redução do risco de perda de inserção periodontal e da necessidade de tratamento periodontal complexo, desconfortável e de alto custo (CLAYDON, 2008).

Instruções de higiene bucal e visitas periódicas ao dentista para a desorganização de biofilme são eficazes para reduzir gengivite e manter dentição saudável ao longo dos anos (AXELSSON et al., 2004). A escova de dente é o dispositivo de higiene oral mais utilizado para o controle de biofilme (PETERSILKA et al. 2002; SALZER et al. 2015). Apesar disso, a maioria da população não limpa os dentes completamente o suficiente para evitar o acúmulo de placa (CLAYDON, 2008). A eficácia clínica da escova de dente está correlacionada ao tempo de escovação, habilidade individual na remoção de placa, frequência em que esta remoção é executada, motivação do paciente e a instrução de higiene bucal profissional (PETERESILKA et al., 2002; LANG et al.,1993).

O XI European Workshop of Periodontology recomendou a escovação diária duas vezes ao dia com uso de dentifrício fluoretado (CHAPPLE et al., 2015). Uma revisão sistemática mostrou que um único exercício de escovação reduz em aproximadamente 42% os níveis de placa (POKLEPOVIC et al., 2012). Ensaios clínicos randomizados (ROSEMA et al., 2008; SCHIFF et al., 2006; SHARMA et al., 2002) mostraram que a escovação manual sem o auxílio de dispositivos de remoção de placa interdental reduz os níveis de placa e gengivite e mantém a saúde gengival.

A eficácia da escovação, entretanto, é questionável em áreas interproximais. Apesar de permitir a desorganização do biofilme das superfícies vestibular e lingual/ palatina esta pode não alcançar as superfícies proximais (CLAYDON, 2008; IMAI et al., 2010; SÄLZER et al., 2015; WORTHINGTON et al., 2019). Consequentemente, estudos relatam que as superfícies proximais dos dentes possuem maior frequência de acúmulo de biofilme e de inflamação gengival do que as faces livres (AXELSON & LINDHE, 1981; CUMMING & LÖE, 1973).

Dessa forma, a remoção de placa interdental é reconhecida como procedimento necessário e essencial na manutenção de saúde gengival (AMERICAN DENTAL ASSOCIATION, 2016; CHAPPLE et al., 2015). O uso diário de fio dental é o procedimento recomendado para a remoção de placa interdental de

áreas no qual a papila gengival preenche todo espaço interproximal (AMERICAN DENTAL ASSOCIATION, 2016). Contudo, o suporte científico para essa recomendação é limitado. Revisões sistemáticas avaliaram o efeito do fio dental combinado a escovação (HAPS, 2008; WORTHINGTON et al., 2019). Berchier e colaboradores (2008) mostraram que o uso de fio dental não tem efeito adicional a escovação nos índices de placa e sangramento gengival. Sambunjak e colaboradores (2011) apontaram benefício estatisticamente significante do fio combinado com escovação apenas na redução de gengivite em até 6 meses de acompanhamento. Uma metarevisão desses estudos concluiu que há uma fraca evidência para suportar o uso de fio dental (SÄLZER et al., 2015). Em 2019, Worthington e colaboradores relatam em uma revisão sistemática o benefício adicional do uso do fio dental para redução da inflamação gengival. Porém afirmam que esta evidência é de baixa certeza.

A avaliação da efetividade dos métodos de limpeza interdental deve considerar a eficácia, a aceitabilidade e a adesão do indivíduo ao método (ASADOORIAN et al., 2006; WARREN; CHATER, 1996). Apesar de ser frequentemente recomendado pelos profissionais, a adesão dos pacientes ao uso deste dispositivo é baixa (SCHÜZ et al., 2009). Pacientes relatam que a pouca adesão está relacionada com a falta de motivação e dificuldades na execução da técnica (ASADOORIAN, et al., 2006). Dessa forma, o comportamento individual do paciente é o fator-chave para alcançar as metas saúde gengival, porque, para ser eficaz, o fio dental precisa ser utilizado de forma eficaz e contínua (SCHÜZ et al., 2009).

Portanto, há uma fraca evidência científica disponível sobre a eficácia do uso do fio dental que suporte sua recomendação como medida essencial para a saúde bucal. Dessa forma, ensaios clínicos randomizados que contemplem essas limitações são fundamentais para avaliar a eficácia do fio dental no tratamento de gengivite em adultos.

2 ARTIGO - EFFICACY OF DENTAL FLOSS FOR GINGIVITIS TREATMENT IN ADULTS: A RANDOMIZED CLINICAL TRIAL.

Este artigo será submetido ao periódico Journal of Clinical Periodontology, Wiley, ISSN: 1600-051X, Fator de impacto = 4.046; Qualis A1. As normas para publicação estão descritas no Anexo H

Efficacy of dental floss for gingivitis treatment in adults: a randomized clinical trial.

Ananda Barrachini Londero[1]
Carlos Heitor Cunha Moreira[1]

Authors' affiliations:
[1]Post-Graduation in Dentistry Sciences Program, Federal University of Santa Maria, Santa Maria, Brazil.

Corresponding Author:
C.H.C. Moreira
Universidade Federal de Santa Maria
Rua Marechal Floriano Peixoto, n. 1184, 7º andar, Periodontia. CEP: 97015-372. Santa Maria – RS – Brazil
Telephone number: + 55 (55) 3220-9269
Fax: not available
E-mail: carlosheitormoreira@gmail.com

Running Title: Efficacy of dental floss for gingivitis treatment in adults: a randomized clinical trial.

Keywords: clinical trial, dental floss, dental plaque, gingival disease, toothbrushing.

Conflict of Interest and Source of Funding:

This study was financed in part by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior – Brasil (CAPES) – Finance Code 001. All authors declare they have no conflict of interest related to this study.

Abstract

Aim: This blinded randomized clinical trial evaluated the efficacy of dental floss plus toothbrush, compared to toothbrushing alone, in the treatment of proximal gingivitis in adults.

Methods: Forty-nine subjects, systemically healthy, without loss of proximal clinical attachment and with generalized gingivitis at proximal sites were included in the study. Subjects who were smokers with fixed orthodontic appliance or restraint and pregnant women were not eligible.. At baseline, subjects were randomized into two groups according to the use of dental floss: toothbrushing group without the use of dental floss (TB) and Group toothbrushing and dental floss (DF). For two months, subjects attended a weekly consultation for professional removal dental plaque and buccal hygiene instruction. Index of Gingival Bleeding (GI) and Plate Index (PII) at baseline, 30 and 60 days were measured by a blinded evaluator. Linear Mixed Models were used to compare the means of IPI and GI between groups.

Results: The difference in PII ($p = 0.718$) and GI ($p = 0.612$) between the groups was not significant statistically. The means of PII and IG decreased in both groups over time. Only between the baseline period and 30 days the GI reduction was significant statistically.

Conclusion: The reductions in PII and GI averages were observed in both groups. The disorganization of biofilms by the toothbrush when performed efficiently achieves results similar to those observed when in addition to brushing individuals also used floss.

Clinical Relevance

Scientific rationale for the study: Evidence that supports the use of dental floss is limited.

Principal findings: The disorganization of biofilms by the toothbrush when performed efficiently can reduce PII and GI scores as well as brushing plus dental floss.

Practical implications: Considering that 95% of population has gingivitis, is essential to teach how brushing should be done to reach and maintain gingival health.

Introduction

Biofilms that remains organized on surface of teeth are the main etiological factor for caries and periodontal disease (Axelsson et al., 2004; Marsh, 2006). Gingivitis, an inflammatory disease triggered by the host's response to the accumulation and maintenance these biofilms on dental surface has high prevalence in different populations (Lang & Bartold, 2018). Daily removal of biofilms is a fundamental core of the gingivitis treatment and maintenance of periodontal health (Imai et al., 2010; Lang & Bartold, 2018). Toothbrush can remove supragingival biofilm on the buccal and lingual / palatal surfaces, but special devices (such as floss) are often recommended to reach into the interdental area (Worthington et al., 2019). Nevertheless, low-certainty evidence suggest that flossing, in addition to toothbrushing, may reduce gingivitis (Worthington et al., 2019).

Proximal surfaces of teeth have a higher frequency of biofilm accumulation and gingival inflammation than free surfaces (Axelsson et al., 2004). Although toothbrush is the most common hygiene device for biofilm personal control (Petersilka et al., 2002; Sälzer et al., 2015), toothbrush may not reach effectively the proximal surfaces (Claydon, 2008; Imai et al., 2010; Sälzer et al., 2015; Worthington et al., 2019). Therefore, daily use of other devices is recommended procedure for removal of interdental biofilm. Dental floss is the instrument most adequate and recommended for removing biofilms when gingival papilla completely fulfill interproximal space (ADA, 2016).

Although it often be recommended by professionals, the adherence of patients to the use of this device is low (Schüz et al., 2009). Subjects report that poor adherence is related to lack of motivation and difficulties in performing the

technique (Asadoorian & Locker, 2006). Thus, individual patient behavior is the key factor in achieving gum health goals (Schüz et al., 2009).

This controversy about dental floss efficacy has been highlight in recent systematic reviews and they did not determine definitive results about the additional benefit of flossing associated with mechanical brushing in terms of gingival inflammation (Poklepovic et al., 2012; Sälzer et al., 2015; Worthington et al., 2019; Yaacob et al., 2014). Thus, the aim of this study is to evaluate the efficacy of oral hygiene performed only with toothbrush in comparison to brushing associated with dental floss in terms of gingival inflammatory scores in patients with proximal gingivitis. The hypothesis was that there is no difference among the two groups in terms of gingival inflammation after 2 months of intervention.

Materials and methods

Study design and sample

This study is a randomized clinical trial with a follow-up time of two months.

Subjects were invited to participate to the study through the screening service of the dental school of the Federal University of Santa Maria, social media and publicity posters.

Individuals with at least 18 years of age, without loss of proximal clinical attachment, with papilla completely filling the interdental space and with at least 24 teeth were eligible. In addition, individuals should present, Gingival Index score 2 (LÖE, 1967) in more than 15% of proximal sites. The distal sites of the posterior teeth are not being counted in the analysis because they are not areas of flossing.

Dental students, individuals with xerostomia, pregnant women, diabetics, smokers, patients with orthodontic appliances and / or restraint, individuals requiring antimicrobial prophylaxis to perform oral exams; who have used antibiotics / anti-inflammatories in the last three months and who have psychomotor disorders were not included.

The study is been conducted at the Federal University of Santa Maria and these partial results were collected between June 2017 and April 2019.

Sample size calculation

The sample size calculation was performed considering the following parameters (Rosema et al., 2008): mean gingival bleeding in the group with manual brushing without the use of dental floss of 0.59 (standard deviation: 0.31), mean gingival bleeding in the group with manual brushing and flossing of 0.40 (standard deviation: 0.19) and 1: 1 ratio in the sample size between the two groups, 95% confidence interval, 80% test power. A total of 58 subjects were estimated to meet these requirements. 30% were added due to follow-up losses, resulting in a sample number estimating 76 individuals.

Ethical considerations

Eligible individuals provided informed consent. This study was conducted by following the Guidelines and Norms Regulating Research involving humans. The research protocol was submitted and approved by the Research Ethics Committee of the Federal University of Santa Maria, RS, Brazil (CAAE: 53831715.5.0000.5346) and ClinicalTrials.gov (53831716.5.0000.5346).

Pre-experimental period

Prior to the start of the study, subjects are informed in detail about the objectives of the investigation. After, subjects who show interest are clinically examined. If eligible, they participated of a pre-experimental period, with maximum duration of 10 days, which had as aim to remove plaque retentive factors. Procedures such as supragingival scaling, restorations reshape and sealing of cavities were performed according to individual needs.

Randomization and experimental groups

Block randomization sequence was generated by computer program (Random Allocation Software, version 1.0, May 2004). Opaque envelopes were serially numbered (from 1 to 76), which matched the sequence from the first to the last subject to be randomized. The randomization process was performed by a researcher not involved in data collection (A.B.L.).

Participants were randomized into two experimental groups according to the use of dental floss:

- Group dental floss and toothbrush (DF)
- Group only toothbrush (TB)

Experimental period

Follow up period was 60 days. At baseline, all subjects received polishing with rubber cup (Microdont®, São Paulo, SP, Brazil) and abrasive paste (Pedra Pomes).

After the baseline examination, the clinical staff member (A.B.L.) responsible for revealing the experimental group to which the subject belongs, delivers the hygiene materials corresponding to the group and provides standardized oral hygiene guidelines. The oral hygiene guidelines were ever carried out by the same researcher. The other researchers involved were blind to the experimental groups which individuals were randomized.

Initially one researcher (A.B.L.) verified the sites with presence of plaque and gingivitis in the individual. According to individual needs, the researcher demonstrates in the individual's mouth how brushing should be performed, emphasizing areas with presence of plaque and gingivitis. The participant accompanies the demonstration in front of a mirror. Next, the individual was asked to perform tooth brushing in front of the mirror and the investigator corrects the inadequacies. This procedure was performed weekly, from the baseline, up to 60 days in both groups.

All study subjects receive a soft toothbrush (Colgate® Twister® Compact Head, New York, USA) and fluoride dentifrice (Colgate® Triple Action®, 90 grams, New York, USA). Individuals are instructed to brush their teeth twice a day (Chapple et al., 2015)(AMERICAN DENTAL ASSOCIATION, 2016; applying the dentifrice across the width of the brush bristles at one point in order to standardize the amount used (± 0 , 5 grams).

For subjects in the dental floss group, orientation of flossing is performed on all proximal surfaces present. Initially the researcher uses the dental floss in the mouth of the individual who visualizes in the mirror. Next, the individual makes use of the dental floss in all areas and the researcher corrects the technique when necessary. This procedure is performed weekly, from the baseline, up to 60 days.

