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Michel Luís Reckziegel

CORRELAÇÃO ENTRE PLACA E INFLAMAÇÃO GENGIVAL EM PACIENTES COM HISTÓRICO DE PERIODONTITE COM DIFERENTES INTERVALOS DE HIGIENE BUCAL

Santa Maria, RS
2018

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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 para obtenção do grau de **Mestre em Ciências Odontológicas.**

Orientadora: Profa. Dra. Karla Zanini Kantorski

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2018

DEDICATÓRIA

À Deus e a meu anjo da guarda "MÃE",
que guiam meu caminho, possibilitando todos os meus sonhos. A meu anjo, que de algum lugar se orgulha pelas minhas conquistas. Te amo mãe!!

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" A vida é muito curta para ser pequena. "

(Benjamin Disraeli)

RESUMO

CORRELAÇÃO ENTRE PLACA E INFLAMAÇÃO GENGIVAL EM PACIENTES COM HISTÓRICO DE PERIODONTITE COM DIFERENTES INTERVALOS DE HIGIENE BUCAL

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Avaliar a correlação entre a formação de placa dental e os parâmetros gengivais em indivíduos com história periodontal que realizam higiene bucal de alto padrão em diferentes intervalos. Quarenta e dois indivíduos com história de periodontite foram randomizados para diferentes frequências de autocontrole de placa: 12, 24 e 48 horas (G12, G24 e G48). O Índice de Placa (IPl) e o Índice Gengival (IG) foram avaliados no início do estudo, 15, 30 e 90 dias. As diferenças intragrupos foram determinadas usando ANOVA para medidas repetidas. As diferenças intergrupos no início do estudo foram verificadas usando um teste qui-quadrado e teste t independente. O coeficiente de correlação de Spearman entre IPl e IG para os diferentes grupos foi calculado no início do estudo, 15, 30 e 90 dias. Correlações positivas, estatisticamente significantes, foram encontradas entre o IPl e IG em todos os grupos e aumentaram durante o período experimental, início do estudo ρ:(G12 = 0,18, G24 = 0,08 e G48 = 0,15), dia 15 ρ:(G12 = 0,25, G24 = 0,13 e G48 = 0,23), dia 30 ρ:(G12 = 0,23, G24 = 0,18 e G48 = 0,26) e dia 90 do estudo ρ:(G12 = 0,28, G24 = 0,18 e G48 = 0,21). Todos os grupos tiveram um aumento nas médias de IPV e ISG entre o início do estudo e 90 dias. No G48, houveram os maiores aumentos de IPV e ISG durante o estudo. No G12, as porcentagens de IG 1 mantiveram-se estáveis, em contraste com o aumento observado nos valores do IG 2. No G24, as maiores migrações de IPl e IG foram os escores 0 e 1. Entretanto, no G48, houve um aumento significativo nos escores IG 1 e 2, chegando ao final do estudo com a maioria dos sítios com escores de IPl 2 (39,2%). Na avaliação de indivíduos com história periodontal, com diferentes frequências, com elevados padrões de higiene bucal, com baixos índices de sangramento e seguindo um protocolo estruturado e monitorado, concluímos que a correlação entre a formação de placa e as alterações gengivais é fraca e que a frequência de higiene bucal altera os parâmetros gengivais. Assim, indivíduos que realizam altos padrões de higiene em intervalos diários de 12h e 24h, manterão a saúde gengival quando comparados com indivíduos que usam intervalos de higiene maiores que 24 horas.

Palavras-chave: Doenças periodontais. Gengivite. Placa dental. Escovação. Correlação

ABSTRACT

CORRELATIONS BETWEEN PLAQUE AND GINGIVAL INFLAMATION IN PATIENTS WITH PERIODONTITIS HISTORY USING DIFFERENT OF ORAL HYGIENE INTERVALS

AUTHOR: Michel Luís Reckziegel
ADVISOR: Karla Zanini Kantorski

To evaluate the correlation between dental plaque formation and gingival parameters in individuals with periodontal history who perform high standard oral hygiene at different intervals. Forty-two individuals with a history of periodontitis were randomized to different frequencies of self-control plaques: 12, 24 and 48 hours (G12, G24 and G48). Plate Index (PII) and Gingival Index (GI) were assessed at baseline, 15, 30 and 90 days. Intragroup differences were determined using repeated measures ANOVA. Intergroup differences at baseline were verified using a chi-square test and independent t-test. The Spearman correlation coefficient between PII and GI for the different groups was calculated at baseline, 15, 30 and 90 days. Positive, statistically significant correlations were found between PII and GI in all groups and increased during the experimental period, baseline (G12 = 0.18, G24 = 0.08 and G48 = 0.15), day 15 (G12 = 0.25, G24 = 0.13 and G48 = 0.23), day 30 (G12 = 0.23, G24 = 0.18 and G48 = 0.26) and day 90 of the study (G12 = 0.28, G24 = 0.18 and G48 = 0.21). All groups had an increase in the means of visible plaque and gingival bleeding between the beginning of the study and 90 days. In G48, there were the largest increases in Visible Plaque and Gingival Bleeding during the study. In G12, the percentages of IG 1 remained stable, in contrast to the increase observed in IG 2 values. In G24, the highest IGI and IG migrations were scores 0 and 1. However, in G48, there was an increase significant in the IG 1 and 2 scores, reaching the end of the study with the majority of sites with PII 2 scores (39.2%). In the evaluation of individuals with periodontal history, with different frequencies, with high standards of oral hygiene, with low bleeding rates and following a structured and monitored protocol, we conclude that the correlation between plaque formation and gingival alterations is weak and that frequency of oral hygiene changes the gingival parameters. Thus, individuals who perform high hygiene standards at daily intervals of 12h and 24h will maintain gum health when compared to individuals who use hygiene intervals longer than 24 hours.

Keywords: Periodontal diseases. Gingivitis. Dental plaque. Brushing. Correlation

SUMÁRIO

1 INTRODUÇÃO

A gengivite induzida pela placa é uma inflamação causada pelo acúmulo de microrganismos na margem gengival (MARIOTTI, 1999). A etiologia bacteriana da gengivite foi estabelecida por Löe et al., 1965. Neste estudo, o acúmulo de placa sobre a gengiva saudável produziu gengivite entre 10 a 21 dias e a restituição dos procedimentos de higiene bucal por 7 a 10 dias reestabeleceu saúde gengival. Dados epidemiológicos mostram alta prevalência de gengivite na população adulta de países desenvolvidos e em desenvolvimento (LI et al., 2010; MINISTÉRIO DA SAÚDE, 2011), além de ser o tipo mais frequente de doença periodontal (PAGE; BAAB, 1985).

Os sinais clínicos são restritos à gengiva e são reversíveis com a remoção do fator etiológico sem qualquer prejuízo ao periodonto de suporte (MARIOTTI, 1999). Além das repercussões locais, a condição gengival produz impacto na qualidade de vida. 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 pode reduzir indiretamente a perda dentária.

Algumas diferenças no acúmulo de placa podem ser explicadas por fatores relacionados ao hospedeiro ou hábitos praticados pelo próprio indivíduo, como o tipo de dieta, composição e acúmulo de saliva subgengival, presença ou ausência de inflamação subgengival, diferença nos receptores de fixação bacteriana nos tecidos e na formação da película adquirida no dente. Outro fator que pode influenciar a formação de biofilme pode ser a composição de microrganismos do próprio biofilme. (HAFFAJEE et al. 2009).

