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Periodontal monitoring in orthodontic treatment with orthodontic aligners: proof of concept

Acompanhamento periodontal em tratamento com alinhadores ortodônticos: prova de conceito

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Resumo

Introdução: O impacto dos alinhadores nas condições periodontais e protocolos clínicos de higiene têm sido investigados. Objetivo: Este estudo teve como objetivo avaliar a condição periodontal de pacientes em tratamento ortodôntico com alinhadores ClearCorrect e comparar as condições de saúde periodontal após o uso do enxaguatório bucal BlueM e da espuma BlueM como protocolos clínicos para higiene oral e de alinhadores. Material e método: Em 16 pacientes, o tratamento ortodôntico foi realizado utilizando alinhadores, e foi conduzido um acompanhamento periodontal. A amostra de pacientes foi dividida em 3 grupos randomizados: Controle, Enxaguatório e Espuma, com cada paciente passando por todos os três grupos. Todos os pacientes receberam instruções para limpar os alinhadores com água e escova de dentes. O uso de uma pasta de dentes padronizada foi indicado. Um exame periodontal foi realizado no período inicial e a cada 2 meses usando sondagem do sulco gengival, nível de inserção, recessão, índice de sangramento e presença de biofilme. Resultado: Diferenças significativas foram observadas na sondagem distal dos dentes ao comparar o período inicial e o grupo de enxaguatório na análise intergrupos, independentemente do lado da boca e do dente avaliado. Ao avaliar o sangramento, o período inicial mostrou 1,8 vezes mais risco de sangramento do que a espuma, 1,9 vezes mais risco do que o controle e 2,4 vezes mais do que o grupo de enxaguatório. Em relação à presença de biofilme, os dados do período inicial mostraram 1,4 vezes mais risco de ter biofilme do que a espuma e 1,9 vezes mais risco do que os grupos de enxaguatório. Em relação ao controle, não houve diferença estatisticamente significativa. Conclusão: Os pacientes que usaram enxaguatório bucal BlueM tiveram uma menor chance de sangramento e presença de biofilme, assim como melhora da profundidade de sondagem periodontal distal quando comparada ao período inicial.

Descritores: Alinhadores ClearCorrect; saúde periodontal; enxaguatório BlueM; espuma BlueM; tratamento ortodôntico.

Abstract

Introduction: The impact of aligners in the periodontal conditions and protocols for hygiene were investigated. **Objective:** This study assessed the periodontal condition of patients undergoing orthodontic treatment with ClearCorrect aligners and compare periodontal health conditions after the use of BlueM mouthwash and foam as clinical protocols for oral and aligner hygiene. **Material and method:** In 16 patients' treatment was performed using aligners, and a periodontal follow-up was conducted. The sample was divided into 3 randomized groups: Control, Mouthwash, and Foam, with each patient passing through all groups. The use of a standardized toothpaste was indicated. A periodontal examination was performed on baseline and every 2 months using gingival sulcus probing, insertion level, recession, bleeding on probe index, and biofilm presence. **Result:** Significant differences were observed in distal probing of the teeth when comparing baseline and the mouthwash group in the intergroup analysis, irrespective of the side of the mouth and the tooth evaluated. When assessing bleeding on probe, baseline showed 1.8 times more risk of bleeding on probe than



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foam, 1.9 times more risk than the control, and 2.4 times more than mouthwash group. Regarding biofilm presence, baseline data showed 1.4 times more risk of having biofilm than foam, and 1.9 times more risk than mouthwash groups. In relation to the control, there was no statistically significant difference. **Conclusion**: Patients when using BlueM mouthwash had a lower chance of bleeding on probe and presence of biofilm, as well as an improvement in distal periodontal probing depth when compared to baseline situation.

Descriptors: ClearCorrect aligners; periodontal health; BlueM mouthwash; BlueM foam; orthodontic treatment.

INTRODUCTION

In recent years, there has been an increased demand from patients for orthodontic treatments that offer enhanced comfort and meet more demanding aesthetic standards. In this context, orthodontic aligners have emerged as an innovative alternative. These removable thermoplastic trays demonstrate efficiency in dental movements, providing convenience in fabrication, speed, ease of cleaning, and favorable aesthetics^{1,2}.

