A randomized controlled trial of a power brush/irrigator/mouthrinse routine on plaque and gingivitis reduction in orthodontic patients

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ABSTRACT

Objectives: To assess plaque and gingivitis reduction in orthodontic patients after 4 weeks’ use of an oscillating-rotating power brush, irrigator, and mouthrinse.

Materials and Methods: This was a randomized, examiner-blind, clinical trial comparing plaque and gingivitis outcomes for an experimental power brush/irrigator/mouthrinse oral hygiene routine vs a dental prophylaxis followed by regular manual brushing (positive control). Fifty-one participants with fixed orthodontic appliances in the upper and lower jaw and a minimum of 15 gingival bleeding sites were randomly assigned to experimental or positive control treatment. Both groups were instructed to use their products at least twice daily. At baseline, week 1, and week 4, plaque was evaluated using digital plaque imaging analysis and a conventional subjective index. Gingival inflammation and bleeding were also measured. Analysis of covariance was used to compare groups.

Results: Fifty-one participants (mean age = 13.9 years) were randomized; 50 (25 per group) completed the study. At baseline, group means were not statistically different (P > .1) for gingival inflammation or bleeding. At week 4, the experimental and control groups had a 10.0% to 32.7% and 5.9% to 6.7% reduction vs baseline, respectively, in plaque (across both methods); 12.6% and 8.3% reduction, respectively, in gingival inflammation; and 50.6% and 37.8% reduction, respectively, in bleeding. At week 4, group differences favoring the experimental group were statistically significant (P < .05) for gingival inflammation, gingival bleeding, and plaque (by conventional and digital imaging indexes).

Conclusions: Use of a power brush/irrigator/mouthrinse resulted in statistically significantly greater plaque and gingivitis reductions than prophylaxis followed by manual brushing in patients with fixed appliances over 4 weeks. (Angle Orthod. 2019;89:378–384.)

KEY WORDS: Plaque reduction; Gingivitis; Orthodontic patients; Power toothbrush; Mouthrinse; Irrigator

INTRODUCTION

Efficient plaque removal is known to be essential for the prevention of dental caries, gingivitis, and periodontal disease.1-3 Achieving optimal oral hygiene is especially difficult for patients with fixed orthodontic appliances, as they must overcome the physical barriers of their appliances for effective dental plaque removal. Plaque can become trapped around appliances, often leading to demineralization and the development of white spot lesions.4-6

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The challenge of preventing plaque-induced diseases in patients needing orthodontic care is complicated by the fact that most orthodontic patients are children and adolescents, an age group particularly susceptible to poor compliance. A US national survey found that three in five adolescents have had caries in permanent teeth and 15% had untreated dental decay. The American Academy of Periodontology reported that chronic gingivitis is common among children, exacerbated by hormonal changes during puberty.

To improve oral health in adolescents undergoing orthodontic treatment, advanced oral hygiene products with specialized features (eg, oscillating-rotating electric toothbrush with orthodontic brush head) have been introduced. Clinical trials with orthodontic patients are needed, however, to evaluate their efficacy. The aim of the present study was to examine the effect of a power brush, irrigator, and mouthrinse compared with prophylaxis and manual toothbrushing on plaque and gingival health in orthodontic patients over 4 weeks.

MATERIALS AND METHODS

The study was carried out at the University Medical Center of the Johannes Gutenberg-University of Mainz, and participants were recruited from the Department of Orthodontics. Before study initiation, the protocol was approved by an institutional review board (Freiburger Ethik-Kommission International, code 07/2113), and written informed consent was obtained from participants and their guardians.

Subject eligibility was assessed at a screening visit and was limited to healthy and well-aligned participants, age 12 years and older, with fixed orthodontic appliances (Roth Prescription, 0.022" slot) in the upper and lower jaw, and with at least 15 bleeding sites according to the Löe-Silness Gingival Index (LSGI). Participants with fewer than 16 natural teeth, requirements for pre-medication for dental care, antibiotic usage 2 weeks prior to study initiation, severe periodontal disease, and/or dye allergies were excluded.