Existem evidências que o nível e a consistência das respostas do tecido gengival frente ao acúmulo de placa podem variar significantemente entre os indivíduos mesmo sem diferenças na qualidade e quantidade de placa. (ABBAS et al. 1986), sugerindo que as respostas estão relacionadas com características individuais, tais como fatores genéticos ou de origem ambiental. (ABBAS et al 1986, TATAKIS & TROMBELLI 2004, TROMBELLI, 2008). Trombelli et al. 2004 em um ensaio clínico

randomizado usando o modelo de gengivite experimental, demonstraram que indivíduos com similares acúmulos de placa apresentam respostas diferentes de inflamação gengival sendo classificados como “alta resposta” e “baixa resposta”.

De David et al. 2018, avaliaram a correlação entre acúmulo de placa (IPl) e inflamação gengival (IG) em indivíduos com saúde gengival e sem doença periodontal que realizaram higiene bucal efetiva em diferentes frequências durante 30 dias. Houve manutenção da correlação entre IP e IG ao longo desse período somente nos grupos G48 e G72, no qual o aumento na média de biofilme resultou em aumento na média de inflamação gengival. Nos grupos de G12 e G24, apesar da média de IP ter dobrado, ocorreu manutenção das médias de IG, e o coeficiente de correlação diminuiu em relação ao baseline. Dessa forma, o aumento nos níveis de biofilme não foi suficiente para modificar a condição inicial da gengiva em indivíduos que realizaram higiene bucal mais frequente de até 24h, que pode ser explicado devido ao tempo de sucessão microbiana não ter sido suficiente para formação de bactérias mais patogênicas.

A escovação manual é o método mais utilizado para controle de placa (VAN DER WEIJDEIN; SLOT, 2015) e responsável pela reversibilidade da gengivite/mucosite peri-implante. A efetividade desse procedimento depende da habilidade individual na remoção de placa e da frequência em que esta remoção é executada (JEPSEN, 1998). 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 (SLOT et al., 2012).

Dessa forma, não há evidência científica disponível sobre a correlação entre frequências de escovação, desorganização efetiva do biofilme e alterações clínicas gengivais em pacientes com histórico periodontal. Portanto, ressalta-se a importância de avaliar a correlação existente entre a condição gengival frente ao acúmulo de biofilme em pacientes com histórico periodontal que realizam higiene bucal em diferentes frequências.

2 ARTIGO - CORRELAÇÃO ENTRE PLACA E O ESTADO GENGIVAL EM PACIENTES COM HISTÓRICO DE PERIODONTITE COM DIFERENTES INTERVALOS DE HIGIENE BUCAL

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Correlations between plaque and gingival status in patients with periodontitis history using different of oral hygiene intervals

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Running title: Plaque control, gingival health and

Keywords: Dental plaque; periodontal diseases; gingivitis; oral hygiene, tooth brushing: periodontal history.

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Abstract

Aim: To evaluate the correlation between dental plaque formation and gingival parameters in individuals with periodontal history who perform high standard oral hygiene at different intervals.

Materials and Methods: Forty-two individuals with a history of periodontitis were randomized to different frequencies of self-control plaque: 12, 24, and 48 hours (G12, G24 and G48). Plate Index (PlI) and Gingival Index (GI) were evaluated at baseline, 15, 30 and 90 days. Intragroup differences were determined using repeated measures ANOVA. Intergroup differences at the baseline were verified using a chi-square test and independent t-test. The Spearman correlation coefficient between PlI and GI for different groups was calculated at baseline, 15, 30 and 90 days.

Results: Statistically significant positive correlations were found between PlI and GI in all groups and increased over the experimental period, baseline (G12 = 0.18, G24 = 0.08 and G48 = 0.15), day 15 (G12 = 0.25, G24 = 0.13 and G48 = 0.23), day 30 (G12 = 0.23, G24 = 0.18 and G48 = 0.26) and day 90 of the study (G12 = 0.28, G24 = 0.18 and G48 = 0.21). All groups had an increase in the means of Visible Plaque and Gingival Bleeding between the baseline and 90 days. In the G48, there were the highest increases in Visible Plaque and Gingival Bleeding during the study. In G12, percentages of GI 1 remained stable, in contrast to the increase observed in GI 2 values. In G24, the highest PlI and GI migrations were scores 0 and 1. However, in G48, there was a significant increase in GI scores 1 and 2, reaching the end of the study with the majority of sites with Pli 2 (39.2%).

Conclusions: In the evaluation of individuals with periodontal history, with high standards of oral hygiene, with low bleeding rates and following a structured and monitored protocol, we conclude that the correlation between plaque formation and gingival alterations is weak and that the frequency of oral hygiene alters the gingival parameters. Thus, individuals who perform high standards of hygiene at daily intervals will maintain gum health when compared to individuals who use prolonged hygiene intervals.

Clinical Relevance

Scientific rationale for study: The correlation between dental plaque accumulation and gingival health has already been established. However, the correlation between self-performed oral hygiene of high standard at different intervals in patients with periodontal history is not yet fully determined.

Principal findings: In individuals with periodontal history, with high standards of oral hygiene, the frequency of oral hygiene is related to the formation of dental plaque, which changes the stability of the gingival parameters.

Practical implications: Individuals with periodontal history who perform high standards of oral hygiene at daily intervals will maintain lower plaque and gingival scores in difference for individuals who use hygiene intervals longer than 24 hours.

Introduction

Plaque induced gingivitis is an inflammation caused by the accumulation of microorganisms in the gingival margin (Mariotti, 1999). Clinical signs are restricted to the gingiva and are reversible with the removal of the etiological factor without any damage to the support periodontium (Mariotti, 1999). However, gingivitis has been inplicated as a periodontitis precursor. Schatzle et al. 2003 showed that gingival health maintenance was associated with an average cumulative attachment loss less than 2 mm, while sites with gingivitis presented clinical attachment loss greater than 3 mm over 26 years. Lang et al. 2009 observed that teeth associated with inflamed gingiva had a significantly greater risk of tooth loss than teeth with healthy or slightly inflamed gums.

Gingivitis prevention and treatment included regular measures of oral hygiene, such as tooth brushing and interproximal approaches. The effectiveness of the oral hygiene depends on: 1) individual ability to remove plaque from all tooth surfaces; 2) and frequency. The American Dental Association (2015) recommend self-performed plaque control (SPPC) two twice a day to prevent caries and gingivitis, but the evidences that support this recommendation are limited (Chapple et al. 2015). We have demonstrated that SPPC adequate performed once daily is enough to prevent gingival status alterations for both, patients without (Pinto et al. 2013, de Freitas et al. 2016) and with (Mayer et al. 2018) periodontitis history.

Despite the association between dental plaque and gingivitis is well established by the studies of Loe and coworkers (1965), the correlation between plaque accumulation and gingival inflammation can be modulated by oral hygiene standard (De David et al. 2018) and by factors related to the host (Trombelli et al. 2004). Abbas et al. (1986) showed that the gingival response to plaque accumulation may vary between individuals without differences in both, quantity and quality of the plaque. De David and coworkers (2018) showed that in individuals with high standards of SPPC without periodontitis history, the oral hygiene frequency governed the correlation between plaque and gingival status.

