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Efficacy of Flossing and Mouthrinsing Regimens on Plaque and Gingivitis: A randomized clinical trial

Comparative Effectiveness of Flossing and Mouthrinse Regimens on Plaque and Gingivitis: A 12-week virtually supervised clinical trial

Role of Manual Dexterity on Mechanical and Chemotherapeutic Oral Hygiene Regimens

Habits, Practices and Beliefs Regarding Floss and Mouthrinse among Habitual and Non-Habitual Users

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Inside this Issue

This special issue of the *Journal of Dental Hygiene* was sponsored by

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A Message from our Sponsor

Michael C. Lynch, DMD, PhD

On behalf of Johnson & Johnson Consumer Inc., we are proud to support the publication of a special issue of the *Journal of Dental Hygiene,* in conjunction with the American Dental Hygienists' Association's Annual Conference in Louisville, Kentucky, June 24-26, 2022.

While it is well understood by dental professionals that proper daily oral hygiene, i.e., mechanical methods and chemotherapeutic agents, is crucial for the prevention of oral diseases, it is less understood by many professionals what each component of the routine contributes. The goal of this special issue is to share exciting new clinical data on adjunctive oral hygiene regimens, as well as the potential barriers for patients in the adoption of these modalities.

Daily oral hygiene recommendations have remained fundamentally unchanged for over a century. In 1908, the organization now known as the American Dental Association published its first patient dental education pamphlet with recommendations to brush at least twice daily, clean between teeth with floss and a toothpick and see a dentist at least twice a year.[1] Over the ensuing years, many other professional organizations and experts shared similar recommendations to the public.

LISTERINE® Antiseptic Mouthwash was first marketed as an oral antiseptic to dental professionals in 1895, but it wasn't until 1914 that it was sold directly to consumers.[2] LISTERINE® has been studied and published in hundreds of peer-reviewed publications spanning back more than a century, beginning with *The Journal of Infectious Diseases* in 1906.[3] In this special issue of the *Journal of Dental Hygiene*, two long-term (12-week) clinical trials demonstrate the adjunctive benefits of various regimens to twice daily brushing, adding to the large body of evidence on the benefits of LISTERINE® mouthrinse products containing essential oils.

The first paper describes a supervised clinical trial investigating the effects of various oral hygiene routines; all routines included twice daily brushing. These included supervised product usage of rinsing with LISTERINE®, professional flossing by a dental hygienist, and supervised self-flossing on the reduction of plaque, gingivitis, and gingival bleeding, compared to a negative control rinse. Twice daily rinsing with LISTERINE® statistically significantly improved gingival health at all measurement points and in all assessments. For example, interproximal plaque was statistically significantly reduced for the LISTERINE® group (22.8% reduction), but not flossing by a dental hygienist (4.96% reduction) or supervised flossing (2.41% reduction) groups at week 12. In other words, the LISTERINE® group had 4.6 times greater reduction in interproximal plaque when compared to the flossing by a dental hygienist group. Additionally, interproximal gingivitis was statistically significantly reduced for all groups at week 12: LISTERINE® (46.4% reduction), flossing by a dental hygienist (26.4% reduction) and supervised flossing (21.6% reduction). This means that the LISTERINE® group had 1.8 times greater reduction in interproximal gingivitis when compared to the flossing by a dental hygienist group.[4]

The second 12-week clinical trial investigated the effects of various combinations of supervised mechanical and chemotherapeutic regimens on the prevention and reduction of plaque, gingivitis, and gingival bleeding. Due to the Covid-19 pandemic, virtual supervision was required to conduct the study. Participants using LISTERINE®, in combination with brushing or with brushing and flossing, experienced statistically significant reductions in supragingival plaque, gingivitis, and gingival bleeding compared to brushing only, and brushing and flossing at 12 weeks. Furthermore, brushing and flossing provided no additional plaque reduction compared to brushing only but did provide reductions in gingivitis and gingival bleeding compared to brushing only at 12 weeks.[5]

The second study included two additional components, dexterity and behavior.[6,7] To clarify the role of dexterity on clinical measures of gingivitis, a licensed occupational therapist evaluated study participants' dexterity using a validated test. The results provide evidence of the correlation between dexterity scores and the effectiveness of various oral hygiene regimens;

less manual dexterity can limit dental flossing effectiveness. The results also demonstrated that the use of LISTERINE® improved interproximal gingival health and mitigated the dexterity variable.