On the other hand, fixed orthodontic devices have been associated with the accumulation of bacterial plaque due to challenges in proper hygiene, becoming an etiological factor for enamel demineralization, dental caries, and periodontal diseases³⁻⁵. Initially characterized by polymicrobial inflammation, if left uncontrolled, periodontal disease can progress to bone resorption, compromising dental support and leading to tooth loss⁶. However, it is crucial to emphasize that the impact of fixed appliances on oral microbiota may be a transient effect, depending on the effective oral hygiene control by each patient⁷.

Orthodontic movement induces remodeling throughout the entire periodontium, including the bony structures and components of soft tissues. The presence of periodontal inflammation can hinder this remodeling process and potentially compromise treatment outcomes⁸. Patients with periodontal disease may experience compromised orthodontic treatment progression and an extended estimated treatment duration⁹. Up to 10% of patients with a history of previous orthodontic treatment exhibit greater loss of periodontal connective tissue attachment compared to the general population¹⁰. Proper hygiene, guided by a dental professional, can prevent the onset of periodontal disease regardless of the orthodontic appliance used¹¹.

However, aligners, being removable unlike conventional braces, allow for easy and adequate patient hygiene, resulting in improved health of the supporting tissues¹²⁻¹⁴. Changes in the microbial community can disrupt the balance between the host and microorganisms, potentially leading to periodontal disease¹³. Despite aligners being removable before meals and during oral hygiene procedures, preventing bacterial contamination and proliferation requires an efficient cleaning protocol for the aligners. Avoiding bacterial buildup on their surfaces aims to maintain periodontal health, prevent cavities, and consequently achieve satisfactory progress in orthodontic treatment^{3,15,16}. BlueM[®] products have been related to an antimicrobial effect against S. mutans, showing bactericidal, bacteriostatic, antibiofilm, and non-cytotoxic effects at low concentrations¹⁷.

This study aims to assess the periodontal condition of patients undergoing orthodontic treatment with ClearCorrect aligners and compare periodontal health conditions after the use of BlueM mouthwash and BlueM foam as clinical protocols for oral and appliance hygiene. The null hypothesis posits that there is no difference between the groups.

MATERIAL AND METHOD

The sample consisted of 16 adult patients (21 to 51 years), representing both genders, who sought orthodontic treatment at the Ilapeo College. Subject participation in the study was voluntary, and each participant provided their informed consent by signing the Ethical Review Board approved Informed Consent Form (CEP UTP/PR).

To calculate the sample power, a priori sample size calculation was performed using GPower 3.1.9.4. The parameters used were: 80% power, 10% error for quantitative measures, four independent groups, and an expected effect size between groups of 25%. With these parameters, the minimum total 'n' would be 224 participants, with 56 in each group. After obtaining a sample totaling 64 participants, with 16 in each group, a post-hoc sample power calculation was performed using the maximum effect size of 25% found between the groups. The sample power found was 46.6%.

The inclusion criteria were indication to orthodontic treatment with aligners and periodontal health individuals without active periodontal disease. As exclusion criteria it was considered patients requiring orthognathic surgery associated to orthodontic treatment; individuals with uncontrolled diabetes and women who were pregnant during the study.

The patient planning included a comprehensive set of diagnostic tools, including panoramic radiography, lateral cephalometric radiography, extra and intraoral photographs, and digital scans of both dental arches. From the planning, a virtual setup was generated. All patients underwent treatment using ClearCorrect aligners (Curitiba, Brazil).

The installation of the aligners was preceded by prophylaxis with pumice, along with guidance on oral hygiene and aligner care. It was established that the aligners should be worn for 22 hours per day, only to be removed for eating and the hygiene of both teeth and aligners, following the manufacturer's recommendations. Each aligner was retained for a minimum of 14 days, and patients attended monthly follow-up appointments.

The patient sample was divided into three randomized groups, and each patient underwent the three groups:

- a) I- Control (CG) The patient solely performed mechanical cleaning using a toothbrush and Tandy toothpaste (Colgate-Palmolive Company®). This toothpaste was chosen because it does not contain components that could interfere with the study results, as for example, triclosan;
- b) II- Mouthwash (MW) the use of BlueM mouthwash (BlueM Europe BV, Netherlands) was recommended three times a day for 30 seconds after brushing;
- c) III- Foam (F) The patients used the preparation known as BlueM Foam (BlueM Europe BV, Netherlands), applied to the aligner three times a day after brushing.