Here, we proposed to study as the self-performed plaque control frequency affect the correlations between plaque and gingival status in individuals with periodontitis history. For this, we performed a randomized clinical trial.

Materials and Methods

Study Design

The present study was a secondary analysis of a single-masked, parallel-desing, randomized clinical trial.

Sample

Individuals with a history of periodontitis treated at the Periodontic Post-Graduation Clinic of the Federal University of Santa Maria (UFSM, Rio Grande do Sul, Brazil) and included in periodontal maintenance of the same institution were eligible. The individuals should present a minimum of 35 years of age, a history of periodontitis (loss of interproximal insertion ≥3 mm in two or more nonadjacent teeth) (Tonetti; Claffey, 2005), with at least 12 teeth in the mouth, in the maximum of 7.5% of sites with bleeding gingival (GI 2) and of 25% of sites with bleeding on probing (Lang and Tonetti, 2003). The following exclusion criteria were used: smoking, pregnancy, diabetes mellitus, xerostomia, psychomotor disturbances, orthodontic appliances, antibiotic/anti-inflammatory use within the previous 3 months. After informed consent, medical history and intra-oral screening exam was performed to verify the elegibility.
The sample size was calculated considering the primary outcome main study. The following parameters were used: mean significant difference of 10% of sites with gingival bleeding (score of 2 or 3 of the Gingival Index), standard deviation of 8.5%, significance level of 5%, power of 80, and attrition rate of 30%. The study was conducted between November 2015 and February 2018 at the Federal University of Santa Maria. A sample of 42 individuals, 14 per group, was estimated.

Randomization and experimental period

Eligible individuals were randomized in 3 experimental groups according to the frequency of SPPC: 12, 24 and 48 hours. A computer program (Random Allocation software, version 1.0, May 2004) was used to randomly allocate participants, and allocation concealment was achieved by sequentially numbered opaque envelopes. One researcher (C.S) provided

participantes with a printed schedule for SPPC and called the participants of the 48 hours group on days that oral hygiene was not scheduled.

Following enrollment, all participants answered to an interview and received coronary polishing with a rubber cup (Microdont®, São Paulo, Brazil) and abrasive past. Each individual received, free of charge, a kit containing: a soft toothbrush (Colgate® Twister® Compact Head, New York, USA), dental floss (Colgate®, tarpaulin, New York, USA), interproximal toothbrush (Bitufo®, São Paulo, Brazil), a tube of dentifrice containing only sodium fluoride (Colgate® Maximum Protection Anticaries®, 90g, New York, USA), and a flask containing fluoridated solution (sodium fluoride 0.05%) (Nova Derme, 1500 ml, Santa Maria, Brazil).

Individuals were instructed to apply the dentifrice so that its transversely covered the width of the toothbrushes bristles at point to standardize the amount of dentifrice used of each oral hygiene (± 0.5 g). Individuals also were oriented to use the fluoridated solution twice daily to provide oral freshness, with the objective to increase adhesion of individuals to the SPPC frequencies, especially in the 48-hour group.

At the end of study, the patients were advised to return their habitual oral hygiene frequency. The dentifrice tubes were weighed to assess compliance (Digital balance scale professional-mini, model 1480, Tania Corp., Japan).

Clinical Parameters

Plaque Index (PlI, Silness & Loe 1964) and Gingival Index (GI, Loe 1967), was evaluated in six sites per tooth at baseline, 15, 30 and 90 days. Clinical parameters were evaluated using millimeter periodontal probe (CP 15 UNC, Neumar, Brazil).

Clinical exams were performed immediately before the scheduled brushing so that the maximum plaque accumulation was evaluated. PlI was evaluated by one examiner (A.P.R). Then, each participant performed oral hygiene without supervision, and subsenquently, another examiner (J.M) evaluated the GI. Both, A.P.R and J.M were blinded for the experimental groups.

Statistical Analysis

Spearman correlation coefficient between PlI and GI for experimental groups was calculated at baseline, 15, 30 and 90 days. Descriptive analysis of age, sex, and clinical parameters at baseline was performed to describe the sample characteristics. Distribution frequency of scores of PlI and of GI was cauculated at baseline, 15, 30 and 90 days. Statistical analysis was performed using a statistical software (SPSS, version 21.0, Chicago, IL, USA). Significance level was set at 5%. The primary analysis of the study was the correlation between PlI and GI.

Ethical considerations

Eligible individuals will be clarified regarding the objectives, risks and benefits of the study, and other information contained in the Informed Consent Form (TCLE), if they accept, participants must sign the TCLE (Appendix A). This study was performed in accordance with the Declaration of Helsinki and was approved by the Ethics Committee in Research of Federal University of Santa Maria (CAAE:50208115.9.0000.5346) and registered in Clinical Trial (ID 50208115.9.0000.5346).

Results

In this study, 42 patients were investigated. A summary of sociodemographic data and patients' behavioral characteristics is described in Table 1. The mean age was 57.56 years, ranging from 49 to 68 years. Most patients have income of more than two minimum wages. The percentage of patients who reported oral brushing more than three times a day was 76.2%. The mean percentage of use of more than one interdental device was 69% of the sample.

The means of Visible Plaque Index (VPI) and Gingival Bleeding Index (GBI) are described in Table 2. All groups had an increase in the means of VPI and GBI between the baseline and 90 days. In the 48-hour group, there were the highest increases in VPI and GBI during the study.

The correlations between Plaque Index (PlI) and Gingival Index (GI) are described in Table 3. The PlI / GI correlations increased for all groups at baseline to 90 days. Baseline (G12 = 0.18, G24 = 0.08 and G48 = 0.15), day 15 (G12 = 0.25, G24 = 0.13 and G48 = 0.23), day 30 (G12 = 0.23, G24 = 0.18 and G48 = 0.26) and day 90 of the study (G12 = 0.28, G24 = 0.18 and G48 = 0.21). Figure 1 shows the fluctuations in PlI and GI scores throughout the study (baseline, 15,

30 and 90 days). In G12, the percentages of GI 1 remained stable, in contrast to the increase observed in the GI 2 values. In G24, the greatest migrations of PlI and GI were scores 0 and 1. However, in G48, a significant increase in GI scores 1 and 2, reaching the end of the study with most sites with PlI 2 (39.2%).

Discussion

This study evaluated the correlation between dental plaque formation and gingival parameters in patients with a history of periodontal disease who performed high standard dental hygiene at 12, 24 or 48 intervals over 90 days. All groups showed an increase in the correlation between PlI and GI. These findings agree with the findings of Haffajee et al. (2009), where a positive association between plaque accumulation and alteration in gingival parameters was observed. The proximity of the GBI values in the G12 / 24 group in the present study suggests that daily hygiene intervals did not allow sufficient time for microbial succession, however we had an increase in all GBI mean values of the groups, ending the experimental period with values to determine gingival health. Studies have shown that there is a change in the microbiota in 2 days of abstinence from oral hygiene and that gingival inflammation would be due to 4 to 9 days of maturation of microbial colonization (Theilade et al., 1966). Thus, in the G12 / 24 group, formation / maturation of effectively disorganized dental plaque every 12 or 24 hours provides plaque compatible with gingival health.