This was a randomized, 2-treatment, parallel group, examiner-blind, 4-week study with 4 study visits. Treatment in the experimental group comprised an oscillating-rotating power brush with dental irrigator (Oral-B ProfessionalCare 8500 DLX OxyJet® Center and EB17 brush head, Procter & Gamble, Marktheidenfeld, Germany) and standard fluoridated dentifrice containing 1450 ppm F as NaF (Blendax Antibelag, Procter & Gamble, Groß-Gerau, Germany). The dental irrigator was used in combination with a diluted alcohol-free antimicrobial mouthrinse containing 0.07% cetylpyridinium chloride (CPC) (Crest Pro-Health, Procter & Gamble, Cincinnati, Ohio). Treatment in the control group was a professional dental prophylaxis at baseline and use of a soft manual toothbrush (Oral-B Indicator 35, Procter & Gamble, Newbridge, UK) and the same standard fluoridated dentifrice as the experimental group. Participants were required to use their assigned treatment products at least twice daily (morning and evening) for the 4 weeks.

At the screening visit, the participants’ oral hard and soft tissue was examined, and a trained examiner used the LSGI to assess eligibility. Participants then received a regular toothpaste (Blendax Antibelag) and soft toothbrush (Oral-B Indicator 35 soft) and were instructed to use these products at home twice daily (morning and evening) for 2 weeks (acclimation period) in place of their standard oral hygiene products. Prior to their next visit (baseline), participants were instructed to perform their last oral hygiene in the morning (not later than 8 AM) and not to eat or drink for 4 hours prior to their afternoon appointment.

At the baseline visit, continuance criteria were reviewed and oral soft tissue was examined. Participants then disclosed plaque with fluorescein, and digital plaque imaging analysis (DPIA) image was done. After a 15-minute fluorescein washout period, LSGI was measured, after which participants had plaque disclosed with a red disclosing solution (Mira-2-Ton, Hager & Werken, Germany). Whole-mouth plaque was assessed using the Modified Quigley-Hein Index (WM-mQHI) and its adaptation was used for measuring facial anterior plaque (FA-mQHI). Participants were randomized to one of two treatment groups using a computer-generated randomization plan, with equal likelihood within each strata category based on number of bleeding sites and categories determined from screening-visit scores. Experimental and control products were provided in identical kit boxes and, to ensure examiner blinding, site staff distributed the products and gave treatment instructions outside the view of the examiners. Participants randomized to the experimental group were given the experimental products and instructed (written and verbal) on product usage. The first product use was supervised on-site. Participants were to brush for 2 minutes with the power brush and a pea-size amount of dentifrice, followed by use of the dental irrigator with the mixture consisting of 280 mL of water and 20 mL of the CPC rinse, to be prepared fresh for each irrigation. Participants were instructed to use the entire 300 mL during each irrigation. Participants randomized to the control group received professional dental prophylaxis and were asked to continue their daily oral routine using their acclimation products. Participants were instructed to perform their last oral hygiene in the morning (not later than 8 AM) and not to eat, drink, or smoke for 4 hours prior to their afternoon week 1 appointment.
At the week 1 and week 4 visits, participant eligibility for continuation in the study was reviewed. Participants then had DPIA, LSGI, and mQHI assessments conducted in the same order and as described for baseline. At the week 1 visit, participants were instructed to perform their last oral hygiene in the morning (not later than 8 AM) and not to eat, drink, or smoke for 4 hours prior to their afternoon week 4 appointment.

Throughout the study, the same trained examiners were used: examiner A/M. for DPIA and examiner J.W. for all other assessments. Any adverse events that were potentially product related were recorded at study visits.

Clinical Measures

The standard procedures for assessing DPIA have been described previously. Plaque was disclosed as follows: rinsing for 10 seconds with 25 mL of phosphate buffer. Rinsing for 1 minute with 5.0 mL of 1240 ppm fluorescein in phosphate buffer; then rinsing for 3 × 10 seconds with 25 mL of phosphate buffer. After rinsing, a trained operator (A.M.) took an image of the 12 upper and lower front teeth. The captured digital images were analyzed by classifying tooth, plaque, and wire/bracket pixels; the percentage of the facial anterior tooth surface covered by plaque was calculated.

The Gingivitis Index (GI) of Löe and Silness was used to score gingival inflammation from 0 to 3, on six gingival areas (mesiobuccal, buccal, distobuccal, mesiolingual, lingual, and distolingual) on the entire dentition, except for third molars as described previously. A participant’s overall whole-mouth inflammation (LSGI) score was calculated by summing the individual scores and dividing by the number of scorable sites examined. The bleeding score (BS) was derived from the LSGI as follows: BS = 1 if the LSGI score was either a 2 or 3; BS = 0 if the GI score was 0 or 1. A participant’s whole-mouth BS was calculated by summing the individual scores and dividing by the number of scorable sites examined.