Additionally, since few published studies have investigated how individuals' beliefs and perceptions might influence flossing or rinsing behaviors, a survey was conducted prior to randomization in the clinical phase. The results demonstrated that while more than 90% of the participants agreed that daily flossing and rinsing would result in healthier gums and protect their teeth from plaque and decay, only 16% reported flossing daily and only 17% reported rinsing with mouthrinse at least daily. Results of this survey suggest that the perceived barriers to flossing and rinsing, rather than beliefs about efficacy or benefits, may be the strongest differentiators in habitual flossing and rinsing.

One of the priorities of the ADHA's National Dental Hygiene Research Agenda (NDHRA) is to support research activities that enhance the profession's ability to promote the health and well-being of the public by testing and evaluating new therapies and prevention modalities. The research presented in this special issue directly addresses this goal and provides additional data-driven, clinically meaningful evidence to assist dental healthcare providers in recommending plaque and gingivitis control methods as part of their patients' daily oral care routines.

Michael C. Lynch, DMD, PhD
Global Director and Fellow -
Scientific Engagement, Oral Health

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Editorial

From Research to Practice

Catherine K. Draper, RDH, MS

JoAnn R. Gurenlian, RDH, MS, PhD, AFAAOM

It has been fifteen years since the *Journal of Dental Hygiene* published a supplemental issue focusing on incorporating antimicrobial mouthrinse strategies into oral hygiene regimens. At that time, the safety and efficacy of antimicrobial mouthrinses were discussed extensively.[1]

Mouthrinse products containing the active ingredients chlorhexidine gluconate, cetylpyridium chloride and essential oils, have been designated as safe and effective by the Food and Drug Administration for the reduction of gingivitis. While chlorhexidine gluconate mouthrinses require a prescription for use, cetylpyridium chloride and essential oil rinses are both available over the counter and the essential oil rinses carry the American Dental Association Seal of Acceptance.

Using an antimicrobial mouthrinse has been shown to benefit the entire mouth, including those areas easily missed during toothbrushing and interdental cleaning.[1] We also know that pathogenic bacteria from oral biofilm are easily shed into the saliva and transferred to the oral mucosa which represents about 80% of the oral cavity,[2] areas of the mouth that will not benefit from daily brushing or flossing!

Yet, in spite of what we know about the efficacy of antimicrobial rinses, clinicians often focus on flossing for interdental cleaning recommendations. Just tell anyone you meet in a social setting that you are a dental hygienist, and they immediately respond with "I know I need to floss more!" Or before you even begin your intraoral examination, your patient is already confessing that they have not been flossing. When the United States Departments of Agriculture and Health and Human Services quietly dropped the mention of flossing from the dietary guidelines for Americans in 2016, the news went global, leaving oral health care professionals and associations to address the fallout to support the habit.[3] A key take away from the publicity regarding flossing, is that we need to know what is being published in the literature to support our recommendations for patient care.

What if we were able to give our patients more options based on the existing science and their individual needs? In this issue, there are two different clinical trials conducted over 12 weeks comparing the use of dental floss to various combinations of toothbrushing, and mouthrinsing with an essential oil rinse product. One of the unique features of both studies is the introduction of daily professional flossing by a dental hygienist in the first clinical trial and virtually supervised flossing in the second trial. While this level of flossing was shown to be effective, the results for the combinations of brushing/rinsing and brushing/flossing/rinsing were compelling for the reduction of gingivitis. Two other manuscripts explore the role of dexterity with flossing and the role of oral health beliefs towards oral hygiene regimens that include flossing and mouthrinsing.