In contrast, prolonged oral hygiene intervals allow more complex bacterial colonization (Heller et al., 2016). As bacterial colonization is not subject to frequent disorganization, qualitative and quantitative changes favor pathogenic species (Haffajee et al., 2009, Teles et al., 2012), initiating a gingival inflammatory response. Thus, the G48 group presented the highest increases in the values of VPI and GBI. These results corroborate other recent studies that evaluated the necessary frequencies of oral hygiene to maintain gingival health, where the highest frequencies presented higher plaque values and higher gingival values (Pinto et al., 2013, De Freitas et al., 2016, De David, 2018). All of the aforementioned studies are composed of a sample of individuals with no history of periodontal disease.

Another important factor to consider is the individual susceptibility to develop gingival and periodontal changes, since the sample deals with patients with periodontal history, and may present individual variations in the gingival response, as well as anatomical differences that may favor plaque accumulation. Trombelli et al. (2004) found that in patients with no

periodontal history, variations in inflammatory responses to plaque accumulation varied from high or low response. Thus, even showing the highest values of VPI and GBI in G48, it was not enough to present the highest correlation values, which can be explained by individuals with different susceptibilities to gingival inflammation in relation to plaque accumulation and associated factors, such as factors genetics.

Mature microbial plaques that persist for long periods of time without interruption are not compatible with gingival health (Theilade et al., 1966). However, effective oral hygiene every 24-hours, represented by G24, presented the lowest values of VPI and GBI, representing the lowest values of correlation between the groups from the baseline up to 90 days. These findings strengthen that the adhesion of the patient with periodontal history to a 24-hour oral hygiene frequency is more accepted and sufficient to prevent the maturation of dental plaques and, therefore, to maintain the gingival parameters compatible with health.

In summary, in the evaluation of individuals with periodontal history, with high standards of oral hygiene, with low bleeding rates and following a structured and monitored protocol, we conclude that the correlation between plaque formation and gingival alterations is weak and that frequency of oral hygiene changes the gingival parameters. The results confirm that the quality of dental plaque disorganization must be associated to periodicity of oral hygiene for stability of gingival parameters in patients with periodontal history and low plaque indexes, limiting its external validity. Thus, individuals who perform high standards of hygiene at daily intervals will maintain gum health when compared to individuals using prolonged hygiene intervals.

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Tables

Table 1- Sociodemographic, behavioral and clinical characteristics in the baseline of the groups.

Parameter		**Group 12h (n=14)**	**Group 24h (n=14)**	**Group 48h (n=14)**	***P***
Age (mean ± SD)*		56.35±7.22	56.42±7.76	59.92±8.09	*0.38*
Gender n (%)#					*0.31*
Male		8(57.1)	4(28.6)	6(42.9)	
Female		6(42.9)	10(71.4)	8(57.1)	
Socioeconomic level n (%)#					
Monthly family income	≤ 1 Brazilian minimum salary	3(21.4)	2(14.3)	4(28.6)	*0.65*
	≥ 2 Brazilian minimum salary	11(78.6)	12(85.7)	10(71.4)	
Educational level	≤ 8 years	6 (42.9)	5(35.7)	7(50)	*0.74*
	> 8 years	8 (57.1)	9(64.3)	7(50)	
Behavioral n (%)#					
Daily brushing frequency	Up to 2	2(14.3)	5(35.7)	3(21.4)	*0.39*
	≥ 3 times	12(85.7)	9(64.3)	11(78.6)	
Interdental device frequency (*week)	Once*	-	1(7.15)	1(7.15)	*0.68*
	2-3 times*	3(21.4)	1(7.15)	2(14.3)	
	4-5 times*	1(7.15)	1(7.15)	-	
	Daily	7(50)	8(57.1)	5(35.7)	
	2 times day	2(14.2)	1(7.15)	1(7.15)	
	≥ 3 times day	1(7.15)	2(14.3)	5(35.7)	
Interdental Device type	Dental floss	2(14.3)	-	6(42.9)	*0.03*
	Interdental brush	3(21.4)	2(14.3)	-	
	More than one device	9(64.3)	12(85.7)	8(57.1)	
Clinical Baseline (mean ± SD)*					
Probing depth		2.36±0.20	2.33±0.25	2.34±0.26	*0.94*
Bleeding on probing		13.52±3.45	14±4.52	13.05±4.27	*0.83*
Clinical attachment levels		2.93±0.82	3.14±0.81	3.44±1.19	*0.37*

* ANOVA (post hoc test Tukey); $p< 0.05$/ # chi-square statistics; $p< 0.05$

Table 2 – Mean group VPI and GBI at baseline, 15, 30 and 90 days.

		G12	G24	G48
VPI	Baseline	3.8	1.8	5.4
	15 days	10.7	8.5	22.4
	30 days	9.3	6.0	19.0
	90 days	10.9	8.1	39.3
GBI	Baseline	4.9	4.2	5.5
	15 days	7.6	5.9	11.4
	30 days	7.6	6.3	15.7
	90 days	10.7	8.0	18.8

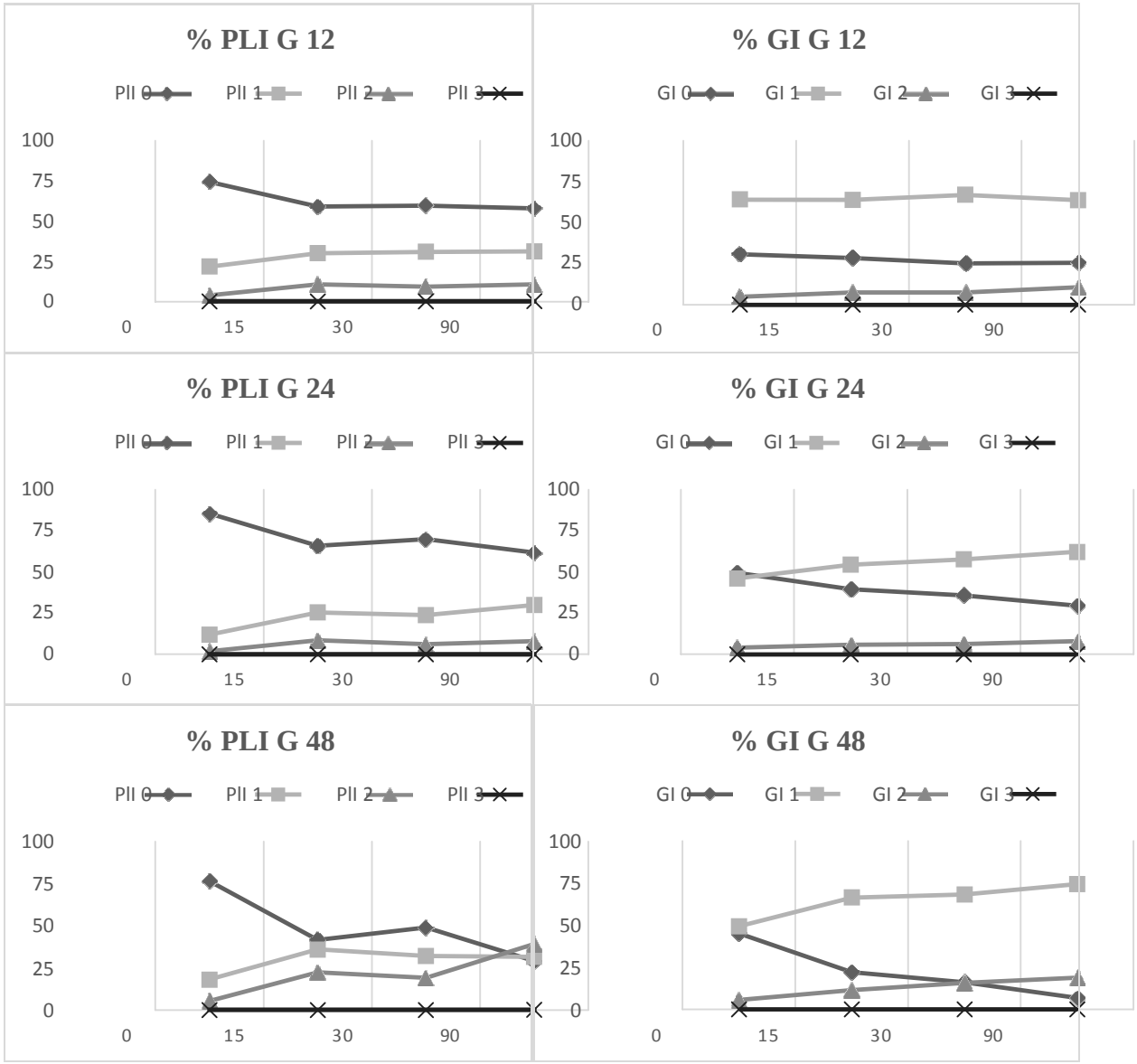
VPI: Visible Plaque Index (VPI = PlI 2+3); GBI: Gingival Bleeding Index (GBI = GI 2+3)