The patient stayed in each group for a minimum of 2 months during the treatment and switched between groups after a one-week washout period without using any product.

All patients were instructed to clean the aligners with cold running water and a toothbrush without using any disinfection product, apart from those indicated in the study groups.

Clinical Periodontal Parameters¹⁸

- a) Probing depth: Standardized probing (Williams probe Hu-Friedy) was performed by a blinded specialist. The examination included probing the gingival sulcus on the mesial (M), distal (D), vestibular (V), and palatal/lingual (P) surfaces of the first molars (16, 26, 36, 46) and central incisors (11, 21, 31, 41). For patients without the first molars, the second molars were considered;
- b) Clinical attachment level and recession in the vestibular region;
- c) Bleeding on probe and biofilm indices, where "yes" indicated presence and "no" indicated absence (Table 1).

All variables' data were obtained at four time points: before the start of orthodontic treatment (Baseline) and after 2 months in each group.

Statistical Analysis

Initially, a descriptive analysis of the data was conducted, providing estimates of mean, median, standard deviation, 1st quartile, 3rd quartile, minimum, and maximum, irrespective of the tooth and group. Subsequently, the normal distribution adherence of the data was assessed using the Shapiro-Wilk test, and as none presented normal distribution, a non-parametric approach was employed with the Kruskall-Wallys test for evaluating differences. Bleeding on probe and biofilm variables were analyzed with simple frequency (n) and relative frequency (%) of categories according to the groups. The difference between groups was assessed with the chi-square test, and the strength of association was estimated by the relative risk. Tests were considered significant when p < 0.05, and the analyses were conducted using SPSS 21.0 (IBM, 2012 SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.).

RESULT

a) Probing depth

Significant differences were observed in distal probing of the teeth when comparing Baseline and the MW group in the intrargroup analysis, irrespective of the side of the mouth and the tooth evaluated (Tables 1 and 2). However, when comparing individual teeth, no significant difference was found, supporting the null hypothesis, confirming that there is no significant difference between the groups.

		•p.s			9.00.00	,							·
						Gr	oup						
	Ba	aseline			CG			F			MW		p-
	mean	1Q	3Q	mean	1Q	3Q	mean	1Q	3Q	mean	1Q	3Q	value*
Probing M	2.0	2.0	3.0	2.0	2.0	2.5	2.0	2.0	2.5	2.0	2.0	2.0	0.068
Probing D	2.5	2.0	3.0	2.0	2.0	3.0	2.0	2.0	3.0	2.0	2.0	2.5	0.016*
Probing V	1.5	1.0	2.0	1.5	1.0	2.0	1.5	1.0	2.0	1.5	1.0	2.0	0.542
Probing P	1.5	1.0	2.0	1.5	1.0	2.0	1.5	1.0	2.0	1.5	1.0	2.0	0.358

Table 1. Comparisons between groups, irrespective of the side of the mouth and the tooth

*p-value for the Kruskall-Wallis test. CG = control group; F = foam; MW = mouthwash

Table 2. Pairwise	comparison	in the	distal	probing	variable
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Pairwise Comparisons	p-value
MW × CG	0.881
MW × F	0.878
MW × Baseline	0.008*
CG x F	0.998
CG × Baseline	0.480
F × Baseline	0.482

*p-value for the Kruskall-Wallis test. CG = control group; F = foam; MW = mouthwash.

Analyzing the left and right sides of the mouth, there was a difference in the distal probing variable when comparing the MW with baseline (Tables 3 and 4).

b) Clinical attachment level and recession

No significant differences were observed in clinical attachment level and recession of the teeth when comparing baseline and the other groups in the intergroup analysis, irrespective of the side of the mouth and the tooth evaluated (Table 5).