The research in this issue shows that there are benefits to brushing, flossing and mouthrinsing. There are also considerations to keep in mind. The studies reported in this issue showed that patients benefitted from daily professional flossing by a dental hygienist or supervised flossing, things that simply may not be practical in the real world. We know there are other interdental aides that are more effective and user friendly. In addition, the research provided shows us that rinsing with an essential oil product is comparable, and in some cases, more effective than brushing and flossing. By considering the evidence, clinicians should be able to provide their patients with solid strategies for optimal oral health outcomes that are tailored to meet what they are able to perform on a regular basis. Does this mean that we tell all our patients to "toss the floss?" No, but the research demonstrates that we can provide a variety of effective options for controlling gingival inflammation and promoting oral health. Adding other mechanical aides along with mouthrinsing may provide opportunities for improved oral health outcomes.

Catherine K. Draper, RDH, MS is the managing editor of the *Journal of Dental Hygiene.*

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Efficacy of Flossing and Mouthrinsing Regimens on Plaque and Gingivitis: A randomized clinical trial

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Abstract

Purpose: Flossing is a well-known component of daily recommended oral care regimens, but patients often find it challenging to perform effectively on a regular basis. The purpose of this 12-week supervised clinical trial was to investigate the effects of twice daily rinsing with a mouthrinse containing a fixed combination of four essential oils (4EO) and supervised daily dental flossing regimens as compared to a negative control 5% hydroalcohol rinse (NC) on the prevention and reduction of plaque, gingivitis, and gingival bleeding.

Methods: Volunteer participants who met the inclusion criteria were randomized into the following groups for the 12-week trial: 1) NC; 2) mouthrinse containing 4EO; 3) professional flossing performed by a dental hygienist (FBH); 4) supervised self-flossing (FUS). All participants received a professional dental prophylaxis prior to beginning the trial. On weekday mornings, all participants brushed on site. After brushing, the rinse groups used their products under supervision, and the floss groups had their teeth flossed by a dental hygienist or self-flossed under supervision. Participants performed their assigned regimen in the evenings and the twice-daily weekend use at home. Each individual assessment of oral hard and soft tissue, plaque, gingivitis, and gingival bleeding at weeks 4 and 12, probing depth and bleeding on probing at week 12 was made by the same calibrated examiner.

Results: Of 156 randomized participants, 149 completed the trial. Use of the 4EO mouthrinse statistically significantly reduced plaque, gingivitis, and gingival bleeding on probing after 12 weeks as compared to the NC rinse. Both flossing interventions statistically significantly reduced interproximal gingivitis and gingival bleeding at 12 weeks compared to the NC rinse; neither flossing intervention significantly reduced interproximal plaque after 12 weeks compared to the NC rinse.

Conclusions: Rinsing with a 4EO mouthrinse statistically significantly improved all oral health outcome measures at all time points compared to a NC rinse in this 12-week clinical trial. While professional and supervised flossing improved gingival health compared to use of the NC rinse, statistically significant plaque reduction with dental flossing was not attained at the end of the 12-week trial.

Keywords: dental plaque, gingivitis, essential oils, mouthrinse, chemotherapeutics, dental floss, oral health

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Introduction

Dental biofilm (plaque), a complex community of microbial cells, attaches to the tooth surface by embedding in an extracellular matrix. Changes in the structure of the microbial communities within biofilm (plaque) serve as a primary etiologic factor in oral diseases such as caries and periodontitis.[1] Controlling plaque biofilm relies on a variety of methods and practices which include mechanical means such as toothbrushing, as well as chemotherapeutics. Dental floss is classified by the Food and Drug Administration as a Class I medical device for removal of plaque and food particles between teeth to reduce tooth decay.[2] However, for many individuals, maintaining oral hygiene standards and mastering mechanical plaque control such as flossing, remains challenging.[3] Chemotherapeutic methods include

the use of toothpastes and mouthrinses to achieve plaque and gingivitis control. Numerous studies of six-month duration or longer and meta-analyses have demonstrated the safety and the efficacy in reducing plaque and gingivitis of a mouthrinse containing a fixed combination of four essential oils (4EO) (Listerine® Antiseptic Mouthwash; Johnson & Johnson Consumer Inc., Skillman, NJ, USA).[4-11]