Table 3 – Correlation between PlI and GI according to experimental group at baseline, 15, 30 and 90 days.

	G12	G24	G48
Baseline	0.18*	0.08*	0.15*
15 days	0.25*	0.13*	0.23*
30 days	0.23*	0.18*	0.26*
90 days	0.28*	0.18*	0.21*

*Spearman correlation coefficient ($p<0.0001$); PlI: Plaque Index; GI: Gingival Index

Figure 1



Plaque Index (PlI); Gingival Index (GI); PlI and GI scores (0, 1, 2, and 3%) for study groups of different intervals oral hygiene.

3 CONCLUSÃO

Concluímos que na avaliação de indivíduos com história periodontal, com altos padrões de higiene bucal, com baixos índices de sangramento, seguindo um protocolo estruturado e monitorado, concluímos que a correlação entre a formação de placa e as alterações gengivais é fraca, e que a freqüência de higiene bucal altera os parâmetros gengivais. Os resultados confirmam que a qualidade da desorganização da placa dentária deve estar associada à periodicidade da higiene bucal para estabilidade dos parâmetros gengivais em pacientes com história periodontal. Com isso, indivíduos que realizam altos padrões de higiene em intervalos diários de até 24 horas manterão a saúde gengival quando comparados com indivíduos que usam intervalos de higiene maiores que 24 horas.

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Apêndice A - Consentimento Livre e Esclarecido

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Título do projeto: Efeito da frequência do auto controle mecânico de placa em pacientes com histórico de periodontite e em manutenção periodontal.

Pesquisador responsável: Karla Zanini Kantorski

Instituição/Departamento: Universidade Federal de Santa Maria, Departamento de Estomatologia

Telefone para contato: (055) 91593232

Pesquisador participante: Juliana Maier/Ana Paula Reiniger/Michel Luís Reckziegel
Telefones para contato: (055) 99385685/ (055) 97263112/ (055) 96669098

- Você está sendo convidado para participar, como voluntário, em uma pesquisa. 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 penalizada de forma alguma.
- Esta pesquisa justifica-se pelo fato de não estar esclarecido até os dias de hoje qual o período que eu, paciente com histórico de periodontite, devo fazer higiene bucal sem que ocorra inflamação na gengiva, o que pode melhorar no meu cuidado bucal.
- Você passará por um processo de sorteio para ver qual a frequência de auto remoção mecânica da placa deverá seguir no período de um três meses. Receberá escova de dentes, pasta de dentes, fio dental ou escova interdental, e frasco com solução de flúor que deverá usar durante o período do estudo.
- A sua participação neste estudo será responder questões sobre dados demográficos (idade, gênero, estado civil, entre outros), dados odontológicos e dados médicos coletados através de uma entrevista e também permitir a avaliação da sua cavidade bucal. Serão anotados dados sobre a quantidade de placa (tecido amolecido amarelo-esbranquiçado) formada sobre seus dentes, se ocorre sangramento ou saída de pus da sua gengiva e medidas 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 que apresentará. Você terá que responder a um questionário sobre as alterações que poderá perceber em sua boca durante o tempo do estudo. As fichas após analisadas ficarão por 5 anos e, depois, imediatamente serão destruídas.

- Durante os exames pode sentir-se cansado e ter algum desconforto nos exames no qual um instrumento odontológico é passado entre sua gengiva e seus dentes, e há um risco mínimo de machucar-se com o instrumento do examinador caso ocorra um movimento brusco. No entanto esta ciente de que os examinadores tentarão diminuir ao máximo estes imprevistos. Durante o período do estudo, poderá ficar com gosto ruim e/ou acúmulo de placa na sua boca.
- Quanto ao cansaço, o exame periodontal será interrompido para descanso sempre que você achar necessário. Os exames realizados na pesquisa são os mesmos realizados que você realizou durante seu tratamento periodontal e suas rechamadas de manutenção. Você já está acostumado com os exames e sabe que seus desconfortos são muito pequenos, mas serão diminuídos ao máximo devido à experiência e o cuidado do examinador. Independente da frequência de escovação você irá bochechar solução fluoretada de menta que dará frescor e um sabor agradável na boca, assim o seu hálito não causará nenhum constrangimento e dificuldade de conviver socialmente.
- Você poderá desenvolver gengivite, caracterizada clinicamente por edema, alteração de cor, sangramento na margem gengival e aumento do fluido crevicular gengival. Uma vez que isso ocorra, você será removido do estudo e será orientado a realizar a escovação dentária com frequência de 12 horas e examinado a cada 7 dias até retornar a saúde gengival. A gengivite é totalmente reversível e não deixará sequelas permanentes, você retornará ao quadro de saúde gengival que apresentava ao iniciar o estudo.
- Como benefício, se durante os exames de sua boca for detectada alguma necessidade odontológica, receberá este tratamento na Universidade Federal de Santa Maria pelas responsáveis da pesquisa antes de começar o estudo.
- 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.
- Também foi informado de que pode 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 vem recebendo.

- Eu_____, de nacionalidade_____, idade_____anos, estado civil _____,profissão _____, residente em _____, RG nº _____, abaixo assinado, concordo em participar do estudo como sujeito. Fui suficientemente informado a respeito das informações que li ou que foram lidas para mim, descrevendo o estudo **"Efeito da frequência do auto controle mecânico de placa em pacientes com histórico de periodontite e em manutenção periodontal".** Eu discuti com a pesquisadora _____sobre a minha decisão em participar nesse estudo. Ficaram claros para mim quais são os propósitos do estudo, os procedimentos a serem realizados, seus desconfortos e riscos, as garantias de confidencialidade e de esclarecimentos permanentes. 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. Concordo voluntariamente em participar deste estudo e poderei retirar o meu consentimento a qualquer momento, antes ou durante o mesmo, sem penalidades ou prejuízo ou perda de qualquer benefício que eu possa ter adquirido.