Subjects receive a 50-meter waxed dental floss box (Colgate®, tarpaulin, New York, USA). The subjects are instructed to use 20 centimeters (18 inches) of floss once a day following the targeted technique (Chapple et al., 2015; AMERICAN DENTAL ASSOCIATION, 2016). Participants were provided with oral hygiene products by the researchers throughout the entire trial. Flow of the study is described at Figure 1.

Clinical Parameters

The clinical parameters evaluated were: Plaque Index (PlI) (Silness & Harald, 1964), Gingival Index (GI) (LÖE, 1967), plaque retentive factor (FRP), probing depth (PD), clinical attachment level (CAL) and bleeding on probing (BoP). PlI, GI and plaque retentive factor were evaluated at the baseline, 30 and 60 days. PD, CAL and BoP were performed at baseline and 60 days (Appendix). FRP is considered the presence of dental calculus, presence of caries lesions with cavities or inadequate restoration. PD was measured as the distance from the gingival margin to the most apical bottom of the sulcus/pocket. CAL was considered as the distance from the cementoenamel junction the most apical bottom of the sulcus/pocket. PD and CAL were measured in millimeters and rounded to the nearest whole millimeter. The interproximal measurements were performed as close as possible to the contact point. BoP was recorded up to 15 seconds after PD measurement and classified into scores: 0 (absence) and 1 (presence).

All clinical parameters were evaluated in six sites per tooth (mesiobuccal, buccal, distobuccal, mesiolingual, lingual, distolingual) using a millimeter periodontal probe (CP 15 UNC, Neumar / Brazil), in all erupted teeth except third molars. The distal sites of the posterior teeth are not being counted in the analysis because they are not areas of flossing.

Examinations were conducted by two blind examiners for the experimental groups. The first examiner (A.P.R.) evaluated PlI. The second examiner (R.C.R.T.), after the patient received their standardized hygiene guidelines, evaluated GI, PD, CAL, and BoP. Quadrants are isolated with cotton rolls and the teeth are gently dried with air jet. An examiner (A.P.R.) evaluates IPI, and FRP. Next, the individual received their oral standardized hygiene following the procedures of the group that is randomized. Thus, the plaque is removed so that

the other examiner (R.C.R.T.), which performs the other evaluations (GI, PD, CAL and BoP), is not influenced by the observation of the amount of plaque present.

Training and calibration of examiners

Two examiners (A.P.R and R.C.R.T) underwent a period of training by an experienced examiner (K.Z.K) for assessments of IPl, GI, CAL, PD and BoP. The training consisted of theoretical evaluation of the periodontal parameters, clinical discussion about each score or category and possible disagreements. The training was completed when a good level of agreement and understanding about the parameters was achieved.

The examiners were also calibrated, prior to data collection, for PD and CAL evaluations using flat oral mirror and millimeter periodontal probe (North Carolina, Neumar®, São Paulo, Brazil). Intra-examiner reproducibility was assessed in 7 subjects by means of duplicate tests with an interval of one hour. Intraclass Correlation Coefficient (ICC) to PD and CAL was 0.78 and 1.00 respectively.

Statistical Analysis

Data were processed and analyzed using the Statistical Package for Social Science (SPSS for Windows, version 23.0, SPSS Inc., Chicago, IL, USA). PlI, GI, PD, CAL, percentage of sites with BoP and the percentage of sites with different GI scores were presented as a mean and standard error. Data were analyzed by intention to treat. Mixed linear models were used for the analysis and comparison of experimental groups. The best covariance structure (component symmetry) was tested. The parameters of the model were estimated through maximum probability. The level of significance was set at 5%.

Results

Forty-nine individuals were randomized between the experimental groups, however, three did not complete the study (Figure 2). Table 1 describes the socio demographic, behavioral and clinical characteristics of the participants at baseline. All subjects had generalized gingivitis at the start of the study. There

were no significant statistically differences in PD (P = 0.54), BoP (P = 0.77), CAL (P = 0.54), GI (P = 0.77) and PII between the experimental groups when subjects were included in the study. Thirty four subjects reported using floss less than once daily. At baseline, 29 of the 49 participants reported brushing their teeth at least 2 times daily. Despite this, most individuals reported experiencing gingival bleeding.

Table 2 and 3 presents the means of GI and GBI and PII and VPI respectively, in the two experimental groups at baseline, 30 and 60 days. The means of PII and GI decreased in both groups over time. There was no significant statistically difference between the groups PII (p = 0.718) and GI (p = 0.612). Only between the baseline period and 30 days the GI reduction was significant.

In the group that used only the toothbrush, mean values of PII reduced in the period 30 and 60 days in relation to the baseline. In the group that used dental floss and toothbrush, although there was a decrease in the average of PII, in the 60 days there was an increase of this average in relation to the time 30 days. With regard to GI, the means decreased more in the period 60 days than in the period 30 days in both groups.

Discussion

This study indicated that comprehensive OHI and weekly professional removal of dental plaque may significantly reduce gingival inflammation and biofilm accumulation in adults with generalized proximal gingivitis and intact papillae in both experimental groups. Adjunctive use of dental floss did not add significant benefit over a 60-day period, in terms of reduction of interdental plaque and gingival inflammation. The levels of gingival inflammation reduced significantly almost half in both groups during the experimental period. Compared to reduction in GI means, GBI levels presented more expressive results than GI levels. This can be explained because GBI is a dichotomous index that indicates presence or absence of bleeding, evaluating with more precision gingival inflammation.

In agreement with other studies (Halla-Junior & Oppermann, 2004; Rosema et al., 2008), manual toothbrush reduced interproximal gingival inflammation. There was a reduction of 20.8 % (almost half) in GBI levels on TB group from baseline to time 60 days. Similar result was found on DF group. As reported in figure 3, in 30 days there is a higher reduction percentage of sites with gingival bleeding at DF compared to TB group (23.4% and 17.8% respectively). Nevertheless, this was not significant statistically; evidencing that dental floss was not significant to reduce gingival inflammation in this population.

Plaque index, was reduced already in the period of 30 days at TB and DF groups. On the other hand, there was an increase in the mean at 60 day in relation to 30 day in the group that used dental floss and toothbrush. This may be related to the motivation of patients to flossing and toothbrushing their teeth, since possibly they started the study motivated (novelty and Hawthorne effect) to change their habit, but over time they may have returned to do what they did before the experimental period.

With regard to the reduction of gingivitis, there seems to be some evidence that dental floss in combination with toothbrush provides a statistically significant benefit in reducing gingivitis compared with toothbrush alone (Sälzer et al., 2015; Worthington et al., 2019). Although the differences of these studies be statistically significant, the evidence is still low to very low-certainty. Differently from this study, where participants had generalized gingivitis at baseline, the effects observed in these reviews may not be clinically important because many participants had a low level of gingival inflammation at the beginning of studies (Worthington et al., 2019). In addition, a few clinical trials were available to be included in these reviews, highlighting the importance of this trial.

The present study corroborated with the results found in other studies that evaluate the adjunctive benefit of flossing to toothbrushing in terms of biofilm and gingival inflammation control (Graziani et al., 2018; Halla-Junior & Oppermann, 2004; Haps, 2008; Rosema et al., 2008). The reason for such lack of efficacy of dental floss might be because of poor patients adherence to the use of this device (Schüz et al., 2009). To be effective, dental floss needs to be used effectively and continuously (Schüz et al., 2009).

This study has strengths and weaknesses. Strengths include that, to our knowledge, this is the first study that all adults beginning the experimental period

with generalized gingivitis. In other studies, subjects started the experimental period with a little or no gingival inflammation, which makes it difficult to evaluate the efficacy of an interproximal hygiene device. Despite this, no other chemical agent was used to control the participants' biofilm in addition to the use of dental floss, manual toothbrush and toothpaste,

Other strength is that this study was conducted in Brazil, contributing data from a developing country. Previous data come only from high-income countries. There is a lack of data related to the benefit of flossing for gingivitis inflammation from low- and middle-income countries (Worthington et al., 2019). To our knowledge, there is only one study from developing country evaluating the additional benefit of flossing to manual toothbrush (Halla-Junior & Oppermann, 2004).

One limitation was the frequency of professional biofilm removal which may has not be sufficient to reach gingival health. The 60-day period may be insufficient for participants to learn and change behavior of flossing (Schüz et al. 2009). We used a weekly professional intervention and the participants did oral hygiene at home as recommended, without supervision. Perhaps, to test the real efficacy of dental floss, professional biofilm disorganization should be performed every 48 hours (Lang, Cumming, & Löe, 1973).

Manual toothbrushing is the principal device for plaque control and reduces gingivitis in the short and long term (Tonetti et al. 2015, Yaacob et al., 2014).The rationale for considering interdental cleaning as a separate procedure is because manual toothbrushing may not effectively reach proximal surfaces (Claydon, 2008). Thus, our study was based on recent evidence from the literature that evaluated the additional benefit of dental floss use to mechanical toothbrushing in the reduction of gingival inflammation (Haps, 2008; Imai et al., 2010; Sälzer et al., 2015; Sambunjak et al., 2019; Worthington et al., 2019).

Overall, in adults with generalized gingivitis and no interdental attachment loss, toothbrushing when properly executed, is capable of reduce proximal plaque and gingival inflammation. Similar to results observed when dental floss was used. At baseline of this trial, despite most individuals reported brushing their teeth at least 2 times daily, almost all reported experiencing gingival bleeding. The clinical efficacy of toothbrush is correlated with brushing time, individual ability to remove plaque, frequency at which removal is performed,

patient motivation, and professional oral hygiene instruction (Petersilka et al., 2002; Ronis et al., 1993).

Therefore, is important highlight the importance of dentists spent more time in IHB and stimulate behavior changes to reach and maintain buccal health. Although most subjects report toothbrush their teeth at least once a day, we know that 95% of the population have gingivitis (Lang & Bartold, 2018) .So, probably they not clean their teeth enough to prevent biofilm formation (Claydon, 2008). Repeated IHB, in-mouth demonstration and continuous reinforcement of patient's motivation, such as understanding by individuals that buccal health only will be reach with adequate daily personal biofilm removal are crucial for proper long-term plaque control and maintenance of gingival and periodontal health.

It can be concluded that disorganization of biofilms by the toothbrush, when performed efficiently, resulted in significant reductions in gingival inflammation and presence of biofilm. Inclusion of dental flossing into this brushing regime was not significant to improve the parameters evaluated in adults with generalized proximal gingivitis.

References

Asadoorian, J., & Locker, D. (2006). The impact of quality assurance programming: a comparison of two canadian dental hygienist programs. *Journal of dental education*, *70*(9), 965–971. https://doi.org/70/9/965 [pii]

Axelsson, P., & J. Lindhe. (1981). Effect of controlled oral hygiene procedure on caries and periodontal disease in adults. *Journal of Clinical Periodontology*.

Axelsson, P., Nyström, B., & Lindhe, J. (2004). The long-term effect of a plaque control program on tooth mortality, caries and periodontal disease in adults: Results after 30 years of maintenance. *Journal of Clinical Periodontology*, *31*(9), 749–757. https://doi.org/10.1111/j.1600-051X.2004.00563.x

Chapple, I. L. C., Van Der Weijden, F., Doerfer, C., Herrera, D., Shapira, L., Polak, D., … Graziani, F. (2015). Primary prevention of periodontitis: Managing gingivitis. *Journal of Clinical Periodontology*, *42*(S16), S71–S76. https://doi.org/10.1111/jcpe.12366

Claydon. (2008). Current concepts in toothbrushing and interdental cleaning. *Periodontology 2000*, *48*(1), 10–22. Recuperado de http://www.embase.com/search/results?subaction=viewrecord&from=export&id=L352153598%5Cnhttp://dx.doi.org/10.1111/j.1600-0757.2008.00273.x%5Cnhttp://elvis.ubvu.vu.nl:9003/vulink?sid=EMBASE&issn=09066713&id=doi:10.1111/j.1600-0757.2008.00273.x&atitle=Curren

Cumming, B. R., & Löe, H. (1973). Consistency of plaque distribution in individuals without special home care instruction. *Journal of Periodontal Research*. https://doi.org/10.1111/j.1600-0765.1973.tb00748.x

De Freitas, G. C., Pinto, T. M. P., Grellmann, A. P., Dutra, D. A. M., Susin, C., Kantorski, K. Z., & Moreira, C. H. C. (2016). Effect of self-performed mechanical plaque control frequency on gingival inflammation revisited: A randomized clinical trial. *Journal of Clinical Periodontology*, *43*(4), 354–358. https://doi.org/10.1111/jcpe.12520

Graziani, F., Palazzolo, A., Gennai, S., Karapetsa, D., Giuca, M. R., Cei, S., … Nisi, M. (2018). Interdental plaque reduction after use of different devices in young subjects with intact papilla: A randomized clinical trial. *International Journal of Dental Hygiene*, *16*(3), 389–396. https://doi.org/10.1111/idh.12318

Halla-Junior, R., & Oppermann, R. V. (2004). Evaluation of dental flossing on a group of second grade students undertaking supervised tooth brushing. *Oral Health & Preventive Dentistry*, *2*(2), 111–118.

Haps, S. (2008). CE Berchier DE Slot S Haps GA Van der Weijden. *Journal of Dentistry*, (1), 265–279.