In a systematic review conducted by Worthington et al., very low certainty of evidence was found for the efficacy of flossing, as an adjunct to toothbrushing, to reduce gingivitis over a one-to-six-month time frame.[12] In addition, there were inconsistent results among the studies included in the review and very low certainty of evidence in regard to the proportion of bleeding sites and plaque.[12] The Worthington review included two controlled studies conducted in unsupervised settings comparing 4EO and dental flossing in their ability to control accumulation of plaque and subsequently prevent/reduce gingivitis.[12] While unsupervised, in order to monitor compliance, both studies weighed the mouthrinse and floss on a monthly basis.[13,14] In the study by Barouth et al., it was shown that rinsing twice daily with 4EO was at least as good as daily flossing in reducing interproximal plaque and gingivitis.[13] The study by Sharma et al. showed that 4EO was at least as good as daily flossing in reducing interproximal gingivitis and significantly more effective than flossing in controlling interproximal plaque.[14]

As these studies were unsupervised, monitoring of the proper use of products and proper technique was not possible. Supervision during flossing studies is a method used to ensure correct use of product and proper technique. A review of the literature identified a lack of long-term supervised adult studies evaluating oral care regimens that included the use of floss for the reduction of plaque and gingivitis. Graves et al. compared the effectiveness of three types of dental floss and toothbrushing in reducing interproximal bleeding in a two-week supervised study.[15] While flossing, in combination with toothbrushing, was shown to be more effective than toothbrushing alone in reducing interproximal bleeding, the need for longer term clinical trials examining the efficacy of flossing was indicated.[15] The purpose of this 12-week supervised clinical trial was to investigate the effects of twice daily rinsing with a 4EO mouthrinse, as compared to professional and supervised flossing and the use of a negative control mouthrinse (5% hydroalcohol) on the reduction of plaque, gingivitis, and gingival bleeding.

Methods

This randomized, controlled clinical trial was conducted at Salus Research, Inc. (Fort Wayne, IN, USA), an American Dental Association (ADA) qualified site,[16] from September 2018 to December 2018. The principles of the International Council on Harmonisation Guidance for Good Clinical Practice were applied to this trial. The trial protocol was approved by the Institutional Ethics Committee on research involving humans (IntegReview Institutional Review Board, Austin, TX, USA.) and was registered on clinicaltrials.gov (NCT04696536). In 2016, the ADA Council on Scientific Affairs modified the Seal of Acceptance program guidelines for chemotherapeutic products for control of gingivitis.[17] The revised clinical protocol guidelines indicate that the study duration length be a minimum of three months and include measurements at baseline and three months with the option of including an intermediate time point. Therefore, this clinical trial was three months in duration.

The randomization schedule was generated using a validated program created by the Biostatistics Department at Johnson & Johnson Consumer Inc. (JJCI). Participants were assigned in equal allocation to each treatment group using a block randomization with block size of eight. Each participant was assigned a unique randomization number that determined treatment assignment. The principal investigator (PI) and examiners were blinded to the treatment regimens of the participant groups. The personnel dispensing the test products or supervising their use did not participate in the examination of participants to minimize potential bias. Other staff members, including the PI and examiners, did not have access to the area where the product was being used.