Santa Maria,_____de_____de 201_.

_____

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 pesquisador responsável

Se você tiver alguma consideração ou dúvida sobre a ética da pesquisa, entre em contato: Comitê de Ética em Pesquisa – UFSM - Cidade Universitária - Bairro Camobi, Av. Roraima, nº1000 - CEP:
97.105.900 Santa Maria – RS. Telefone: (55) 3220-9362 – Fax: (55)3220-8009
Email: comiteeticapesquisa@smail.ufsm.br. Web: www.ufsm.br/cep

Apêndice B – Entrevista

Nome:_____

Gênero: ( )M ( )F Profissão:_____

Endereço:_____

Telefone(s) para contato:_____

Idade:_____anos. Data de nascimento:_____

Estado civil: ( ) casado(a) ( ) separado(a) ( ) divorciado(a) ( ) viúvo(a) ( ) solteiro(a)

Cor/ raça: ( ) branca ( ) preta ( ) parda ( ) indígena ( ) amarela

Dados Odontológicos

Qual a freqüência com que você realiza escovação dos dentes?

_____

Que tipo de escova usa? ( )Macia ( )Média ( )Dura

Faz uso de dispositivo interdental?

_____

Qual? ( )Fio ( )Escova interdental ( )Escova unitufo ( )Outro_____

Com que frequência (vezes por semana)?

_____

Faz uso de dentifrício? Qual?

_____

Faz uso de alguma solução pra bochecho? Qual?

_____

Você usa o bochecho com que objetivo?

_____

Tem sangramento gengival? ( )Sim ( )Não. Se sim, quando ele ocorre? _____

Tem sensibilidade nos dentes? ( )Sim ( )Não. Sente mau gosto na boca? ( )Sim ( )Não.

Sente mau hálito? ( )Sim ( )Não. Alguém já comentou a respeito do seu hálito? ( )Sim ( )Não.

Dados Médicos

Está em tratamento médico atualmente? ( )Sim ( )Não. Qual?
_____

Esteve em tratamento nos últimos 3 meses? ( )Sim ( )Não. Qual?_____

Apresenta alguma doença sistêmica? _____

Está tomando alguma medicação?
_____

Nível socioeconômico e Escolaridade

Qual é a renda da sua família?_____salários mínimos.

( )Não respondeu ( )Não recebe salário

Qual é seu grau de escolaridade? _____

Qual o grau de escolaridade do chefe da sua família?
_____

Apêndice C – Exames Periodontais

Fichas de exame clínico periodontal – IPI, IG E FCG

Período do exame: ( ) Baseline ( )15 dias ( )30 dias ( )45 dias ( )60 dias ( )90 dias

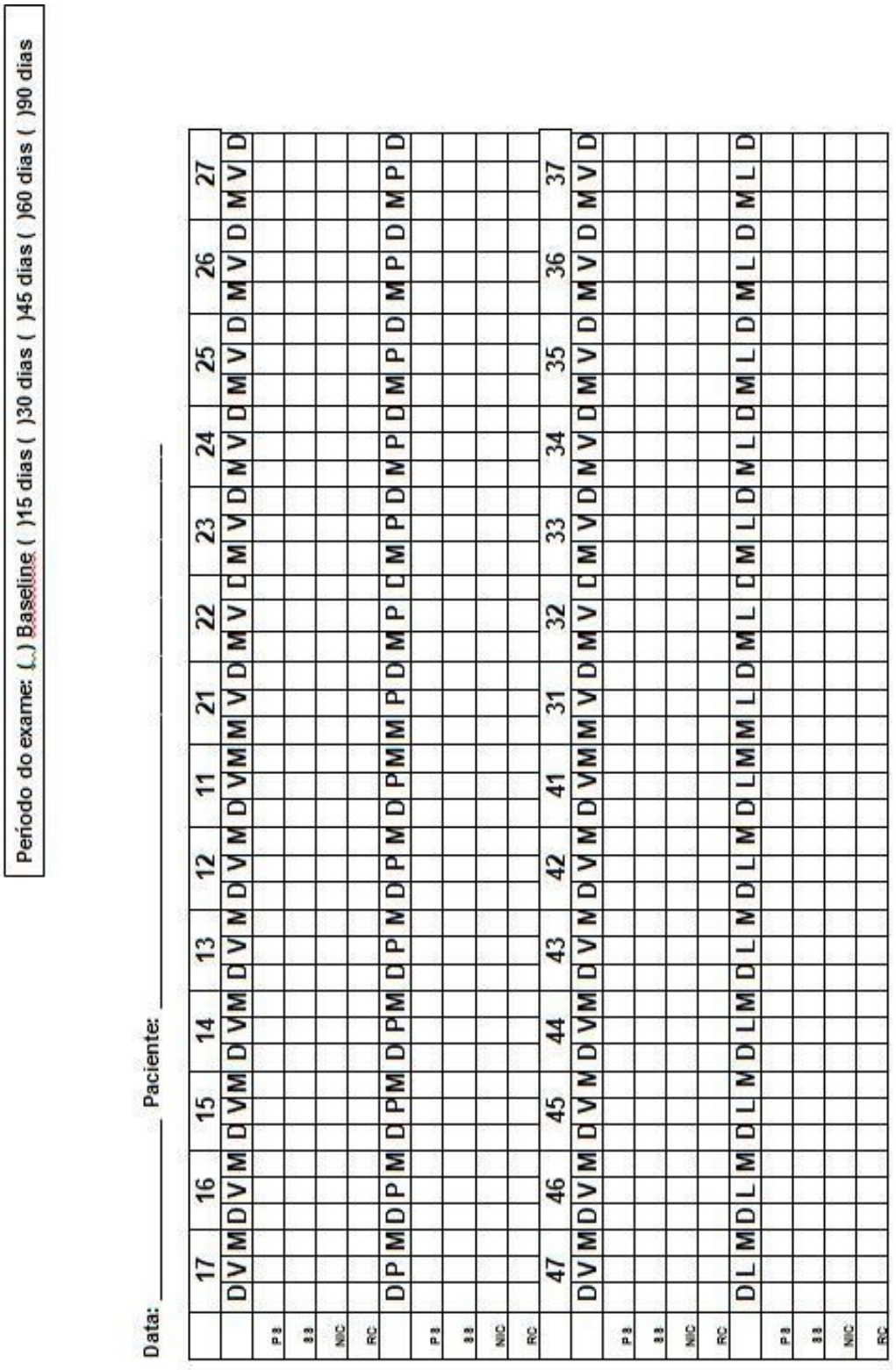
Data: _____ Paciente: _____ Examinador: _____

	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	D	V	M	D	V	M	D	V	M	D	V	M	D	V	M	D	V	M	D
IPI																																								
IG																																								
	D	P	M	D	P	M	D	P	M	D	P	M	D	P	M	D	P	M	D	P	M	D	P	M	D	P	M	D	P	M	D	P	M	D	P	M	D	P	M	D
IPI																																								
IG																																								
	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	D	V	M	D	V	M	D	V	M	D	V	M	D	V	M	D	V	M	D
IPI																																								
IG																																								
	D	L	M	D	L	M	D	L	M	D	L	M	D	L	M	D	L	M	D	L	M	D	L	M	D	L	M	D	L	M	D	L	M	D	L	M	D	L	M	D
IPI																																								
IG																																								

Número total de dentes:

	DENTE	SÍTIO	VALOR
FCG 1			
FCG 2			
FCG 3			
FCG 4			
FCG 5			
FCG 6			
FCG 7			
FCG 8			

Fichas de exame clínico periodontal – PS, SS, NIC



Apêndice D – Questionamentos Referentes à Adesão a Frequência Randomizada

Paciente:_____

EXAME 15 DIAS

Por algum motivo, durante os 15 dias anteriores, você não realizou a frequência de escovação recomendada? ( ) SIM ( ) NÃO ( ) NÃO LEMBRA

Se sim, quantos dias não realizou a frequência correta?_____

Se sim, qual o motivo que o fez não realizar a frequência correta?