Imai, P., Johnson, T. M., Nickerson, J., Poklepovic, T., Sambunjak, D., Tugwell, P., & Worthington, H. V. (2010). Flossing for the management of periodontal diseases and dental caries. *Cochrane Database of Systematic Reviews*, (12). https://doi.org/10.1002/14651858.cd008829

Kinane, D. F., Shiba, H., & Hart, T. C. (2005). The genetic basis of periodontitis. *Periodontology 2000*, *39*(1), 91–117. https://doi.org/10.1111/j.1600-0757.2005.00118.x

Lang, N. P., & Bartold, P. M. (2018). Periodontal health. *Journal of Clinical Periodontology*, *45*(August 2016), S9–S16. https://doi.org/10.1111/jcpe.12936

Lang, N. P., Cumming, B. R., & Löe, H. (2010). Toothbrushing Frequency as It Relates to Plaque Development and Gingival Health. *Journal of Periodontology*, *44*(7), 396–405. https://doi.org/10.1902/jop.1973.44.7.396

LÖE, H. (1967). Löe Gingival Index'67. *Journal of Periodontology*, 610–616. Recuperado de http://www.belgeler.com/blg/33cm/le-gingival-index-67

Marsh, P. D. (2006). Dental plaque as a biofilm and a microbial community - Implications for health and disease. *BMC Oral Health*, *6*(SUPPL. 1), 1–7. https://doi.org/10.1186/1472-6831-6-S1-S14

Murakami, S., Mealey, B. L., Mariotti, A., & Chapple, I. L. C. (2018). Dental plaque–induced gingival conditions. *Journal of Clinical Periodontology*, *45*(August 2017), S17–S27. https://doi.org/10.1111/jcpe.12937

Petersilka, G. J., Ehmke, B., & Flemmig, T. F. (2002). Antimicrobial effects of mechanical debridement. *Periodontology 2000*, *28*(1), 56–71. https://doi.org/10.1034/j.1600-0757.2002.280103.x

Pinto, T. M. P., De Freitas, G. C., Dutra, D. A., Kantorski, K. Z., & Moreira, C. H. (2013). Frequency of mechanical removal of plaque as it relates to gingival inflammation: A randomized clinical trial. *Journal of Clinical Periodontology*, *40*(10), 948–954. https://doi.org/10.1111/jcpe.12135

Poklepovic, T., Sambunjak, D., Johnson, T. M., Imai, P., Tugwell, P., Nickerson, J. W., … Worthington, H. V. (2012). Interdental brushing for the management of periodontal diseases and dental caries in adults. *Cochrane Database of Systematic Reviews*, (12). https://doi.org/10.1002/14651858.CD009857

Ronis, D. L., Lang, W. P., Farghaly, M. M., & Passow, E. (1993). Tooth Brushing, Flossing, and Preventive Dental Visits by Detroit-area Residents in Relation to Demographic and Socioeconomic Factors. *Journal of Public Health Dentistry*, *53*(3), 138–145. https://doi.org/10.1111/j.1752-7325.1993.tb02692.x

Rosema, N. A. M., Timmerman, M. F., Versteeg, P. A., van Palenstein Helderman, W. H., Van der Velden, U., & Van der Weijden, G. A. (2008). Comparison of the Use of Different Modes of Mechanical Oral Hygiene in Prevention of Plaque and Gingivitis. *Journal of Periodontology*, *79*(8), 1386–1394. https://doi.org/10.1902/jop.2008.070654

Sälzer, S., Slot, D. E., Van Der Weijden, F. A., & Dörfer, C. E. (2015). Efficacy of inter-dental mechanical plaque control in managing gingivitis - A meta-review. *Journal of Clinical Periodontology*, *42*(S16), S92–S105. https://doi.org/10.1111/jcpe.12363

Sambunjak, D., Nickerson, J. W., Pericic, T. P., Johnson, T. M., Imai, P., Tugwell, P., & Worthington, H. V. (2019). Flossing for the management of periodontal diseases and dental caries in adults. *Cochrane Database of Systematic Reviews*, *2019*(4). https://doi.org/10.1002/14651858.CD008829.pub3

Schüz, B., Wiedemann, A. U., Mallach, N., & Scholz, U. (2009). Effects of a short behavioural intervention for dental flossing: Randomized-controlled trial on planning when, where and how. *Journal of Clinical Periodontology*, *36*(6), 498–505. https://doi.org/10.1111/j.1600-051X.2009.01406.x

Silness, J., & Harald, L. (1964). Periodontal Disease in Pregnancy: II Correlation between oral hygiene and periodontal condition. *Acta Odontol Scand*, *22*, 121–135. https://doi.org/10.1097/jpn.0b013e31821072e4

Tonetti, M. S., Eickholz, P., Loos, B. G., Papapanou, P., Der, U. Van, Armitage, G., … Fundak, A. ([s.d.]). Article Type: Supplement Article Principles in Prevention of Periodontal Diseases. https://doi.org/10.1111/jcpe.12368

Tonetti, M. S., Greenwell, H., & Kornman, K. S. (2018). Staging and grading of periodontitis: Framework and proposal of a new classification and case definition. *Journal of periodontology*, *89*(January), S159–S172. https://doi.org/10.1002/JPER.18-0006

Worthington, H. V., Macdonald, L., Pericic, T. P., Sambunjak, D., Johnson, T. M., Imai, P., & Clarkson, J. E. (2019). Home use of interdental cleaning devices, in addition to toothbrushing, for preventing and controlling periodontal diseases and dental caries. *Cochrane Database of Systematic Reviews*, *2019*(4). https://doi.org/10.1002/14651858.CD012018.pub2

Yaacob, M., Hv, W., Sa, D., Deery, C., Ad, W., Pg, R., & Am, G. (2014). Powered versus manual toothbrushing for oral health (Review) SUMMARY OF FINDINGS FOR THE MAIN COMPARISON. *Cochrane Database of Systematic Reviews*, (6). https://doi.org/10.1002/14651858.CD002281.pub3.www.cochranelibrary.com

Tables

Table 1- Sociodemographic, behavioral and clinical parameters of experimental groups at baseline

Parameter	Toothbrush (n=25)	Toothbrush+ Dental floss (n=24)	P
Age	25.4±14,5	24.75±14.37	0.9
Gender n(%)[#]			0.3
Male	13 (52)	9 (37,5)	
Female	12 (48)	15 (62,5)	
Income	3840±3574.4	2806.82±2123.6	0.25
Interdental Device n(%)[#]			0.3
Do not use	8 (32)	11 (45,8)	
Less than once a day	10 (40)	5 (20,8)	
Once a day	7 (28)	8 (33.3)	
Frequency of brushing n(%)[#]			0.14
Once a day or less	1(4)	4(16.7)	
Twice a day or more	24 (96)	20 (83.3)	
Report of gingival bleeding n(%)[#]			0.67
Yes	20 (80)	18 (75)	
No	5 (20)	6 (25)	
Clinical parameters ($\bar{x}$ ± sd)*			
PII	0.6±0.38	0.7±0.41	0.59
GI	1.4±0.15	1.4±0.15	0.77
PD	1.68±0.22	1.63±0.33	0.54
CAL	0.05±0.1	0.05±0.07	0.54
BoP	36.89±19.45	35.25±18.63	0.77

PII = Plaque Index; GI = Gingival Index; PD= Probing depth; BoP = Bleendig on probing; CAL = Clinical attachment level.

*T-test

[#] chi-square statistics

Table 2- Gingival Index and GBI mean (standard error) for proximal sites during the experimental period in each experimental group.

		Toothbrush (n=25)	Toothbrush+dental floss (n=24)
GI	*Baseline*	1.4 (0.15)^{A,a}	1.4 (0.17)^{A,a}
	30 days	1.2 (0.12)^{A,b}	1.2 (0.12)^{A,b}
	60 days	1.2 (0.15)^{A,b}	1.2 (0.16)^{A,b}
GBI	*Baseline*	41.5 (2.70) ^{A,a}	42.6 (2.80) ^{A,a}
	30 days	23.9 (2.70) ^{A,b}	19.2 (2.80) ^{A,b}
	60 days	20.7 (2.70) ^{A,b}	18.4 (2.90) ^{A,b}

Mixed linear models analysis
Different uppercase letters demonstrate intergroup differences (P <0.05)
Different lowercase letters show intragroup differences (P <0.05)

Table 3 - Plaque Index and VPI means (standard error) for proximal sites during the experimental period in each experimental group.

		Toothbrush (n=25)	Toothbrush+ dental floss (n=24)
PII	*Baseline*	0.6 (0.38) ^{A,a}	0.7(0.41) ^{A,a}
	30 days	0.48 (0.28) ^{A,b}	0.37 (0.30) ^{A,b}
	60 days	0.41(0.26) ^{A,b}	0.47 (0.43) ^{A,b}
VPI	*Baseline*	17.0 (3.00) ^{A,a}	21.9 (3.10) ^{A,a}
	30 days	10.3 (3.00) ^{A,}	9.8 (3.20) ^{A,b}
	60 days	8.7 (3.00) ^{A,b}	13.6 (3.30) ^{A,b}

Mixed linear models analysis
Different uppercase letters demonstrate intergroup differences (P <0.05)
Different lowercase letters show intragroup differences (P <0.05)

Figures

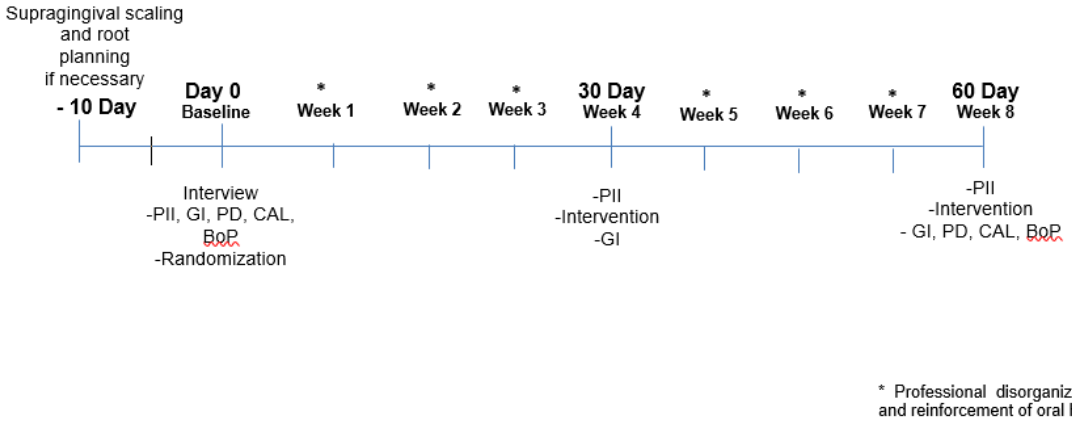

Figure 1 Study Outline

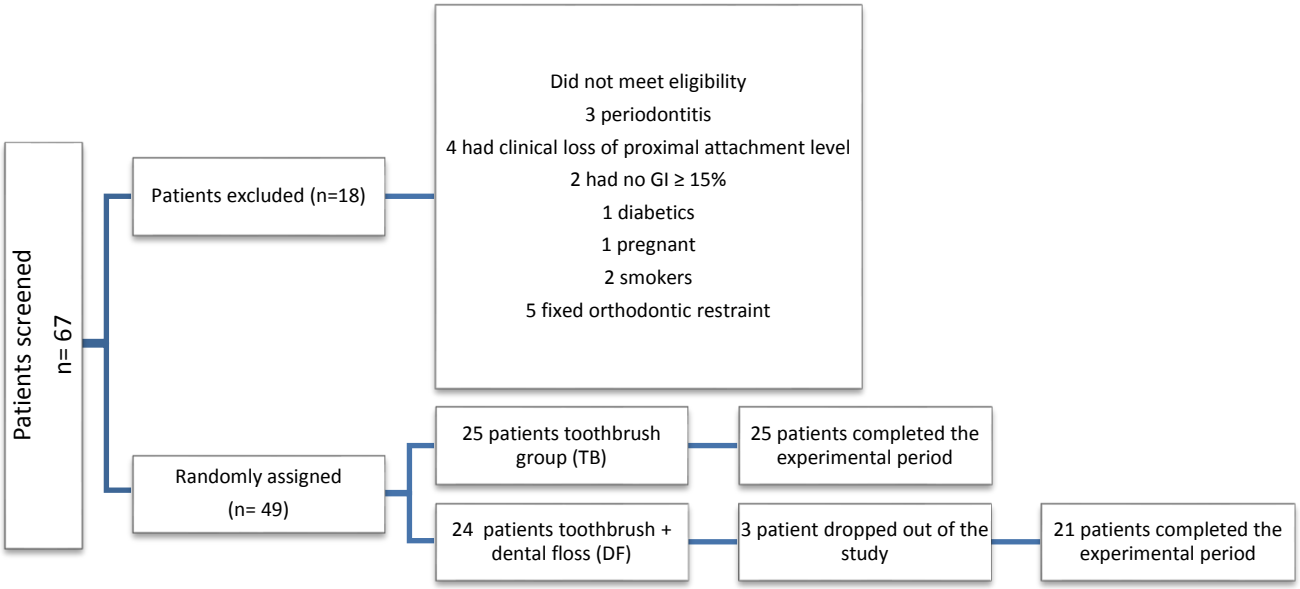

Figure 2 Study Flowchart

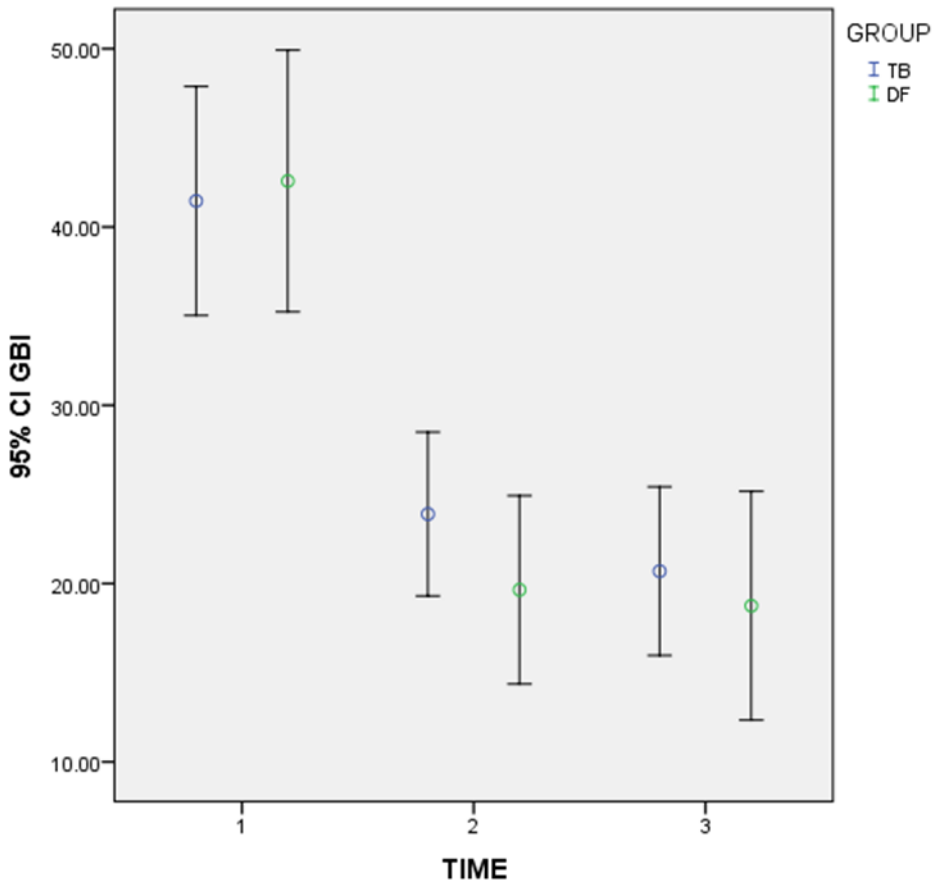

Figure 3 GBI reduction in different times.