Sample

Participants were from the Fort Wayne, Indiana area and were selected for screening from the clinical test site's database based upon the following inclusion criteria: males and females in good general health over the age of 18 years, with no known allergies to commercial dental products, and at least 20 teeth with scorable facial and lingual surfaces. All participants needed to have evidence of gingivitis (although no minimum score on the Modified Gingival Index (MGI) was required), no evidence of severe periodontitis, and a minimum of 10 bleeding sites based on the Bleeding Index (BI).[18,19] Participants were eligible for the trial if they had no sites with >5 mm probing depth, and a maximum of three sites of 5 mm probing depth. Participants agreed to attend onsite (in the clinical setting) daily sessions on weekdays for study procedures. Other inclusion criteria included the

absence of fixed or removable orthodontic appliances or removable partial dentures and significant oral soft tissue pathology excluding plaque-induced gingivitis based on a clinical examination and discretion of the investigator/dental examiner. Female participants of childbearing potential were eligible if they had a negative pregnancy test and agreed to use medically acceptable methods of birth control for one month prior to the baseline evaluation and throughout the trial.

Exclusion criteria included dental prophylaxis within four weeks prior to baseline, needing antibiotics prior to dental treatment, use of certain medications within the last month (antibiotics, anti-inflammatory or anticoagulant therapy), use of chemotherapeutic oral care products within two weeks, being pregnant or lactating, use of smokeless tobacco, vaping or e-cigarettes or suspected substance abuse, and any other medical or psychiatric condition that would make the volunteer inappropriate for the trial in the judgment of the PI.

Participants were not permitted to have non-emergency dental procedures during the trial period. After receiving a thorough explanation of the trial and the opportunity to ask questions in private, all participants provided written informed consent on a document which complied with the requirements of the Health Insurance Portability and Accountability Act.

Interventions

After receiving a dental prophylaxis, qualified participants were randomized into one of four treatment groups: 1) rinsing with a 5% hydroalcohol rinse (NC); 2) rinsing with an alcohol-containing product with a fixed combination of four essential oils: menthol, thymol, eucalyptol, and methyl salicylate (4EO); 3) professional flossing by a dental hygienist (FBH); and 4) self-flossing under supervision (FUS). All groups were required to brush with a fluoride dentifrice (Cavity Protection; Colgate-Palmolive, New York, NY, USA) prior to using their assigned regimen and were supplied with an ADA soft, flat-trim reference toothbrush sourced through the ADA. Participants assigned to FUS and FBH groups were instructed in a flossing method based on the ADA-recommended technique,[20] and were required to demonstrate competency. Those subjects assigned to FUS were observed daily by calibrated staff members and received reinforcement of flossing technique as needed throughout trial duration. The assigned products and materials for at-home use were provided to participants following clinical assessments. All trial products and materials were provided by the trial sponsor (Johnson & Johnson Consumer Inc., Skillman, NJ, USA).

Throughout the trial, all groups completed their first daily use of their assigned products/regimen under supervision at the trial site Monday through Friday. All groups brushed for one minute (timed) prior to proceeding with their assigned protocol. Participants assigned to the 4EO and NC groups rinsed for 30 seconds (timed) using 20ml of the assigned product. The professional flossing group (FBH) had their teeth flossed by a dental hygienist while the FUS group flossed under observation. Both groups used the same waxed floss product (REACH® Waxed Unflavored Dental Floss; JJCI, Skillman, NJ, USA.). Flossing was only performed once a day. Participants in both flossing groups flossed their own teeth on the weekends. All groups performed the second daily and weekend use of their assigned products unsupervised at home. Participants maintained diaries to document trial product use; diaries were reviewed, and the mouthrinse was weighed to track compliance at all assessment visits.

Assessments

Participants were assessed at baseline, week 4, and week 12. Assessments at weeks 4 and 12 were made after the participants had refrained from using their assigned product for at least eight (but not more than 18) hours and not eating at for least four hours. All assessment visits included a review of inclusion/exclusion criteria and concomitant medications, oral examination of hard and soft tissues, and adverse event monitoring before other measurements were taken. Each clinical assessment was performed consistently throughout the trial by the same trained and calibrated clinical examiner. Calibration included annual intra-examiner repeatability exercises as part of the site's standard operating procedures.