_____

EXAME 30 DIAS

Por algum motivo, durante os 15 dias anteriores, você não realizou a frequência de escovação recomendada? ( ) SIM ( ) NÃO ( ) NÃO LEMBRA

Se sim, quantos dias não realizou a frequência correta? _____

Se sim, qual o motivo que o fez não realizar a frequência correta?

_____

EXAME 45 DIAS

Por algum motivo, durante os 15 dias anteriores, você não realizou a frequência de escovação recomendada? ( ) SIM ( ) NÃO ( ) NÃO LEMBRA

Se sim, quantos dias não realizou a frequência correta?_____

Se sim, qual o motivo que o fez não realizar a frequência correta?

_____

EXAME 60 DIAS

Por algum motivo, durante os 15 dias anteriores, você não realizou a frequência de escovação recomendada? ( ) SIM ( ) NÃO ( ) NÃO LEMBRA

Se sim, quantos dias não realizou a frequência correta?_____

Se sim, qual o motivo que o fez não realizar a frequência correta?
_____

EXAME 90 DIAS

Por algum motivo, durante os 30 dias anteriores, você não realizou a frequência de escovação recomendada? ( ) SIM ( ) NÃO ( ) NÃO LEMBRA

Se sim, quantos dias não realizou a frequência correta? _____

Se sim, qual o motivo que o fez não realizar a frequência correta?
_____

Anexo A – Aprovação do Comitê de Ética em Pesquisa

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

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: EFEITO DA FREQUÊNCIA DO AUTO CONTROLE MECÂNICO DE PLACA EM PACIENTES COM HISTÓRICO DE PERIODONTITE E EM MANUTENÇÃO PERIODONTAL

Pesquisador: KARLA ZANINI KANTORSKI

Área Temática:

Versão: 3

CAAE: 50208115.9.0000.5346

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

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.374.622

Apresentação do Projeto:

O projeto corresponde a uma tese de doutorado vinculada ao Programa de Pós-graduação em Ciências Odontológicas. Está apresentado da seguinte forma: "A gengivite induzida por placa bacteriana e considerada a doenca oral mais comum em individuos dentados e o tipo mais frequente de doenca periodontal. O estabelecimento de habitos adequados de higiene bucal, com remocao do biofilme supragengival atraves de auto controle mecanico de placa utilizando escovas multicerdas e dispositivos interdentais, sao fundamentais para reducao da presenca de inflamacao no periodonto e reducao do risco de perda dentaria futura. Porem, a efetividade desse procedimento na prevencao e tratamento da gengivite depende de dois fatores: a capacidade do individuo em remover placa de todas as superficies dentarias e a frequencia em que esta remocao e executada. O objetivo deste ensaio clinico randomizado cego e avaliar diferentes frequencias de auto remocao mecanica da placa em individuos com historico de periodontite e em manutencao periodica e preventiva a fim de avaliar quais frequencias sao compativeis com a manutencao da saude gengival. Sessenta sujeitos com no maximo 5% dos sitios com IG=2 (saude gengival) serao randomizados em tres grupos experimentais com diferentes frequencias de auto remocao mecanica de placa: Grupo 12 horas, 24 horas e 48 horas. Os exames de IPI, IG, PS, SS, NIC e fluido crevicular gengival serao realizados no baseline, 15, 30, 60 e 90 dias. Analise descritiva (media e

Endereço: Av. Roraima, 1000 - prédio da Reitoria - 2º andar
Bairro: Camobi **CEP:** 97.105-970
UF: RS **Município:** SANTA MARIA
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desvio padrao) sera realizada para todos os parametros clinicos avaliados. Diferencas intra- e intergrupos serao analisadas por ANOVA de Medidas Repetidas e ANOVA de Modelos Mistos, respectivamente seguidas pelo teste Tukey (Post Hoc). O nivel de significancia sera de 5%."

Os pesquisadores justificam através de cálculo amostral o número de individuos em cada grupo. Apresentam critérios de elegibilidade e exclusão.

Apresentam orçamento, sendo que os custos serão cobertos pelos pesquisadores.

O cronograma foi reapresentado e prevê início da parte experimental em marco de 2016.

Objetivo da Pesquisa:

Objetivo geral: avaliar o efeito da frequência de auto remoção mecânica de placa supragengival (escova multicerda + dispositivo interdental) sobre o "status" gengival em pacientes com histórico de periodontite em manutenção periódica preventiva.

Objetivos Específicos

- Avaliar como diferentes frequências de auto remoção mecânica de placa interferem no acúmulo do biofilme supragengival;
- Avaliar como diferentes frequências de auto remoção mecânica de placa interferem no volume de fluido crevicular gengival;
- Analisar diferentes padrões de acúmulo de biofilme supragengival, em regiões proximais, relacionando-os aos diferentes tipos de dispositivos interdentais utilizados;
- Avaliar possíveis fatores ou indicadores de risco no desenvolvimento da gengivite de acordo com as diferentes frequências de auto remoção mecânica de placa (através da coleta de dados demográficos, médicos e odontológicos). .

Avaliação dos Riscos e Benefícios:

Os pesquisadores assim descrevem:

Durante os exames os participantes poderao se sentir cansados ou apresentarem algum desconforto no momento em que instrumento odontologico (sonda periodontal) e passado entre a gengiva e os dentes, e ha um risco minimo de acontecer algum ferimento com o instrumento do examinador caso ocorra um movimento brusco do paciente ou operador. No entanto, os

examinadores tentarao diminuir ao maximo os imprevistos.

Quanto ao cansaco, o exame periodontal sera interrompido para descanso sempre que o paciente achar necessario.

Os exames realizados na pesquisa sao os mesmos realizados durante o tratamento periodontal e as rechamadas de manutencao. Alem de o paciente estar familiarizado com os exames, os possiveis desconfortos gerados por eles sao muito pequenos e serao minimizados devido a experiencia e cuidado do examinador. Durante o periodo que os individuos terao que realizar a higiene bucal com frequencia pre-determinada, poderao ficar com gosto ruim e/ou acumulo de placa na boca. Entretanto, independente da frequencia de escovacao todos os individuos irao bochechar solucao fluoretada de menta que dara frescor e um sabor agradavel na boca, assim o halito nao causara nenhum constrangimento e dificuldade de conviver socialmente.