3 CONCLUSÃO

Com base nos resultados desta dissertação, concluímos que a desorganização dos biofilmes pela escova multicerdas, quando realizada de forma eficiente, resultou em reduções significativas na inflamação gengival e na presença de placa visível. A inclusão de fio dental neste regime de escovação não foi significativa para melhorar os parâmetros avaliados em adultos com gengivite generalizada proximal.

REFERÊNCIAS

ASADOORIAN, J.; LOCKER, D. The impact of quality assurance programming: a comparison of two canadian dental hygienist programs. **Journal of dental education**, [s. l.], v. 70, n. 9, p. 965–971, 2006.

AXELSSON, P.; J. LINDHE. **Effect of controlled oral hygiene procedure on caries and periodontal disease in adultsJournal of Clinical Periodontology**, 1981.

AXELSSON, P.; NYSTRÖM, B.; LINDHE, J. The long-term effect of a plaque control program on tooth mortality, caries and periodontal disease in adults: Results after 30 years of maintenance. **Journal of Clinical Periodontology**, [s. l.], v. 31, n. 9, p. 749–757, 2004.

CHAPPLE, Iain L. C. et al. Primary prevention of periodontitis: Managing gingivitis. **Journal of Clinical Periodontology**, [s. l.], v. 42, n. S16, p. S71–S76, 2015.

CLAYDON. Current concepts in toothbrushing and interdental cleaning. **Periodontology 2000**, [s. l.], v. 48, n. 1, p. 10–22, 2008.

CUMMING, Boyd R.; LÖE, Harald. **Consistency of plaque distribution in individuals without special home care instructionJournal of Periodontal Research**, 1973.

DE FREITAS, Guilherme Camponogara et al. Effect of self-performed mechanical plaque control frequency on gingival inflammation revisited: A randomized clinical trial. **Journal of Clinical Periodontology**, [s. l.], v. 43, n. 4,

p. 354–358, 2016.

GRAZIANI, F. et al. Interdental plaque reduction after use of different devices in young subjects with intact papilla: A randomized clinical trial. **International Journal of Dental Hygiene**, [s. l.], v. 16, n. 3, p. 389–396, 2018.

HALLA-JUNIOR, R.; OPPERMANN, R. V. Evaluation of dental flossing on a group of second grade students undertaking supervised tooth brushing. **Oral Health & Preventive Dentistry**, [s. l.], v. 2, n. 2, p. 111–118, 2004.

HAPS, S. CE Berchier DE Slot S Haps GA Van der Weijden. **Journal of Dentistry**, [s. l.], n. 1, p. 265–279, 2008.

IMAI, Pauline et al. Flossing for the management of periodontal diseases and dental caries. **Cochrane Database of Systematic Reviews**, [s. l.], n. 12, 2010.

KINANE, Denis F.; SHIBA, Hideki; HART, Thomas C. The genetic basis of periodontitis. **Periodontology 2000**, [s. l.], v. 39, n. 1, p. 91–117, 2005.

LANG, Niklaus P.; BARTOLD, P. Mark. Periodontal health. **Journal of Clinical Periodontology**, [s. l.], v. 45, p. S9–S16, 2018.

LANG, Niklaus P.; CUMMING, Boyd R.; LÖE, Harald. Toothbrushing Frequency as It Relates to Plaque Development and Gingival Health. **Journal of Periodontology**, [s. l.], v. 44, n. 7, p. 396–405, 2010.

LÖE, HARALD. Löe Gingival Index'67. **Journal of Periodontology**, [s. l.], p. 610–616, 1967.

MARIOTTI, A. Dental plaque-induced gingival diseases. **Ann. Periodontol.,** Chicago v. 4, p. 7-19, Dec. 1999.

MARSH, Philip D. Dental plaque as a biofilm and a microbial community - Implications for health and disease. **BMC Oral Health**, [s. l.], v. 6, n. SUPPL. 1, p. 1–7, 2006.

MURAKAMI, Shinya et al. Dental plaque–induced gingival conditions. **Journal of Clinical Periodontology**, [s. l.], v. 45, p. S17–S27, 2018.

PETERSILKA, Gregor J.; EHMKE, Benjamin; FLEMMIG, Thomas F. Antimicrobial effects of mechanical debridement. **Periodontology 2000**, [s. l.], v. 28, n. 1, p. 56–71, 2002.

PINTO, Tatiana M. P. et al. Frequency of mechanical removal of plaque as it relates to gingival inflammation: A randomized clinical trial. **Journal of Clinical Periodontology**, [s. l.], v. 40, n. 10, p. 948–954, 2013.

POKLEPOVIC, Tina et al. Interdental brushing for the management of periodontal diseases and dental caries in adults. **Cochrane Database of Systematic Reviews**, [s. l.], n. 12, 2012.

RONIS, David L. et al. Tooth Brushing, Flossing, and Preventive Dental Visits by Detroit-area Residents in Relation to Demographic and Socioeconomic Factors. **Journal of Public Health Dentistry**, [s. l.], v. 53, n. 3, p. 138–145, 1993.

ROSEMA, Nanning A. M. et al. Comparison of the Use of Different Modes of Mechanical Oral Hygiene in Prevention of Plaque and Gingivitis. **Journal of Periodontology**, [s. l.], v. 79, n. 8, p. 1386–1394, 2008.

SÄLZER, Sonja et al. Efficacy of inter-dental mechanical plaque control in

managing gingivitis - A meta-review. **Journal of Clinical Periodontology**, [s. l.], v. 42, n. S16, p. S92–S105, 2015.

SAMBUNJAK, Dario et al. Flossing for the management of periodontal diseases and dental caries in adults. **Cochrane Database of Systematic Reviews**, [s. l.], v. 2019, n. 4, 2019.

SCHIFF, T. et al. A clinical investigation of the efficacy of three diferente treatment regimens for the control of plaque and gingivitis. **J Clin Dent,** Yardley, v. 17, n. 5, p. 138-144, 2006.

SCHÜZ, Benjamin et al. Effects of a short behavioural intervention for dental flossing: Randomized-controlled trial on planning when, where and how. **Journal of Clinical Periodontology**, [s. l.], v. 36, n. 6, p. 498–505, 2009.

SHARMA, N. C. et al. Comparative effectiveness of an essential oil mouthrinse and dental floss in controlling interproximal gingivitis and plaque. **Am J Dent,** San Antonio, v. 15, n. 6, p. 351-355, Dec. 2002.

SILNESS, John; HARALD, Löe. Periodontal Disease in Pregnancy: II Correlation between oral hygiene and periodontal condition. **Acta Odontol Scand**, [s. l.], v. 22, p. 121–135, 1964.

TONETTI, Maurizio S. et al. Article Type: Supplement Article Principles in Prevention of Periodontal Diseases. [s. l.], [s.d.].

TONETTI, Maurizio S.; GREENWELL, Henry; KORNMAN, Kenneth S. Staging and grading of periodontitis: Framework and proposal of a new classification and case definition. **Journal of periodontology**, [s. l.], v. 89, p. S159–S172, 2018.

WORTHINGTON, Helen V. et al. Home use of interdental cleaning devices, in

addition to toothbrushing, for preventing and controlling periodontal diseases and dental caries. **Cochrane Database of Systematic Reviews**, [s. l.], n. 4, 2019.

YAACOB, M. et al. Powered versus manual toothbrushing for oral health (Review) SUMMARY OF FINDINGS FOR THE MAIN COMPARISON. **Cochrane Database of Systematic Reviews**, [s. l.], n. 6, 2014.

APÊNDICE A – ENTREVISTA

Entrevista

1) **Nome:**_____
2) **Telefone(s):**_____
3) **Endereço:**_____
4) **Gênero:** ( )M ( )F
5) **Data de nascimento:**_____ **Idade:**_____ anos.
6) **Raça:** ( ) branca; ( ) preta; ( ) parda; ( ) indígena; ( ) amarela

Dados odontológicos:

7) **Qual a frequência com que você realiza escovação dos dentes?**

   ( ) não escova; ( ) menos de uma vez ao dia (escova somente alguns dias); ( )1 vez por dia; ( ) 2 vezes por dia; ( ) três vezes ou mais que três vezes por dia.

8) **Que tipo de escova você usa?** ( ) macia; ( ) média; ( ) dura
9) **Qual frequência com que você utiliza dispositivo de limpeza interdental?**

   ( ) não utiliza; ( ) menos de uma vez ao dia (utiliza somente alguns dias); ( )1 vez por dia

10) **Qual tipo de dispositivo de limpeza interdental você usa?**

    ( ) fio; ( ) escova interdental; ( ) escova unitufo; ( )outro_____

11) **Você usa pasta de dentes?** ( ) sim ( ) não
12) **Você usa alguma solução para bochecho?** ( ) sim ( ) não
13) **Você observa que suas gengivas sangram?** ( ) sim ( ) não
14) **Você sente sensibilidade nos dentes?** ( ) sim ( ) não

15) **Você sente mau hálito na boca?** ( ) sim ( ) não

16) **Alguém já comentou a respeito do seu hálito?** ( ) sim ( ) não

17) **Você procurou o dentista nos últimos 6 meses?** ( ) sim ( ) não

18) **Quando foi a última visita ao dentista?** ( ) até 3 meses; ( ) 3 a 6 meses; ( ) 6 meses a 1 ano; ( ) mais que 1 ano; ( ) nunca visitou

19) **Motivo da última consulta:** ( ) dor de dente; ( ) dor na boca; ( ) batidas e quedas; ( ) exames de rotina.
Outros:_____

20) **Tipo de serviço que você procurou na última consulta:** ( ) dentista particular; ( ) dentista público (posto de saúde, faculdade, escola)

Dados médicos:

21) **Você está fazendo tratamento médico atualmente?**

( ) sim ( ) não. **Qual?**

_____

22) **Você esteve em tratamento médico nos últimos 3 meses?**

( ) sim ( ) não. **Qual?** _____

23) **Você tem alguma doença sistêmica?**

( ) sim ( ) não. **Qual?** _____

24) **Você está tomando alguma medicação?**

( ) sim ( ) não. **Qual?** _____

Nível socioeconômico e escolaridade

25) **No mês passado, quanto receberam em Reais, juntas, todas as pessoas que moram na sua casa? (Incluindo valores de salários, bolsa família, pensão, aposentadoria e outros rendimentos)** _____ reais.

26) **Você trabalha?** ( ) sim ( ) não

27) Você estou até: ( )não estudou; ( )1º grau incompleto; ( )1º grau completo; ( )2º grau incompleto; ( )2º grau completo; ( )3º grau incompleto; ( )3º grau completo

28) Quantos anos de estudo você tem?