						Gro	up						
Left side	b	aseline			CG			F			MW		n voluo*
	MD	1Q	3Q	MD	1Q	3Q	MD	1Q	3Q	MD	1Q	3Q	p-value*
Probing M	2.0	2.0	3.0	2.0	2.0	2.5	2.0	2.0	2.5	2.0	2.0	2.0	0.208
Probing D	3.0	2.0	3.0	2.0	2.0	3.0	2.0	2.0	3.0	2.0	2.0	3.0	0.014*
Probing V	1.5	1.0	2.0	1.5	1.0	2.0	1.5	1.0	2.0	1.5	1.0	2.0	0.742
Probing P	1.5	1.0	2.0	1.5	1.0	2.0	1.5	1.0	2.0	1.0	1.0	2.0	0.336

Table 3. Comparisons between groups separated by the left side of the mouth

*p-value for the Kruskall-Wallis test. CG = control group; F = foam; MW = mouthwash. MD - median

Table 4. Pairwise comparison in the distal probing variable and left side

Pairwise Comparisons	p-valor
MW × CG	0.478
MW × F	0.765
MW × baseline	0.020*
CG × F	0.682
CG × baseline	0.158
F × baseline	0.051

CG = control group; F = foam; MW = mouthwash. * statistically significant,

Table 5. Comparisons between groups, irrespective of the side of the mouth and the too	Table 5. Compariso	ns between groups	s, irrespective of t	the side of the	mouth and the too
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						Gre	oup						
	Ba	aseline			CG			F			MW		p-
	mean	1Q	3Q	mean	1Q	3Q	mean	1Q	3Q	mean	1Q	3Q	value *
Insertion V	1.5	1.0	2.0	1.5	1.0	2.0	1.5	1.0	2.0	1.5	1.0	2.0	0.688
Recession V	0.0	0.0	0.0	0.0	00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.432
* 1 6 1		1 11.						. 1	,				

*p-value for the Kruskall-Wallis test. CG = control group; F = foam; MW = mouthwash.

c) Bleeding on probe and biofilm index

When assessing bleeding on probe, baseline showed 1.8 times more risk of presenting bleeding on probe (13.5%) than F group (7.6%), 1.9 times more risk than CG (7.0%), and 2.4 times more than MW group (5.5%).

Regarding the presence of biofilm, baseline showed 1.4 times more risk of presenting biofilm (11.3%) than F (7.8%), 1.9 times more risk than MW (5.9%). There was no statistically significant difference compared to the CG (Table 6).

				Bleed	ling		_		Bio	film		
Group		No		Yes				No		Yes		
	N	% total	N	% total	p-value*	RR (IC 95%)	N	% total	N	% total	p-value*	RR (IC 95%)
MW	99	19.3%	28	5.5%	< 0.001	2.4 (1.7 - 3.5)	97	18.9%	30	5.9%	< 0.001	1.9 (1.3 - 2.8)
CG	91	17.8%	36	7.0%	< 0.001	1.9 (1.4 - 2.6)	83	16.2%	44	8.6%	0.090*	1.3 (0.9 - 1.8)
F	88	17.2%	39	7.6%	< 0.001	1.8 (1.3 - 2.4)	87	17.0%	40	7.8%	0.028	1.4 (1.1 - 2.0)
Baseline	58	11.3%	69	13.5%	(ref)		69	13.5%	58	11.3%	(ref)	

Table 6. Results of the	analysis of blee	eding and prese	nce of biofilm

*p-value chi-squared test – difference among the groups. RR = relative risk; IC = confidence interval; CG = control group; F = foam; MW = mouthwash.

DISCUSSION

Orthodontic treatment using aligners allows for easier oral hygiene, consequently promoting good periodontal health in patients, as evidenced by the reduction in plaque levels, gingival

inflammation, and bleeding on probing^{12,14,19-22}. Several factors may be related to improved dental hygiene in patients using aligners, such as the older age of patients (usually adults), higher patient motivation, a significant increase in brushing frequency, and the removable nature of the appliance^{19,23}. The results obtained in this study did not show a significant difference in probing depth between baseline and when in the use of aligners, even when combined with mouthwash and foam. In other words, there was no improvement or worsening in the oral health of the sample patients when comparing tooth by tooth. This situation may have occurred due to the small sample size, resulting in a lower chance of rejecting the null hypothesis.

Regarding biofilm, Miethke, Vogt¹⁹ observed a significant number of bacteria and biofilm on the surface of aligners. The most important factor in bacterial colonization has been shown to be related to the roughness and configuration of the surface. In irregular surfaces, bacteria are protected from shear forces or dislodgment, and rougher surfaces present greater difficulty in cleaning, facilitating the growth of microorganisms. Another important aspect to highlight is the larger surface area of the aligners^{24,25}. The antibiofilm activity of BlueM® might represent an important indication for its use associated with clear aligners¹⁷.