Supragingival plaque accumulation was measured on six surfaces (mesiobuccal, buccal, distobuccal, mesiolingual, lingual, and distolingual) of all 28 teeth (excluding third molars, crowns, and surfaces with cervical restorations) using mQHI. With mQHI, each surface is normally given a score of 0 to 5 as follows: 0 = no plaque, 1 = separate flecks of plaque at the cervical margin; 2 = thin continuous band of plaque (up to 1 mm) at the cervical margin; 3 = band of plaque wider than 1 mm but covering less than one third of the crown; 4 = plaque covering at least one third but less than two thirds of the crown; 5 = plaque covering two thirds or more of the crown. In this study of orthodontic patients, WM-mQHI was adapted for assessing facial anterior plaque such that scores of 3 and 4 were as follows: 3 = plaque extension up to one third of the tooth surface and thin plaque strip around the wire; 4 = plaque extension up to two thirds of the tooth surface and broad plaque strip around the wire. Average whole-mouth plaque scores and facial anterior plaque scores were calculated separately for each participant by totaling the scores and dividing by the number of scorable sites examined.

Statistical Methods

The primary measurement used for recruiting and sample-size determination was gingivitis, although both gingivitis and plaque assessments after 4 weeks of treatment were of interest. With 50 participants per test group completing the research, there was a minimum of 85% power to detect a mean difference between groups for gingival bleeding and inflammation using two-sided testing and a 5% significance level. This estimate assumed an effect size, mean difference between groups divided by the standard deviation, of approximately 0.87 or higher.

Summary statistics (eg, means, standard deviations, frequencies) were used for baseline demographic characteristics of participants, and for plaque (mQHI and DPIA) and gingivitis (LSGI and BS) assessments for each treatment group at baseline and at weeks 1 and 4 of treatment. Comparisons between treatment visits and baseline for plaque and gingivitis were made using paired-difference t-tests, and treatment groups were compared using the analysis of covariance with baseline scores as covariates. Pearson correlations and associated P values were calculated to determine a relationship between FA-mQHI plaque scores and DPIA scores. Statistical tests were two-sided and used a significance level of α = 0.05. Data were analyzed using SAS software: version 9.1 (SAS Institute, Cary, North Carolina).

RESULTS

Sixty-two participants were assessed for eligibility and 51 participants (mean age = 13.9 years) were randomized to treatment. One participant was lost to follow-up by week 1, and 50 participants completed the study (Figure 1). Table 1 summarizes baseline demographic characteristics.

Table 2 shows scores for WM-mQHI plaque, FA-mQHI plaque, and percentage plaque coverage using DPIA. Baseline between-group comparisons showed no significant difference in WM-mQHI plaque (P > .05), but there was a statistically significant lower amount of plaque in the experimental group vs the control group.
At week 1, the experimental group had 8.1% (WM-mQHI), 10.6% (FA-mQHI), and 45.1% (DPIA) reductions in plaque vs baseline; the corresponding figures for the control group were 5.9%, 6.1%, and 22.3%, respectively. At week 4, the experimental group had a 10.0% (WM-mQHI), 10.1% (FA-mQHI), and 32.7% (DPIA) reduction in plaque vs baseline; corresponding figures for the control group were 6.7%, 6.6%, and 5.9%, respectively. Figure 2 shows DPIA images of a subject from each group at Baseline and Week 4. All week 1 and week 4 comparisons relative to baseline for FA-mQHI plaque ($P = .016$) and for DPIA ($P = .020$). At week 1, the experimental group had 8.1% (WM-mQHI), 10.6% (FA-mQHI), and 45.1% (DPIA) reductions in plaque vs baseline; the corresponding figures for the control group were 5.9%, 6.1%, and 22.3%, respectively. At week 4, the experimental group had a 10.0% (WM-mQHI), 10.1% (FA-mQHI), and 32.7% (DPIA) reduction in plaque vs baseline; corresponding figures for the control group were 6.7%, 6.6%, and 5.9%, respectively. Figure 2 shows DPIA images of a subject from each group at Baseline and Week 4. All week 1 and week 4 comparisons relative to baseline.
showed a statistically significant plaque reduction ($P < .01$), except for baseline vs week 4 in the control group using DPIA ($P = .1$).