_____anos

APÊNDICE B – FICHA CLÍNICA

Ficha clínica

Nome:_____

Data:_____ **Avaliação: ( ) *baseline*; ( ) 30; ( ) 60; ( ) 120; ( ) 240 dias**

	17			16			15			14			13			12			11			21			22			23			24			25			26			27		
	D	V	M	D	V	M	D	V	M	D	V	M	D	V	M	D	V	M	D	V	M	M	V	D	M	V	D	M	V	D	M	V	D	M	V	D	M	V	D	M	V	D
IPI																																										
IG																																										
FRP																																										
	D	P	M	D	P	M	D	P	M	D	P	M	D	P	M	D	P	M	D	P	M	M	P	D	M	P	D	M	P	D	M	P	D	M	P	D	M	P	D	M	P	D
IPI																																										
IG																																										
FRP																																										
	47			46			45			44			43			42			41			31			32			33			34			35			36			37		
	D	V	M	D	V	M	D	V	M	D	V	M	D	V	M	D	V	M	D	V	M	M	V	D	M	V	D	M	V	D	M	V	D	M	V	D	M	V	D	M	V	D
IPI																																										
IG																																										
FRP																																										
	D	L	M	D	L	M	D	L	M	D	L	M	D	L	M	D	L	M	D	L	M	M	L	D	M	L	D	M	L	D	M	L	D	M	L	D	M	L	D	M	L	D
IPI																																										
IG																																										
FRP																																										

Número de dentes:	**FRP:** presença ou ausência de cálculo dentário.	**% ≥ IG 2 proximal:**

Data:_____ Avaliação: ( ) *baseline*; ( ) 240 dias

	17			16			15			14			13			12			11			21			22			23			24			25			26			27		
	D	V	M	D	V	M	D	V	M	D	V	M	D	V	M	D	V	M	D	V	M	M	V	D	M	V	D	M	V	D	M	V	D	M	V	D	M	V	D	M	V	D
PS																																										
SS																																										
RG																																										
NIC																																										
	D	P	M	D	P	M	D	P	M	D	P	M	D	P	M	D	P	M	D	P	M	M	P	D	M	P	D	M	P	D	M	P	D	M	P	D	M	P	D	M	P	D
PS																																										
SS																																										
RG																																										
NIC																																										
	47			46			45			44			43			42			41			31			32			33			34			35			36			37		
	D	V	M	D	V	M	D	V	M	D	V	M	D	V	M	D	V	M	D	V	M	M	V	D	M	V	D	M	V	D	M	V	D	M	V	D	M	V	D	M	V	D
PS																																										
SS																																										
RG																																										
NIC																																										
	D	L	M	D	L	M	D	L	M	D	L	M	D	L	M	D	L	M	D	L	M	M	L	D	M	L	D	M	L	D	M	L	D	M	L	D	M	L	D	M	L	D
PS																																										
SS																																										
RG																																										
NIC																																										

Fluido crevicular gengival (FCG)

Data:_____ Avaliação: ( ) *baseline*

Face/ Dente	Volume de FCG
MV 16	
MV 21	
MV 36	
MV 41	

Data:_____ Avaliação: ( ) 30 dias

Face/ Dente	Volume de FCG
MV 16	
MV 21	
MV 36	
MV 41	

Data:_____ Avaliação: ( ) 60 dias

Face/ Dente	Volume de FCG
MV 16	
MV 21	
MV 36	
MV 41	

Data:_____ Avaliação: ( ) 120 dias

Face/ Dente	Volume de FCG
MV 16	
MV 21	
MV 36	
MV 41	

Data:_____ Avaliação: ( ) 240 dias

Face/ Dente	Volume de FCG
MV 16	
MV 21	
MV 36	
MV 41	

ANEXO A – TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

UNIVERSIDADE FEDERAL DE SANTA MARIA
CENTRO DE CIÊNCIAS DA SAÚDE
PROGRAMA DE PÓS-GRADUAÇÃO EM CIÊNCIAS ODONTOLÓGICAS

Termo de consentimento livre e esclarecido

Título do projeto: Efetividade do uso do fio dental para tratamento da gengivite em adultos: um ensaio clínico randomizado

Pesquisador responsável/ Telefone para contato: Karla Zanini Kantorski/ (055) 91593232

Pesquisadores participantes/ Telefones para contato: Camila Silveira Sfreddo/ (055) 91594588**;** Juliana Maier/ (055) 99385685**;** Ana Paula Pereira Reiniger/ (055) 97263112

Instituição/ Curso/ Departamento: Universidade Federal de Santa Maria (UFSM)/ Curso de Odontologia/ Departamento de Estomatologia

Local de coleta: Clínica de Periodontia da UFSM. Rua Mal. Floriano Peixoto, 1184, Santa Maria – RS, CEP 97015-372, sala 710 (7º andar do prédio da antiga Reitoria)

Você está sendo convidado a participar, como voluntário da pesquisa **"Efetividade do uso do fio dental para tratamento da gengivite em adultos: um ensaio clínico randomizado"**, a qual foi aprovada por um comitê de ética[1]. Você precisa decidir se quer participar ou não. Por favor, não se apresse em tomar a decisão. Leia cuidadosamente o que se segue e pergunte ao responsável pelo estudo qualquer dúvida que você tiver. Após ser esclarecido sobre as informações a seguir, no caso de aceitar fazer parte do estudo, assine ao final deste documento. Em caso de recusa, você não será penalizado de forma alguma.

Essa pesquisa pretende avaliar se existe de fato a necessidade do uso de fio dental em conjunto com a escovação dos dentes para tratar a inflamação na gengiva (gengivite). Acreditamos que ela seja importante porque não está esclarecido até os

[1] Comitê de Ética em Pesquisa da UFSM: Av. Roraima, 1000 - 97105-900 - Santa Maria - RS - 2º andar do prédio da Reitoria. Telefone: (55) 3220-9362 - E-mail: cep.ufsm@gmail.com.

dias de hoje se o fio dental é necessário para melhorar a saúde da boca.

Caso decida participar, você passará inicialmente por um processo de sorteio para saber qual o tipo de tratamento você receberá ao longo de 8 meses. Você será solicitado a se apresentar no máximo doze vezes durante a pesquisa na Clínica de Periodontia da UFSM.O tratamento poderá ser: (1) apenas o uso de escova de dentes, ou (2) uso de escova de dentes e de fio dental. Os pesquisadores fornecerão escova de dentes, pasta de dentes, e fio dental usados no período do estudo.

A sua participação nesse estudo consiste em responder uma entrevista sobre informações pessoais como idade, raça, hábitos de higiene da sua boca, saúde geral, educação e renda da sua família.

Você também responderá questionários sobre a influência da condição da sua boca na sua qualidade de vida, alterações observadas na sua boca ao longo do estudo e se você segue o tratamento que será indicado pelos pesquisadores. Você também passará por um exame clínico da sua boca. O exame avaliará: quantidade de placa (tecido amolecido amarelo-esbranquiçado) formada sobre seus dentes; lesões de cárie; presença de sangramento e de perda de osso ao redor dos seus dentes quando é encostado um instrumento odontológico entre sua gengiva e seus dentes. Também será colocado um pedaço de “papel” entre a sua gengiva e seu dente, em alguns dentes, para medir a quantidade de líquido gengival. Por fim, seis radiografias serão realizadas em seus dentes ao longo do estudo.

Durante os exames, você poderá se sentir cansado e ter algum desconforto quando o instrumento odontológico é passado entre sua gengiva e seus dentes, além de haver um risco mínimo de se machucar com o instrumento caso ocorra um movimento brusco de sua parte ou do examinador. No entanto, os examinadores tentarão diminuir ao máximo esses imprevistos. Você poderá ficar com dor leve em sua gengiva após os exames Além disso, você poderá se sentir constrangido ou cansado em responder as questões da entrevista e dos questionários. Contudo, você poderá interromper as perguntas e o exame para descanso sempre que achar necessário. Caso você participe do grupo que não usará o fio dental, você poderá permanecer com algum grau de gengivite ao final do estudo. Se essa situação ocorrer, as pesquisadores oferecerão tratamento pelo período necessário para

estabelecer saúde gengival. A gengivite é totalmente reversível e não deixará sequelas permanentes. Na ocorrência de dano odontológico com a pesquisa, você terá direito a assistência odontológica gratuita garantida pelos pesquisadores.

O benefício direto a você será o tratamento da gengivite e de outras alterações bucais detectadas na Clínica de Periodontia da UFSM pelos responsáveis da pesquisa. Entretanto, o conhecimento sobre o efeito real do uso de fio dental será obtido somente com o término do estudo e análise dos dados.

Você terá acesso aos profissionais responsáveis pela pesquisa para esclarecimento de eventuais dúvidas em qualquer etapa do estudo. É garantido o livre acesso a todas as informações e, sendo de seu interesse, será mantido atualizado sobre os resultados finais da pesquisa após a publicação da mesma.

Se você concordar em participar do estudo, seu nome e identidade serão mantidos em sigilo. A menos que requerido por lei ou por sua solicitação, somente a equipe do estudo e o Comitê de Ética terão acesso a suas informações. As informações do estudo serão divulgadas apenas em eventos ou publicações científicas sem identificação dos voluntários. As fichas, após analisadas, ficarão guardadas na Clínica de Periodontia da UFSM Santa Maria /RS. (Antigo Prédio da Reitoria, Rua Marechal Floriano Peixoto, número 1184, 7º andar, sala 710) pelo período de 5 anos e, depois, imediatamente serão destruídas por incineração.

Você poderá recusar-se a participar do estudo, ou retirar seu consentimento e sair da pesquisa a qualquer momento, mesmo durante o exame, sem precisar justificar, não sofrendo qualquer prejuízo à assistência que esteja recebendo na Faculdade de Odontologia da UFSM.

Autorização

Eu, _____, após a leitura ou a escuta da leitura deste documento e ter tido a oportunidade de conversar com o pesquisador responsável, para esclarecer todas as minhas dúvidas, estou suficientemente informado, ficando claro para que minha participação é voluntária e que posso retirar este consentimento a qualquer momento sem penalidades ou perda de qualquer benefício. Estou ciente também dos objetivos da pesquisa, dos procedimentos aos quais serei submetido, dos possíveis danos ou riscos deles provenientes e da garantia de confidencialidade, bem como de esclarecimentos

[1] **Comitê de Ética em Pesquisa da UFSM: Av. Roraima, 1000 - 97105-900 - Santa Maria - RS - 2º andar do prédio da Reitoria. Telefone: (55) 3220-9362 - E-mail: cep.ufsm@gmail.com.**

sempre que desejar. Fui informado(a) que receberei uma cópia desse termo de consentimento. Estou totalmente ciente de que não há nenhum valor econômico, a receber ou pagar, por minha participação. Ficou claro também que minha participação é isenta de despesas. Diante do exposto e de espontânea vontade, expresso minha concordância em participar deste estudo.

_____

Nome e Assinatura do sujeito ou responsável:

Declaro que obtive de forma apropriada e voluntária o Consentimento Livre e Esclarecido deste sujeito de pesquisa ou representante legal para a participação neste estudo:

_____

Nome e assinatura do responsável pela obtenção do TCLE

Santa Maria, _____ de _____ de 201__.

ANEXO B – TERMO DE CONFIDENCIALIDADE

[1] **Comitê de Ética em Pesquisa da UFSM: Av. Roraima, 1000 - 97105-900 - Santa Maria - RS - 2º andar do prédio da Reitoria. Telefone: (55) 3220-9362 - E-mail: cep.ufsm@gmail.com**

ANEXO C – AUTORIZAÇÃO INSTITUCIONAL

UNIVERSIDADE FEDERAL DE SANTA MARIA
CENTRO DE CIÊNCIAS DA SAÚDE
PROGRAMA DE PÓS-GRADUAÇÃO EM CIÊNCIAS ODONTOLÓGICAS

Autorização institucional

Eu Walter Blaya Perez, abaixo assinado, responsável pela Departamento de Estomatologia do Curso de Odontologia da Universidade Federal de Santa Maria, autorizo a realização do estudo **"Efetividade do uso do fio dental para tratamento da gengivite em adultos: um ensaio clínico randomizado"**, a ser conduzido pelos pesquisadores Karla Zanini Kantorski, Carlos Heitor Cunha Moreira, Thiago Machado Ardenghi, Camila Silveira Sfreddo, Juliana Maier e Ana Paula Pereira Reiniger.

Fui informado, pelo responsável do estudo, sobre as características e objetivos da pesquisa, bem como das atividades que serão realizadas na instituição a qual represento.

Esta instituição está ciente de suas responsabilidades como instituição co-participante do presente projeto de pesquisa e de seu compromisso no resguardo da segurança e bem-estar dos sujeitos de pesquisa nela recrutados, dispondo de infra-estrutura necessária para a garantia de tal segurança e bem-estar.

Santa Maria, 02 de março de 2016.

Walter Blaya Perez
Chefe Dept.º Estomatologia

Assinatura e carimbo do responsável institucional

ANEXO D – REGISTRO NO GABINETE DE PROJETOS DA UFSM

UNIVERSIDADE FEDERAL DE SANTA MARIA - UFSM

1.2.1.20.1.13 Projeto - Informações resumidas

Data: 01/03/2016
Hora: 16:31

Título: EFETIVIDADE DO USO DO FIO DENTAL PARA TRATAMENTO DA GENGIVITE EM ADULTOS: UM ENSAIO CLÍNICO RANDOMIZADO

Número do Projeto: 042388
Classificação Principal: Pesquisa
Situação: Em trâmite para registro
Data Inicial: 04/04/2016 **Data Final:** 31/12/2017
Palavras-chave: Doenças periodontais, Placa dental, Fio dental, Ensaio clínico
Tipo de Evento: Não se aplica

Resumo: A gengivite induzida pela placa é considerada a doença oral mais comum em indivíduos dentados e o tipo mais frequente de doença periodontal. Além das repercussões locais, a gengivite está associada com a redução da qualidade de vida e a um risco maior de perda dentária.A escovação manual é o método mais utilizado para o autocontrole mecânico de placa e, consequentemente, prevenção e tratamento da gengivite. A efetividade da escovação, porém, é questionável em áreas interproximais. Dessa forma, a limpeza interdental é reconhecida como parte essencial na manutenção de saúde gengival e o dispositivo interdental mais recomendado é o fio dental. Entretanto,há uma fraca evidência científica disponível sobre a recomendação do uso diário de fio dental. O objetivo deste ensaio clínico randomizado cego é avaliar a efetividadedo fio dental adjunto a escovação dental, comparado com a escovação sozinha, no tratamento da gengivite em adultos. Setenta e dois sujeitos comgengivite generalizada em sítios proximais serão randomizados em dois grupos experimentais de acordo com o uso de fio dental: Grupo escovação dental manual sem o uso de fio dental (sem fio) e Grupo escovação dental manual euso de fio dental (fio). Os parâmetros Índice de Sangramento Gengival (IG) e Índice de Placa (IPI) serão avaliados no baseline, em 15, 30, 90, 120, 180, 240 e 365 dias.Análise descritiva dos dados de IG e IPI será realizada usando médias, desvios-padrões e percentual médio de sítios com diferentes escores do IG e IPI. As diferenças nas médias de IG e IPI ao longo do tempo entre os grupos e dentro do mesmo grupo serão analisadas através de modelo de Regressão Multinível de Poisson.O desfecho principal será considerado redução no sangramento gengival. A diferença na proporção de sujeitos que atingiram nível de saúde gengival após as intervenções será comparada através do Teste Qui-quadrado com nível de significância de 5%. Adultos com menos de 15% dos sítios com sangramento gengival serão considerados saudáveis. A hipótese conceitual é que ambas intervenções são equivalentes no tratamento da gengivite.