Given that surface roughness and its extent are relevant factors in biofilm presence, aligner hygiene, combined with oral hygiene, becomes crucial for maintaining adequate oral health, considering they remain in the oral cavity for approximately²² hours a day, as recommended. When addressing disinfection substances, studies have shown their effectiveness in cleaning and reducing bacterial counts. It is also suggested that the combination of mechanical cleaning and disinfection substances is the most efficient cleaning method^{3,24-26}. These results differ compared to this study, where the aligner cleaning foam did not demonstrate a significant difference in the oral health of the patients.

Considering literature findings that cleaning and disinfection substances complement each other for good oral health, this study compared the control, mouthwash, and cleaning foam groups with baseline. The patients in the control group showed a lower risk of bleeding on probe than before the treatment, and no significant difference was found in the presence of biofilm when comparing baseline and the control group. These results differ from Zingler et al.²⁷, who suggested that patients using removable orthodontic appliances exhibited high levels of *streptococci* and *lactobacilli mutans salivaris*, along with a high plaque accumulation. Associations were found between the levels of *streptococci mutans salivaris* and *lactobacilli* with the Approximal Plaque Index. Associations were also shown between *streptococci mutans salivaris* and values of the Papillary Bleeding Index.

The group that used mouthwash had less bleeding on probe compared to baseline, as well as a lower presence of biofilm. This could be related to lactoferrin, a substance used in BlueM products with antimicrobial properties, reducing the growth of bacteria, viruses, fungi, and protozoa^{28,29}. Lactoferrin is also known for its immunomodulatory, anti-inflammatory, and anticarcinogenic properties^{30,31}. In addition, the active oxygen released by the products also contributes to a reduction in gingival redness³². These results are in line with the study by Cunha et al.³², which evaluated BlueM toothpaste, based on active oxygen and lactoferrin, and proved to be efficient against dental biofilm compared to toothpaste containing triclosan.

Regarding the other components of the BlueM products' formula, we can highlight sodium perborate, which, in contact with water, undergoes hydrolysis, producing hydrogen peroxide. It is an excellent oropharyngeal antiseptic with immediate action upon contact with oral tissue, not requiring a long time of stay on the mucosa and dental tissue to generate its action³³. Polyvinylpyrrolidone adheres to the mucosa, allowing for longer protection time for the user. Sodium lauryl sulfate has detergent action and can damage the bacterial cell membrane. Methyl salicylate is considered a non-steroidal anti-inflammatory when used topically; it causes hyperemia at the site of application by dilating blood vessels, increasing local circulation, and reducing inflammatory processes. Limonene is used as an anti-inflammatory for oral use and may

have action comparable to ibuprofen, depending on the concentrations used. Honey, on the other hand, possesses antimicrobial and anti-inflammatory characteristics.

Orthodontic aligners are better for periodontal health than fixed appliances and can be recommended for patients at a higher risk of developing gingivitis^{12,19}. Oral hygiene and disinfection substances for orthodontic aligners contribute positively to satisfactory oral health during orthodontic treatment^{3,24,26}.

CONCLUSION

Patients in the mouthwash group had a lower chance of bleeding on probe and the presence of biofilm compared to baseline, and there was no significant difference in periodontal probing when compared tooth by tooth between the groups. New prospective and randomized clinical studies with a larger sample size should be conducted for more definitive results.

AUTHORS' CONTRIBUTIONS

Yasmin Dallarmi Miguel: Data collection, interpretation of data, drafting the paper, final review of the manuscript.

Paola Rebelatto Alcântara: Data collection, interpretation of data, final review of the manuscript. Ana Cláudia Moreira Melo Toyofuku: Conception and design of the study, interpretation of data, final review of the manuscript.

Roberto Hideo Shimizu: Conception and design of the study, interpretation of data, final review of the manuscript.

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CONFLICTS OF INTERESTS

Ana Cláudia M. Melo and Roberto H. Shimizu, we declare that we are Key Opinion Leaders (KOL) for ClearCorrect, the company that manufactures the aligners used in this study. Neither author has any commercial relationship with BlueM, the company that manufactures the products studied and donated by them.

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