Alguns participantes poderao desenvolver gengivite, caracterizada clinicamente por edema, alteracao de cor, sangramento na margem gengival e aumento do fluido crevicular gengival. Uma vez que isso ocorra, o individuo sera removido do estudo e orientado a realizar a ACP com frequencia de 12 horas e examinado a cada 7 dias ate restabelecer saude gengival. A gengivite e reversivel e nao deixara sequelas permanentes, o individuo retornara ao quadro de saude gengival que apresentava ao iniciar o estudo.

Como beneficio, caso algum problema odontologico seja detectado durante o estudo, o participante recebera tratamento odontologico na Universidade Federal de Santa Maria pelos responsaveis da pesquisa. A participacao no estudo tambem ira melhorar o cuidado bucal de pacientes com historico de periodontite e em manutencao periodica, uma vez que visa esclarecer a frequencia de auto remocao mecanica de placa necessaria para que nao ocorra inflamacao gengival.

Consideram-se que riscos e beneficios estao apresentados de maneira adequada. As informacoes foram alteradas e incluidas de maneira coerente em todos os documentos.

Comentários e Considerações sobre a Pesquisa:

.

Considerações sobre os Termos de apresentação obrigatória:

Todos os documentos necessários estão apresentados de maneira 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:

O projeto não apresenta pendências ou inadequações e pode ser aprovado.

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_608326.pdf	14/12/2015 18:06:29		Aceito
Projeto Detalhado / Brochura Investigador	ProjetoDoutoradoJulianaMaier141215.doc	14/12/2015 18:04:44	Juliana Maier	Aceito
Outros	CartaResposta2.doc	14/12/2015 17:58:32	Juliana Maier	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLEmodificado.docx	14/12/2015 17:55:35	Juliana Maier	Aceito
Outros	TermodeConfidencialidadeModificado.jpg	24/11/2015 14:06:54	Juliana Maier	Aceito
Folha de Rosto	FolhadeRostoPlataformaBrasil.doc	19/10/2015 11:41:06	KARLA ZANINI KANTORSKI	Aceito
Outros	AutorizacaoInstitucional.jpg	19/10/2015 11:39:48	KARLA ZANINI KANTORSKI	Aceito
Outros	ProjetoIntegra2.jpg	19/10/2015 11:29:54	KARLA ZANINI KANTORSKI	Aceito
Outros	ProjetoIntegra1.jpg	19/10/2015 11:29:20	KARLA ZANINI KANTORSKI	Aceito

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:
Não

SANTA MARIA, 17 de Dezembro de 2015

Assinado por:
CLAUDEMIR DE QUADROS
(Coordenador)

Anexo B – Registro ClinicalTrials

ClinicalTrials.gov PRS
Protocol Registration and Results System

ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 02/10/2016

ClinicalTrials.gov ID: [Not yet assigned]

Study Identification

Unique Protocol ID:	50208115.9.0000.5346
Brief Title:	Frequency of Self-performed Mechanical Control of Plaque
Official Title:	Effect of Self-performed Mechanical Control of Plaque Frequency in Patients With Historic of Periodontitis and in Maintenance
Secondary IDs:	

Study Status

Record Verification:	February 2016
Overall Status:	Active, not recruiting
Study Start:	February 2016
Primary Completion:	November 2016 [Anticipated]
Study Completion:	June 2017 [Anticipated]

Sponsor/Collaborators

Sponsor:	Universidade Federal de Santa Maria
Responsible Party:	Principal Investigator Investigator: Juliana Maier [jmaier] Official Title: Master in dental science with an emphasis on periodontics Affiliation: Universidade Federal de Santa Maria
Collaborators:	

Oversight

FDA Regulated?:	No
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 50208115.9.0000.5346 Board Name: Comitê de Ética em Pesquisa com Seres Humanos - CEP Board Affiliation: Comitê de Ética em Pesquisa com Seres Humanos da Universidade Federal de Santa Maria Phone: 55553220-9362 Email: cep.ufsm@gmail.com
Data Monitoring?:	No
Plan to Share Data?:	No

Oversight Authorities: Brazil: Ethics Committee

Study Description

Brief Summary: The purpose of this blind randomized clinical trial is to evaluate different frequencies in self-mechanical control of plaque in individuals with historic of periodontitis and in periodic and preventive maintenance in order to assess which frequencies are compatible with maintaining gingival health.

Detailed Description: Thirty nine subjects with at most 5% of the sites for GI= 2 (gingival health) will be randomized into three groups with different frequencies in self-mechanical control of plaque: Group 12 hours, 24 hours and 48 hours. The exams of plaque index, gingival index, probing depth, bleeding on probing, clinical attachment level and gingival crevicular fluid will be performed at baseline, 15, 30, 60 and 90 days.

Conditions

Conditions: Gingivitis
Oral Health

Keywords: Toothbrushing
Gingivitis
Dental Plaque
Periodontal Diseases
Clinical Trial

Study Design

Study Type: Interventional

Primary Purpose: Other

Study Phase: N/A

Intervention Model: Parallel Assignment

Number of Arms: 3

Masking: Single Blind (Investigator)

Allocation: Randomized

Endpoint Classification: N/A

Enrollment: 39 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
12h Group Intervention 'Frequency of mechanical control of plaque (12h)'	Frequency of mechanical control of plaque (12h) Frequency of self-performed oral hygiene: 12 in 12 hours.
24h Group Intervention 'Frequency of mechanical control of plaque (24h)'	Frequency of mechanical control of plaque (24h) Frequency of sel-performed oral hygiene: 24 in 24 hours.
48h Group Intervention 'Frequency of mechanical control of plaque (48h)'	Frequency of mechanical control of plaque (48h) Frequency of self-performed oral hygiene: 48 in 48 hours.

Outcome Measures

Primary Outcome Measure:

1. Gingivitis expressed as an increase in mean gingival index
   [Time Frame: 30,60 and 90 days.] [Safety Issue: No]

Secondary Outcome Measure:

2. Correlations between plaque level and gingival index.
   [Time Frame: 30,60 and 90 days.] [Safety Issue: No]
3. Correlations between volume of gingival fluid with GI scores and bleeding on probing scores.
   [Time Frame: 30,60 and 90 days.] [Safety Issue: No]

Eligibility

Minimum Age:	35 Years
Maximum Age:	
Gender:	Both
Accepts Healthy Volunteers?:	No
Criteria:	Inclusion Criteria:

- Individuals with historic of periodontitis (loss of interproximal insertion ≥3mm in two or more non-adjacent teeth) treated in the Clinic of Postgraduate Periodontics at the Federal University of Santa Maria and included in the periodontal maintenance program;
- Minimum age of 35;
- Individuals with at least 12 teeth in the mouth;
- Maximum of 15% of sites with gingivitis;
- Maximum of 25% of sites with bleeding on probing.

Exclusion Criteria:

- Smokers;
- Pregnant women;
- Individuals with dryness of the mouth (xerostomia);
- Diabetics;
- Psychomotor disturbances;
- Orthodontic equipment;
- Antimicrobial prophylaxis;
- Individuals using any medication associated with gingival overgrowth;
- Individuals that used antibiotic/anti -inflammatory in recent 3 months.

Contacts/Locations

Study Officials:	Karla Z Kantorski Study Director Universidade Federal de Santa Maria
Locations:	

References

Citations:

Anexo C – Normas da Revista *Journal of Clinical Periodontology*

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
- I ntroduction
- 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.

(a) 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 colour, 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 typesize 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
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5.9. Supplementary Material
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