Participantes

Matrícula	Nome	Vínculo Institucional	Função	Bolsa	C. Horária (semanal)	Data Inicial	Data Final
201121333	MICHEL LUIS RECKZIEGEL	Aluno de Graduação	Colaborador		8 horas	04/04/2016	31/12/2017
201140005	RODRIGO DA CUNHA ROSSIGNOLLO TAVARES	Aluno de Graduação	Colaborador		8 horas	04/04/2016	31/12/2017
201470493	JULIANA MAIER	Aluno de Pós-graduação	Participante		12 horas	04/04/2016	31/12/2017
201470494	CAMILA SILVEIRA SFREDDO	Aluno de Pós-graduação	Participante		12 horas	04/04/2016	31/12/2017
201571298	ANA PAULA PEREIRA REINIGER	Aluno de Pós-graduação	Participante		12 horas	04/04/2016	31/12/2017
2199718	CARLOS HEITOR CUNHA MOREIRA	Docente	Participante		4 horas	04/04/2016	31/12/2017
2555364	KARLA ZANINI KANTORSKI	Docente	Orientador		4 horas	04/04/2016	31/12/2017
2565440	THIAGO MACHADO ARDENGHI	Docente	Participante		4 horas	04/04/2016	31/12/2017

Unidades vinculadas ao projeto

Unidade	Função	Data Inicial	Data Final
04.34.00 - DEPTO. ESTOMATOLOGIA - STT	Responsável	04/04/2016	31/12/2017

Página: 1

ANEXO E – APROVAÇÃO NO COMITÊ DE ÉTICA

UNIVERSIDADE FEDERAL DE SANTA MARIA/ PRÓ-REITORIA DE PÓS-GRADUAÇÃO E

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: EFETIVIDADE DO USO DO FIO DENTAL PARA TRATAMENTO DA GENGIVITE EM ADULTOS: UM ENSAIO CLÍNICO RANDOMIZADO

Pesquisador: KARLA ZANINI KANTORSKI

Área Temática:

Versão: 1

CAAE: 53831716.5.0000.5346

Instituição Proponente: Universidade Federal de Santa Maria/ Pró-Reitoria de Pós-Graduação e

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.452.322

Apresentação do Projeto:

O objetivo deste ensaio clínico randomizado cego é avaliar a efetividade do fio dental adjunto a escovação dental, comparado com a escovação sozinha, no tratamento da gengivite em adultos. Setenta e dois sujeitos com gengivite generalizada em sítios proximais serão randomizados em dois grupos experimentais de acordo com o uso de fio dental: Grupo escovação dental manual sem o uso de fio dental (sem fio) e Grupo escovação dental manual e uso de fio dental (fio). Os parâmetros Índice de Sangramento Gengival (IG) e Índice de Placa (IPI) serão avaliados no baseline, em 15, 30, 90, 120, 180, 240 e 365 dias. Análise descritiva dos dados de IG e IPI será realizada usando médias, desvios-padrões e percentual médio de sítios com diferentes escores do IG e IPI. As diferenças nas médias de IG e IPI ao longo do tempo entre os grupos e dentro do mesmo grupo serão analisadas através de modelo de Regressão Multinível de Poisson. O desfecho principal será considerado redução no sangramento gengival. A diferença na proporção de sujeitos que atingiram nível de saúde gengival após as intervenções será comparada através do Teste Qui-quadrado com nível de significância de 5%. Adultos com menos de 15% dos sítios com sangramento gengival serão considerados saudáveis. A hipótese conceitual é que ambas intervenções são equivalentes no tratamento da gengivite.

Endereço: Av. Roraima, 1000 - prédio da Reitoria - 2º andar
Bairro: Camobi **CEP:** 97.105-970
UF: RS **Município:** SANTA MARIA
Telefone: (55)3220-9362 **E-mail:** cep.ufsm@gmail.com

Objetivo da Pesquisa:

- Avaliar a efetividade do fio dental adjunto a escovação dental, comparado com a escovação sozinha, no tratamento da gengivite em adultos.
- Avaliar a efetividade do fio dental adjunto a escovação em desfechos clínicos periodontais secundários:
a) placa;
b) cálculo dentário;
c) nível de inserção clínica.
- Avaliar o efeito das terapias no volume de fluido crevicular gengival.
- Avaliar a incidência de cárie.
- Avaliar o efeito das terapias propostas na qualidade de vida relacionada a saúde bucal.
- Verificar efeitos adversos do fio dental através da:
a) abrasão gengival;
b) fissura gengival.
- Monitorar a adesão do sujeito ao tratamento.

Avaliação dos Riscos e Benefícios:

Durante os exames, o participante voluntário pode sentir-se cansado ou apresentar desconforto pela introdução da sonda periodontal entre o dente e a gengiva. Além disso, pode haver um risco mínimo do participante machucar-se caso haja um movimento brusco de sua parte ou do examinador. No entanto, os examinadores tentarão diminuir ao máximo os imprevistos, e o exame periodontal será interrompido para descanso sempre que o participante achar necessário. O voluntário também pode sentir-se constrangido ou cansado ao responder as perguntas contidas nos questionários. Entretanto, o entrevistador fará esforço para evitar desconforto e constrangimento ao indivíduo. Os participantes do grupo sem o uso de fio dental poderão não apresentar melhora significativa na inflamação gengival. Contudo, a evidência científica não suporta a recomendação regular de fio dental para tratamento da gengivite.

O benefício direto ao participante será o tratamento da gengivite e de outras alterações bucais detectadas na Clínica de Periodontia da UFSM pelos responsáveis da pesquisa. A participação no estudo também irá melhorar o cuidado bucal dos indivíduos, uma vez que visa orientar procedimentos adequados de higiene bucal. Entretanto, o conhecimento científico sobre a efetividade do uso de fio dental será obtido somente com o término do estudo e análise dos

UNIVERSIDADE FEDERAL DE SANTA MARIA/ PRÓ-REITORIA DE PÓS-GRADUAÇÃO E

Continuação do Parecer: 1.452.322

dados. Os pesquisadores pretendem realizar palestra informal para apresentação dos resultados aos sujeitos de pesquisa ao concluírem a pesquisa.

Comentários e Considerações sobre a Pesquisa:
O trabalho consiste em uma tese de doutorado. Os aspectos éticos são respeitados e a metodologia é adequada para que se respondam aos objetivos propostos.

Considerações sobre os Termos de apresentação obrigatória:
São apresentados de forma suficiente e adequada.

Recomendações:
Veja no site do CEP - http://w3.ufsm.br/nucleodecomites/index.php/cep - na aba "orientações gerais", modelos e orientações para apresentação dos documentos. ACOMPANHE AS ORIENTAÇÕES DISPONÍVEIS, EVITE PENDÊNCIAS E AGILIZE A TRAMITAÇÃO DO SEU PROJETO.

Conclusões ou Pendências e Lista de Inadequações:
.

Considerações Finais a critério do CEP:

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_672370.pdf	04/03/2016 11:52:47		Aceito
Outros	RegistroCompletoGAP.pdf	04/03/2016 11:52:23	KARLA ZANINI KANTORSKI	Aceito
Folha de Rosto	FolhaDeRostoPlataformaBrasil.pdf	03/03/2016 14:32:38	KARLA ZANINI KANTORSKI	Aceito
Projeto Detalhado / Brochura Investigador	ProjetoEfetividadedoUsodoFioDentalCEPCamilaSfreddo.docx	02/03/2016 17:14:41	KARLA ZANINI KANTORSKI	Aceito
Outros	AutorizacaoInstitucional.jpg	02/03/2016 17:10:00	KARLA ZANINI KANTORSKI	Aceito
Outros	TermodeConfidencialidade.jpg	02/03/2016 17:08:09	KARLA ZANINI KANTORSKI	Aceito

Endereço: Av. Roraima, 1000 - prédio da Reitoria - 2º andar
Bairro: Camobi **CEP:** 97.105-970
UF: RS **Município:** SANTA MARIA
Telefone: (55)3220-9362 **E-mail:** cep.ufsm@gmail.com

UNIVERSIDADE FEDERAL DE SANTA MARIA/ PRÓ-REITORIA DE PÓS-GRADUAÇÃO E

Continuação do Parecer: 1.452.322

TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.docx	02/03/2016 17:00:31	KARLA ZANINI KANTORSKI	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

SANTA MARIA, 15 de Março de 2016

Assinado por:
CLAUDEMIR DE QUADROS
(Coordenador)

Endereço: Av. Roraima, 1000 - prédio da Reitoria - 2º andar
Bairro: Camobi **CEP:** 97.105-970
UF: RS **Município:** SANTA MARIA
Telefone: (55)3220-9362 **E-mail:** cep.ufsm@gmail.com

ANEXO F – NORMAS PARA PUBLICAÇÃO NO PERIÓDICO JOURNAL OF CLINICAL PERIODONTOLOGY

Author Guidelines

Content of Author Guidelines: 1. General, 2. Ethical Guidelines, 3. Manuscript Submission Procedure, 4. Manuscript Types Accepted, 5. Manuscript Format and Structure, 6. After Acceptance

Relevant Document: Sample Manuscript

Useful Websites: Submission Site, Articles published in *Journal of Clinical Periodontology*, Author Services, Wiley-Blackwell's Ethical Guidelines, Guidelines for Figures

The journal to which you are submitting your manuscript employs a plagiarism detection system. By submitting your manuscript to this journal you accept that your manuscript may be screened for plagiarism against previously published works.

1. GENERAL

Journal of Clinical Periodontology publishes original contributions of high scientific merit in the fields of periodontology and implant dentistry. Its scope encompasses the physiology and pathology of the periodontium, the tissue integration of dental implants, the biology and the modulation of periodontal and alveolar bone healing and regeneration, diagnosis, epidemiology, prevention and therapy of periodontal disease, the clinical aspects of tooth replacement with dental implants, and the comprehensive rehabilitation of the periodontal patient. Review articles by experts on new developments in basic and applied periodontal science and associated dental disciplines, advances in periodontal or implant techniques and procedures, and case reports which illustrate important new information are also welcome.

Please read the instructions below carefully for details on the submission of manuscripts, the journal's requirements and standards as well as information concerning the procedure after a manuscript has been accepted for publication in Journal of Clinical Periodontology. Authors are encouraged to visit Wiley-Blackwell's Author Services for further information on the preparation and submission of articles and figures.

2. ETHICAL GUIDELINES

Journal of Clinical Periodontology adheres to the below ethical guidelines for publication and research.

2.1. Authorship and Acknowledgements

Authors submitting a paper do so on the understanding that the manuscript have been read and approved by all authors and that all authors agree to the submission of the manuscript to the Journal.

Journal of Clinical Periodontology adheres to the definition of authorship set up by The International Committee of Medical Journal Editors (ICMJE). According to the ICMJE authorship criteria should be based on 1) substantial contributions to conception and design of, or acquisition of data or analysis and interpretation of data, 2) drafting the article or revising it critically for important intellectual content and 3) final approval of the version to be published. Authors should meet conditions 1, 2 and 3.

It is a requirement that all authors have been accredited as appropriate upon submission of the manuscript. Contributors who do not qualify as authors should be mentioned under Acknowledgements.

Please note that it is a requirement to include email addresses for all co-authors at submission. If any of the email-addresses supplied are incorrect the corresponding author will be contacted by the journal administrator.

Acknowledgements: Under acknowledgements please specify contributors to the article other than the authors accredited.

2.2. Ethical Approvals

Experimentation involving human subjects will only be published if such research has been conducted in full accordance with ethical principles, including the World Medical Association Declaration of Helsinki (version 2008) and the additional requirements, if any, of the country where the research has been carried out. Manuscripts must be accompanied by a statement that the experiments were

undertaken with the understanding and written consent of each subject and according to the above-mentioned principles. A statement regarding the fact that the study has been independently reviewed and approved by an ethical board should also be included.

When experimental animals are used the methods section must clearly indicate that adequate measures were taken to minimize pain or discomfort. Experiments should be carried out in accordance with the Guidelines laid down by the National Institute of Health (NIH) in the USA regarding the care and use of animals for experimental procedures or with the European Communities Council Directive of 24 November 1986 (86/609/EEC) and in accordance with local laws and regulations.

All studies using human or animal subjects should include an explicit statement in the Material and Methods section identifying the review and ethics committee approval for each study, if applicable. Editors reserve the right to reject papers if there is doubt as to whether appropriate procedures have been used.

2.3 Clinical Trials

Clinical trials should be reported using the CONSORT guidelines available at www.consort-statement.org. A CONSORT checklist should also be included in the submission material.

Journal of Clinical Periodontology encourages authors submitting manuscripts reporting from a clinical trial to register the trials in any of the following free, public clinical trials registries: www.clinicaltrials.gov, http://clinicaltrials.ifpma.org/clinicaltrials/, http://isrctn.org/. The clinical trial registration number and name of the trial register will then be published with the paper.