Comparisons between groups at weeks 1 and 4 found significantly less plaque ($P = .017$) in the experimental group for WM-mQHI plaque at week 4 and for DPIA at both time points ($P = .002$). Figure 3 shows the correlation between FA-mQHI scores and DPIA scores. Correlations between methods were statistically significant ($P = .001$) at baseline ($r = .868$), week 1 ($r = .849$), and week 4 ($r = .860$).

Table 3 shows scores for gingival inflammation and bleeding. There were no statistically significant differences ($P > .698$) between groups at baseline. At week 1, the experimental and control groups had 10.9% and 7.5% reductions vs baseline, respectively, in LSGI, and 50.0% and 33.8% reductions, respectively, in BS. At week 4 vs baseline, the experimental and control groups had 12.6% and 8.3% reductions, respectively, in LSGI and 50.6% and 37.8% reductions, respectively, in BS. For both LSGI and BS gingivitis scores, all week 1 and week 4 comparisons vs baseline showed a statistically significant reduction ($P < .001$). Between-group comparisons at weeks 1 and 4 showed statistically significantly lower LSGI and BS scores for the experimental group at both week 1 ($P \leq .034$) and week 4 ($P \leq .043$).

No product-related adverse events were apparent.

**DISCUSSION**

The present study in orthodontic patients compared the efficacy of brushing with a power brush/irrigator in combination with a CPC rinse to a positive control.
treatment consisting of dental prophylaxis followed by manual brushing. A professional dental prophylaxis is known to limit plaque formation and reduce the risk of gingival inflammation, and it can be considered a gold standard for managing plaque. However, the benefits of intermittent professional cleaning are short lived as plaque reaccumulates rapidly, so complementary approaches such as the experimental routine in this trial are necessary.

At week 4 in this trial, both groups showed a reduction vs baseline in gingival inflammation and bleeding, with statistically significantly greater reductions for the experimental group. Plaque was assessed by a traditional subjective index (mQHI) adapted to measure facial anterior plaque in orthodontic patients and an objective digital method (DPIA). Both WM-mQHI and DPIA plaque measures showed a reduction at week 4 in the experimental group while the control group mean score only improved statistically from baseline for WM-mQHI. Both measures revealed the superiority of the experimental group’s approach at week 4, with DPIA also revealing superiority (P < .005) at week 1. Facial anterior plaque, as measured by an adaptation of mQHI, did not differentiate between groups at either week 1 or week 4 of treatment (P > .05), but this measure was well correlated (P < .001) with DPIA at baseline and at both treatment time points, suggesting DPIA was the more sensitive of the two methods for facial anterior plaque evaluations. DPIA has been considered a convenient quantitative technique for assessing plaque levels in patients with fixed orthodontic appliances and has been used to demonstrate greater plaque removal benefits with the oscillating-rotating toothbrush and orthodontic brush head vs controls in orthodontic patients.

The experimental group in this study combined three different components, each of which has demonstrated gingivitis and plaque reduction individually. The CPC rinse might also enhance patient compliance as it is alcohol free so does not have alcohol-associated burning. In extrapolating these outcomes to the typical orthodontic patient, it is important to consider the study period. Statistically significant benefits were seen for the experimental group at 4 weeks; however, future research is needed to confirm longer-term benefits. While studies lasting 6 months or longer, typically with a dental prophylaxis at baseline, have historically been used to assess gingivitis prevention resulting from intervention, shorter-term models such as the one used in this trial also provide valuable information. Many patients do not receive regular dental cleanings, so a short-term model without a prophylaxis at study onset

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* Means were adjusted for the baseline scores at weeks 1 and 4. * Comparison to baseline was statistically significant (P < .001).
demonstrates the ability of an intervention to quickly reduce gingivitis and plaque.

CONCLUSIONS
• The results of this 4-week study showed statistically significantly greater plaque and gingivitis reductions for the oscillating-rotating electric brush technology when combined with oral irrigation and 0.07% CPC alcohol-free mouthrinse in comparison with prophylaxis and manual brushing in orthodontic patients wearing fixed appliances.

REFERENCES