2.4 DNA Sequences and Crystallographic Structure Determinations

Papers reporting protein or DNA sequences and crystallographic structure determinations will not be accepted without a GenBank or Brookhaven accession number, respectively. Other supporting data sets must be made available on the publication date from the authors directly.

2.5 Conflict of Interest and Source of Funding

Journal of Clinical Periodontology requires that all authors (both the corresponding author and co-authors) disclose any potential sources of conflict of interest. Any interest or relationship, financial or otherwise that might be perceived as influencing an author's objectivity is considered a potential source of conflict of interest. These must be disclosed when directly relevant or indirectly related to the work that the authors describe in their manuscript. Potential sources of conflict of interest include but are not limited to patent or stock ownership, membership of a company board of directors, membership of an advisory board or committee for a company, and consultancy for or receipt of speaker's fees from a company. If authors are unsure whether a past or present affiliation or relationship should be disclosed in the manuscript, please contact the editorial office at cpeedoffice@wiley.com. The existence of a conflict of interest does not preclude publication in this journal.

The above policies are in accordance with the Uniform Requirements for Manuscripts Submitted to Biomedical Journals produced by the International Committee of Medical Journal Editors (http://www.icmje.org/). It is the responsibility of the corresponding author to have all authors of a manuscript fill out a conflict of interest disclosure form, and to upload all forms together with the manuscript on submission. The disclosure statement should be included under Acknowledgements. Please find the form below:

Conflict of Interest Disclosure Form

2.6 Appeal of Decision

Under exception circumstances, authors may appeal the editorial decision. Authors who wish to appeal the decision on their submitted paper may do so by e-mailing the editorial office at cpeedoffice@wiley.com with a detailed explanation for why they find reasons to appeal the decision.

Please note that all revisions and resubmissions of papers should also include a separate rebuttal and a tracked changes document to assist in peer review.

2.7 Permissions

If all or parts of previously published illustrations are used, permission must be obtained from the copyright holder concerned. It is the author's responsibility to obtain these in writing and provide copies to the Publishers.

3. MANUSCRIPT SUBMISSION PROCEDURE

Manuscripts should be submitted electronically via the online submission site http://mc.manuscriptcentral.com/jcpe. The use of an online submission and peer review site enables immediate distribution of manuscripts and consequentially speeds up the review process. It also allows authors to track the status of their own manuscripts. Complete instructions for submitting a paper is available on the submission site. Further assistance can be obtained from the Senior Editorial Office Assistant, Kim Harris, at cpeedoffice@wiley.com.

Please note that all revisions and resubmissions of papers should also include a separate rebuttal and a tracked changes document to assist in peer review.

3.1. Manuscript Files Accepted

Main manuscripts should be uploaded as Word (.doc) or Rich Text Format (.rft) files (not write-protected). The text file must contain the entire manuscript including title page, abstract, clinical reference, main text, references, acknowledgement, statement of source of funding and any potential conflict of interest, tables, and figure legends, but no embedded figures. In the text, please reference any figures as for instance 'Figure 1', 'Figure 2' etc. to match the tag name you choose for the individual figure files uploaded.

Figure files should be uploaded separately to the main text. GIF, JPEG, PICT or Bitmap files are acceptable for submission, but only high-resolution TIF or EPS files are suitable for printing.

Manuscripts should be formatted as described in the Author Guidelines below.

Please ensure that ALL items (figures and tables) are cited in the main text.

3.2. Blinded Review

All manuscripts submitted to Journal of Clinical Periodontology will be reviewed by two or more experts in the field. Papers that do not conform to the general aims and scope of the journal will, however, be returned immediately without review.

Journal of Clinical Periodontology uses single blinded review. The names of the reviewers will thus not be disclosed to the author submitting a paper.

3.3. Suggest a Reviewer

Journal of Clinical Periodontology attempts to keep the review process as short as possible to enable rapid publication of new scientific data. In order to facilitate this process, please suggest the name and current email address of one potential international reviewer whom you consider capable of reviewing your manuscript. In addition to your choice the editor will choose one or two reviewers as well.

3.4. Suspension of Submission Mid-way in the Submission Process

You may suspend a submission at any phase before clicking the 'Submit' button and save it to submit later. The manuscript can then be located under 'Unsubmitted Manuscripts' and you can click on 'Continue Submission' to continue your submission when you choose to.

3.5. E-mail Confirmation of Submission

After submission you will receive an e-mail to confirm receipt of your manuscript. If you do not receive the confirmation e-mail after 24 hours, please check your e-mail address carefully in the system. If the e-mail address is correct please contact your IT department. The error may be caused by some sort of spam filtering on your e-mail server. Also, the e-mails should be received if the IT department adds our e-mail server (uranus.scholarone.com) to their whitelist.

3.6 Resubmissions

If your manuscript was given the decision of reject and resubmit, you might choose to submit an amended version of your manuscript. This should be submitted as a new submission following the guidelines above under 3.2. In addition you should upload comments to the previous review as “supplementary files for review”.

4. MANUSCRIPT TYPES ACCEPTED

Journal of Clinical Periodontology publishes original research articles, reviews, clinical innovation reports and case reports. The latter will be published only if they provide new fundamental knowledge and if they use language understandable to

the clinician. It is expected that any manuscript submitted represents unpublished original research.

Original Research Articles must describe significant and original experimental observations and provide sufficient detail so that the observations can be critically evaluated and, if necessary, repeated. Original articles will be published under the heading of clinical periodontology, implant dentistry or pre-clinical sciences and must conform to the highest international standards in the field.

Clinical Innovation Reports are suited to describe significant improvements in clinical practice such as the report of a novel surgical technique, a breakthrough in technology or practical approaches to recognized clinical challenges. They should conform to the highest scientific and clinical practice standards.

Case Reports illustrating unusual and clinically relevant observations are acceptable but their merit needs to provide high priority for publication in the Journal. On rare occasions, completed cases displaying non-obvious solutions to significant clinical challenges will be considered.

Reviews are selected for their broad general interest; all are refereed by experts in the field who are asked to comment on issues such as timeliness, general interest and balanced treatment of controversies, as well as on scientific accuracy. Reviews should take a broad view of the field rather than merely summarizing the authors´ own previous work, so extensive citation of the authors´ own publications is discouraged. The use of state-of-the-art evidence-based systematic approaches is expected. Reviews are frequently commissioned by the editors and, as such, authors are encouraged to submit a proposal to the Journal. Review proposals should include a full-page summary of the proposed contents with key references.

5. MANUSCRIPT FORMAT AND STRUCTURE

5.1. Format

Language: The language of publication is English. Authors for whom English is a second language may choose to have their manuscript professionally edited before submission to improve the English. It is preferred that manuscript is professionally edited. Please refer to English Language Editing Services offered by Wiley at http://wileyeditingservices.com/en/.

Japanese authors can also find a list of local English improvement services at http://www.wiley.co.jp/journals/editcontribute.html. All services are paid for and arranged by the author, and use of one of these services does not guarantee acceptance or preference for publication.

Abbreviations, Symbols and Nomenclature: Journal of Clinical Periodontology adheres to the conventions outlined in Units, Symbols and Abbreviations: A Guide for Medical and Scientific Editors and Authors. Abbreviations should be kept to a minimum, particularly those that are not standard. Non-standard abbreviations must be used three or more times and written out completely in the text when first used.

5.2. Structure

All articles submitted to Journal of Clinical Periodontology should include:

Title Page

Conflict of Interest and Source of Funding

Clinical Relevance

Abstract

Introduction

Materials and Methods

Results

Discussion

References

Tables (where appropriate)

Figure Legends (where appropriate)

Figures (where appropriate and uploaded as separate files)

All manuscripts should emphasize clarity and brevity. Authors should pay special attention to the presentation of their findings so that they may be communicated

clearly. Technical jargon should be avoided as much as possible and be clearly explained where its use is unavoidable.

Title Page: The title must be concise and contain no more than 100 characters including spaces. The title page should include a running title of no more than 40 characters; 5-10 key words, complete names of institutions for each author, and the name, address, telephone number, fax number and e-mail address for the corresponding author.

Conflict of Interest and Source of Funding: Authors are required to disclose all sources of institutional, private and corporate financial support for their study. Suppliers of materials (for free or at a discount from current rates) should be named in the source of funding and their location (town, state/county, country) included. Other suppliers will be identified in the text. If no funding has been available other than that of the author's institution, this should be specified upon submission. Authors are also required to disclose any potential conflict of interest. These include financial interests (for example patent, ownership, stock ownership, consultancies, speaker's fee,) or provision of study materials by their manufacturer for free or at a discount from current rates. Author's conflict of interest (or information specifying the absence of conflicts of interest) and the sources of funding for the research will be published under a separate heading entitled "Conflict of Interest and Source of Funding Statement".

See Editor-in-Chief Maurizio Tonetti's Editorial on Conflict of Interest and Source of Funding and www.icmje.org/#conflicts for generally accepted definitions.

Abstract: is limited to 200 words in length and should not contain abbreviations or references. The abstract should be organized according to the content of the paper.

For Original Research Articles the abstract should be organized with aim, materials and methods, results and conclusions.

For clinical trials, it is encouraged that the abstract finish with the clinical trial registration number on a free public database such as clinicaltrials.gov.

Clinical Relevance: This section is aimed at giving clinicians a reading light to put the present research in perspective. It should be no more than 100 words and should not be a repetition of the abstract. It should provide a clear and concise explanation of the rationale for the study, of what was known before and of how the present results advance knowledge of this field. If appropriate, it may also contain suggestions for clinical practice.

It should be structured with the following headings: scientific rationale for study, principal findings, and practical implications.

Authors should pay particular attention to this text as it will be published in a highlighted box within their manuscript; ideally, reading this section should leave clinicians wishing to learn more about the topic and encourage them to read the full article.

Acknowledgements: Under acknowledgements please specify contributors to the article other than the authors accredited.

5.3. Original Research Articles

These must describe significant and original experimental observations and provide sufficient detail so that the observations can be critically evaluated and, if necessary, repeated. Original articles will be published under the heading of clinical periodontology, implant dentistry or pre-clinical sciences and must conform to the highest international standards in the field.

The word limit for original research articles is 3500 words, and up to 7 items (figures and tables) may be included. Additional items can be included as supplementary files online (please see 5.9 below).

Main Text of Original Research Articles should be organized with

Introduction,

Materials and Methods,

Results and Discussion.

References (Harvard, see section 5.7)

The background and hypotheses underlying the study, as well as its main conclusions, should be clearly explained. Please see Sample Manuscript.

Introduction: should be focused, outlining the historical or logical origins of the study and not summarize the results; exhaustive literature reviews are not appropriate. It should close with the explicit statement of the specific aims of the investigation.

Material and Methods: must contain sufficient detail such that, in combination with the references cited, all clinical trials and experiments reported can be fully reproduced. As a condition of publication, authors are required to make materials and methods used freely available to academic researchers for their own use. This includes antibodies and the constructs used to make transgenic animals, although not the animals themselves.

Clinical trials should be reported using the CONSORT guidelines available at www.consort-statement.org. A CONSORT checklist should also be included in the submission material. If your study is a randomized clinical trial, you will need to fill in all sections of the CONSORT Checklist. If your study is not a randomized trial, not all sections of the checklist might apply to your manuscript, in which case you simply fill in N/A.

Journal of Clinical Periodontology encourages authors submitting manuscripts reporting from a clinical trial to register the trials in any of the following free, public clinical trials registries: www.clinicaltrials.gov, http://clinicaltrials.ifpma.org/clinicaltrials/. The clinical trial registration number and name of the trial register will then be published with the paper.

(b) Statistical Analysis: As papers frequently provide insufficient detail as to the performed statistical analyses, please describe with adequate detail. For clinical trials intention to treat analyses are encouraged (the reasons for choosing other types of analysis should be highlighted in the submission letter and clarified in the manuscript).

(c) DNA Sequences and Crystallographic Structure Determinations: Papers reporting protein or DNA sequences and crystallographic structure determinations will not be accepted without a Genbank or Brookhaven accession number, respectively. Other supporting data sets must be made available on the publication date from the authors directly.

(d) Experimental Subjects: Experimentation involving human subjects will only be published if such research has been conducted in full accordance with ethical principles, including the World Medical Association Declaration of Helsinki (version 2008) and the additional requirements, if any, of the country where the research has been carried out. Manuscripts must be accompanied by a statement that the experiments were undertaken with the understanding and written consent of each subject and according to the above mentioned principles. A statement regarding the fact that the study has been independently reviewed and approved by an ethical board should also be included.

When experimental animals are used the methods section must clearly indicate that adequate measures were taken to minimize pain or discomfort. Experiments should be carried out in accordance with the Guidelines laid down by the National Institute of Health (NIH) in the USA regarding the care and use of animals for experimental procedures or with the European Communities Council Directive of 24 November 1986 (86/609/EEC) and in accordance with local laws and regulations.

All studies using human or animal subjects should include an explicit statement in the Material and Methods section identifying the review and ethics committee approval for each study, if applicable. Editors reserve the right to reject papers if there is doubt as to whether appropriate procedures have been used.

Results: should present the observations with minimal reference to earlier literature or to possible interpretations.

Discussion: may usefully start with a brief summary of the major findings, but repetition of parts of the abstract or of the results section should be avoided. The discussion section should end with a brief conclusion and a comment on the potential clinical relevance of the findings. Statements and interpretation of the data should be appropriately supported by original references.

The discussion may usefully be structured with the following points in mind (modified from the proposal by Richard Horton (2002), The Hidden Research Paper, The Journal of the American Medical Association, 287, 2775-2778). Not all points will apply to all studies and its use is optional, but we believe it will improve the discussion section to keep these points in mind.

Summary of key finding

* Primary outcome measure(s)

* Secondary outcome measure(s)

* Results as they relate to a prior

hypothesis Strengths and Limitations of

the Study

* Study Question

* Study Design

* Data Collection

* Analysis

* Interpretation

* Possible effects of bias on outcomes

Interpretation and Implications in the Context of the Totality of Evidence

* Is there a systematic review to refer to?

* If not, could one be reasonably done here and now?

* What this study adds to the available evidence

* Effects on patient care and health policy

* Possible mechanisms

Controversies Raised by This Study Future Research Directions

* For this particular research collaboration

* Underlying mechanisms

* Clinical research

5.4. Clinical Innovation Reports

These are suited to describe significant improvements in clinical practice such as the report of a novel surgical technique, a breakthrough in technology or practical approaches to recognized clinical challenges. They should conform to the highest scientific and clinical practice standards.

The word limit for clinical innovation reports is 3000 words, and up to 12 items (figures and tables) may be included. Additional items can be included as supplementary files online (please see 5.9 below).

The main text of Clinical Innovation Reports should be organized with

Introduction,

Clinical Innovation Report,

Discussion and Conclusion

References (see section 5.7)

5.5. Case Reports

Case reports illustrating unusual and clinically relevant observations are acceptable but their merit needs to provide high priority for publication in the Journal. On rare occasions, completed cases displaying non-obvious solutions to significant clinical challenges will be considered.

The main text of Case Reports should be organized with

Introduction,

Case report,

Discussion and Conclusion

References (see section 5.7)

5.6. Reviews

Reviews are selected for their broad general interest; all are refereed by experts in the field who are asked to comment on issues such as timeliness, general interest and balanced treatment of controversies, as well as on scientific accuracy. Reviews should take a broad view of the field rather than merely summarizing the authors´ own previous work, so extensive citation of the authors´ own publications is discouraged. The use of state-of-the-art evidence-based systematic approaches is expected. Reviews are frequently commissioned by the editors and, as such, authors are encouraged to submit a proposal to the Journal. Review proposals should include a full-page summary of the proposed contents with key references.

The word limit for reviews is 4000 words.

The main text of Reviews should be organized with

Introduction,

Review of Current Literature,

Discussion and Conclusion

References (see section 5.7)

5.7. References

It is the policy of the Journal to encourage reference to the original papers rather than to literature reviews. Authors should therefore keep citations of reviews to the absolute minimum.

References should be prepared according to the Publication Manual of the American Psychological Association (6th edition). This means in text citations should follow the author-date method whereby the author's last name and the year of publication for the source should appear in the text, for example, (Jones, 1998). The complete reference list should appear alphabetically by name at the end of the paper.

A sample of the most common entries in reference lists appears below. Please note that a DOI should be provided for all references where available. For more information about APA referencing style, please refer to the APA FAQ. Please note

that for journal articles, issue numbers are not included unless each issue in the volume begins with page one.

Journal article

Beers, S. R. , & De Bellis, M. D. (2002). Neuropsychological function in children with maltreatment-related posttraumatic stress disorder. The American Journal of Psychiatry, 159, 483–486. doi:10.1176/appi.ajp.159.3.483

Book

Bradley-Johnson, S. (1994). Psychoeducational assessment of students who are visually impaired or blind: Infancy through high school (2nd ed.). Austin, TX: Pro-ed.

Chapter in an Edited Book

Borstrøm, I., & Elbro, C. (1997). Prevention of dyslexia in kindergarten: Effects of phoneme awareness training with children of dyslexic parents. In C. Hulme & M. Snowling (Eds.), Dyslexia: Biology, cognition and intervention (pp. 235–253). London: Whurr.

Internet Document

Norton, R. (2006, November 4). How to train a cat to operate a light switch [Video file]. Retrieved from http://www.youtube.com/watch?v=Vja83KLQXZs

Please note that all unpublished papers (submitted or in press) included in the reference list should be provided in a digital version at submission. The unpublished paper should be uploaded as a supplementary file for review.

5.8. Tables, Figures and Figure Legends

Tables: should be double-spaced with no vertical rulings, with a single bold ruling beneath the column titles. Units of measurements must be included in the column title.

Figures: All figures should be planned to fit within either 1 column width (8.0 cm), 1.5 column widths (13.0 cm) or 2 column widths (17.0 cm) and must be suitable for photocopy reproduction from the printed version of the manuscript. Lettering on

figures should be in a clear, sans serif typeface (e.g. Helvetica); if possible, the same typeface should be used for all figures in a paper. After reduction for publication, upper-case text and numbers should be at least 1.5-2.0 mm high (10 point Helvetica). After reduction symbols should be at least 2.0-3.0 mm high (10 point). All half-tone photographs should be submitted at final reproduction size. In general, multi-part figures should be arranged as they would appear in the final version. Each copy should be marked with the figure number and the corresponding author's name. Reduction to the scale that will be used on the page is not necessary, but any special requirements (such as the separation distance of stereo pairs) should be clearly specified.

Unnecessary figures and parts (panels) of figures should be avoided: data presented in small tables or histograms, for instance, can generally be stated briefly in the text instead. Figures should not contain more than one panel unless the parts are logically connected; each panel of a multipart figure should be sized so that the whole figure can be reduced by the same amount and reproduced on the printed page at the smallest size at which essential details are visible.

Figures should be on a white background, and should avoid excessive boxing, unnecessary color, shading and/or decorative effects (e.g. 3-dimensional skyscraper histograms) and highly pixelated computer drawings. The vertical axis of histograms should not be truncated to exaggerate small differences. The line spacing should be wide enough to remain clear on reduction to the minimum acceptable printed size. Figures divided into parts should be labelled with a lower-case, boldface, roman letter, a, b, and so on, in the same type size as used elsewhere in the figure. Lettering in figures should be in lower-case type, with the first letter capitalized. Units should have a single space between the number and the unit and follow SI nomenclature or the nomenclature common to a particular field. Thousands should be separated by thin spaces (1 000). Unusual units or abbreviations should be spelled out in full or defined in the legend. Scale bars should be used rather than magnification factors, with the length of the bar defined in the legend rather than on the bar itself. In general, visual cues (on the figures themselves) are preferred to verbal explanations in the legend (e.g. broken line, open red triangles etc.)

Preparation of Electronic Figures for Publication

Although low quality images are adequate for review purposes, print publication requires high quality images to prevent the final product being blurred or fuzzy. Submit EPS (lineart) or TIFF (halftone/photographs) files only. MS PowerPoint and Word Graphics are unsuitable for printed pictures. Do not use pixel-oriented programmes. Scans (TIFF only) should have a resolution of 300 dpi (halftone) or 600 to 1200 dpi (line drawings) in relation to the reproduction size (see below). EPS files should be saved with fonts embedded (and with a TIFF preview if possible). For scanned images, the scanning resolution (at final image size) should be as follows to ensure good reproduction: lineart: >600 dpi; half-tones (including gel photographs): >300 dpi; figures containing both halftone and line images: >600 dpi.

Detailed information on our digital illustration standards can be found at http://authorservices.wiley.com/bauthor/illustration.asp.

Check your electronic artwork before submitting it: http://authorservices.wiley.com/bauthor/eachecklist.asp.

Guidelines for Cover Submission

If you would like to send suggestions for artwork related to your manuscript to be considered to appear on the cover of the journal, please follow these guidelines.

Permissions: If all or parts of previously published illustrations are used, permission must be obtained from the copyright holder concerned. It is the author's responsibility to obtain these in writing and provide copies to the Publishers.

Figure Legends: should be a separate section of the manuscript and should begin with a brief title for the whole figure and continue with a short description of each panel and the symbols used; they should not contain any details of methods.

5.9. Supplementary Material

Supplementary material, such as data sets or additional figures or tables that will not be published in the print edition of the Journal but which will be viewable in the

online edition, can be uploaded as 'Supporting information for review and online publication only'.

Please see http://authorservices.wiley.com/bauthor/suppmat.asp for further information on the submission of Supplementary Materials.

6. AFTER ACCEPTANCE

Upon acceptance of a paper for publication, the manuscript will be forwarded to the Production Editor who is responsible for the production of the journal.

6.1 Proof Corrections

The corresponding author will receive an email alert containing a link to a web site. A working email address must therefore be provided for the corresponding author. The proof can be downloaded as a PDF (portable document format) file from this site. Acrobat Reader will be required in order to read this file. This software can be downloaded (free of charge) from the following Web site: www.adobe.com/products/acrobat/readstep2.html . This will enable the file to be opened, read on screen, and printed out in order for any corrections to be added. Further instructions will be sent with the proof. Hard copy proofs will be posted if no e-mail address is available; in your absence, please arrange for a colleague to access your e-mail to retrieve the proofs. Proofs must be returned to the Production Editor within three days of receipt. As changes to proofs are costly, we ask that you only correct typesetting errors. Excessive changes made by the author in the proofs, excluding typesetting errors, will be charged separately. Other than in exceptional circumstances, all illustrations are retained by the publisher. Please note that the author is responsible for all statements made in his work, including changes made by the copy editor.

6.2 Early View (Publication Prior to Print)

The Journal of Clinical Periodontology is covered by Wiley-Blackwell's Early View service. Early View articles are complete full-text articles published online in advance of their publication in a printed issue. Early View articles are complete and final. They have been fully reviewed, revised and edited for publication, and the authors' final corrections have been incorporated. Because they are in final

form, no changes can be made after online publication. The nature of Early View articles means that they do not yet have volume, issue or page numbers, so Early View articles cannot be cited in the traditional way. They are therefore given a Digital Object Identifier (DOI), which allows the article to be cited and tracked before it is allocated to an issue. After print publication, the DOI remains valid and can continue to be used to cite and access the article.

6.3 Production Tracking

Online production tracking is available for your article once it is accepted by registering with Wiley-Blackwell's Author Services.

6.4 Accepted Articles

'Accepted Articles' have been accepted for publication and undergone full peer review but have not been through the copyediting, typesetting, pagination and proofreading process. Accepted Articles are published online a few days after final acceptance, appear in PDF format only (without the accompanying full-text HTML) and are given a Digital Object Identifier (DOI), which allows them to be cited and tracked. The DOI remains unique to a given article in perpetuity. More information about DOIs can be found online at http://www.doi.org/faq.html. Given that Accepted Articles are not considered to be final, please note that changes will be made to an article after Accepted Article online publication, which may lead to differences between this version and the Version of Record. The Accepted Articles service has been designed to ensure the earliest possible circulation of research papers after acceptance. Given that copyright licensing is a condition of publication, a completed copyright form is required before a manuscript can be processed as an Accepted Article.

Accepted articles will be indexed by PubMed; therefore the submitting author must carefully check the names and affiliations of all authors provided in the cover page of the manuscript, as it will not be possible to alter these once a paper is made available online in Accepted Article format.

6.5 Video Abstracts

Bring your research to life by creating a video abstract for your article! Wiley partners with Research Square to offer a service of professionally produced video abstracts. Learn more about video abstracts at www.wileyauthors.com/videoabstracts and purchase one for your article at https://www.researchsquare.com/wiley/ or through your Author Services Dashboard. If you have any questions, please direct them to videoabstracts@wiley.com.

7. OnlineOpen

OnlineOpen is available to authors of primary research articles who wish to make their article available to non-subscribers on publication, or whose funding agency requires grantees to archive the final version of their article. With Online Open, the author, the author's funding agency, or the author's institution pays a fee to ensure that the article is made available to non-subscribers upon publication via Wiley Online Library, as well as deposited in the funding agency's preferred archive. For the full list of terms and conditions, see

http://wileyonlinelibrary.com/onlineopen#OnlineOpen_Terms

Prior to acceptance there is no requirement to inform an Editorial Office that you intend to publish your paper Online Open if you do not wish to. All Online Open articles are treated in the same way as any other article. They go through the journal's standard peer-review process and will be accepted or rejected based on their own merit.

8. Copyright Assignment

If your paper is accepted, the author identified as the formal corresponding author for the paper will receive an email prompting them to login into Author Services; where via the Wiley Author Licensing Service (WALS) they will be able to complete the license agreement on behalf of all authors on the paper.

For authors signing the copyright transfer agreement

If the Online Open option is not selected the corresponding author will be presented with the copyright transfer agreement (CTA) to sign. The terms and

conditions of the CTA can be previewed in the samples associated with the Copyright FAQs below:

CTA Terms and Conditions:

http://authorservices.wiley.com/bauthor/faqs_copyright.asp

For authors choosing Online Open

If the Online Open option is selected the corresponding author will have a choice of the following Creative Commons License Open Access Agreements (OAA):

Creative Commons Attribution Non-Commercial License OAA

Creative Commons Attribution Non-Commercial -NoDerivs License OAA

To preview the terms and conditions of these open access agreements please visit the

Copyright FAQs hosted on Wiley Author Services

http://authorservices.wiley.com/bauthor/faqs_copyright.asp and visit http://www.wileyopenaccess.com/details/content/12f25db4c87/Copyright--License.html.

If you select the OnlineOpen option and your research is funded by The Welcome Trust and members of the Research Councils UK (RCUK) you will be given the opportunity to publish your article under a CC-BY license supporting you in complying with Welcome Trust and Research Councils UK requirements. For more information on this policy and the Journal's compliant self archiving policy please visit: http://www.wiley.com/go/funderstatement.

For RCUK and Welcome Trust authors click on the link below to preview the terms and conditions of this license:

Creative Commons Attribution License OAA

To preview the terms and conditions of these open access agreements please visit the

Copyright FAQs hosted on Wiley Author Services

Subsequently the final copyedited and proofed articles will appear either as Early View articles in a matter of weeks or in an issue on Wiley Online Library; the link to the article in PubMed will automatically be updated.