The following assessments were conducted at baseline, week 4 and week 12: oral examination of hard and soft tissue, MGI, BI, probing depth and bleeding on probing (BOP, baseline and week 12 only), six-site Turesky modification of the Quigley-Hein Plaque Index (TPI) and Proximal Marginal Plaque Index (PMI).[18,19,21-24] The PMI was added to the assessments as an additional method for scoring plaque to corroborate the TPI results. All plaque assessments were supragingival measures. The primary efficacy endpoints were interproximal mean MGI and interproximal mean TPI at week 12. Secondary endpoints included interproximal mean MGI and interproximal mean TPI at week 4, whole mouth mean TPI and whole mouth mean MGI at weeks 4 and 12, whole mouth and interproximal mean BI and interproximal percent gingival bleeding sites at week 4, whole and interproximal mean BI and interproximal percent

gingival bleeding sites at weeks 4 and 12, and whole mouth and interproximal mean PMI at weeks 4 and 12. Exploratory endpoints were whole mouth and interproximal probing depth and BOP at week 12. Measurements were made at six sites for each graded tooth (mesiofacial, facial, distofacial, mesiolingual, lingual, distolingual). BOP measures were based on 1 = yes bleeding, 0 = no bleeding.

Statistical analyses

A sample size of 37 completed participants per group provides approximately 80% probability that the half-width for the confidence interval (CI) for the difference between two treatments is no more than 0.2, assuming a population standard deviation (SD) of 0.4, based on the historical database for MGI and TPI clinical trial data from the trial sponsor. This sample size also provides 90% power to detect a standardized effect size (difference between treatment means divided by SD) of at least 0.8. Sample sizes were estimated using PASS version 14.0.4 (NCSS Statistical Software, LLC, Kaysville, UT, USA).

Between-treatment efficacy comparisons were based on a mixed effects model for repeated measures analysis (MMRM), considering within-participants correlation as unstructured and with model terms for treatment and visit, and the corresponding baseline value as a covariate, including all participants with at least one assessment after baseline.[25,26] Treatment-by-visit and baseline-by-visit terms were included to make treatment comparisons and estimate treatment differences at specific visits. The 4EO and floss groups were compared for superiority to the NC group, with each comparison performed at the 0.05 level of significance, two-sided. Differences between 4EO and floss groups were assessed using 95% confidence intervals.

Comparisons between the 4EO and the flossing intervention groups were focused on estimation, specifically using point estimates and 95% confidence intervals, rather than hypothesis testing. This approach was taken due to the lack of previous information on long-term flossing as evaluated in this study, particularly the FBH group. However, a 95% confidence interval for the difference between 4EO and a floss group, amounts to a test of the null hypothesis that the two population means are equal at the 5% significance level, where the null hypothesis is rejected only if the interval does not contain zero.

Participant whole mouth mean MGI, whole mouth mean BI, and whole mouth mean TPI were calculated at baseline and each post-baseline assessment time point by taking the mean of all observed scores at that time point. Interproximal means were calculated in the same way. Whole mouth percent gingival bleeding sites were calculated by taking the total number of sites with bleeding score >0 divided by the total number of sites assessed for each participant. Interproximal percent gingival bleeding sites were calculated in the same way but considering only interproximal sites. The interproximal mean for PMI was calculated similarly to the interproximal MGI, BI, and TPI. No imputation of missing data was performed.

For each of the secondary endpoints, the same MMRM approach, statistical testing and estimation procedures were applied. For the exploratory endpoints, each of which was assessed only at baseline and week 12 (therefore the MMRM approach was not applicable), the same treatment comparisons and confidence intervals were performed based on an analysis of covariance model with treatment as a factor and the corresponding baseline measure as a covariate. Demographic and baseline characteristics were compared across treatment groups using analysis of variance (ANOVA), Chi-square test, or Fisher's exact test.

Results

Of the 156 randomized participants, 149 completed the trial. Four participants withdrew their consent and three were lost to follow-up. Trial group distribution is shown in Figure 1. The sample demographics and baseline gingival health characteristics are presented in Table I. Other than age, there were no significant differences among the groups for any other demographic data or for any average baseline data for all measurements.

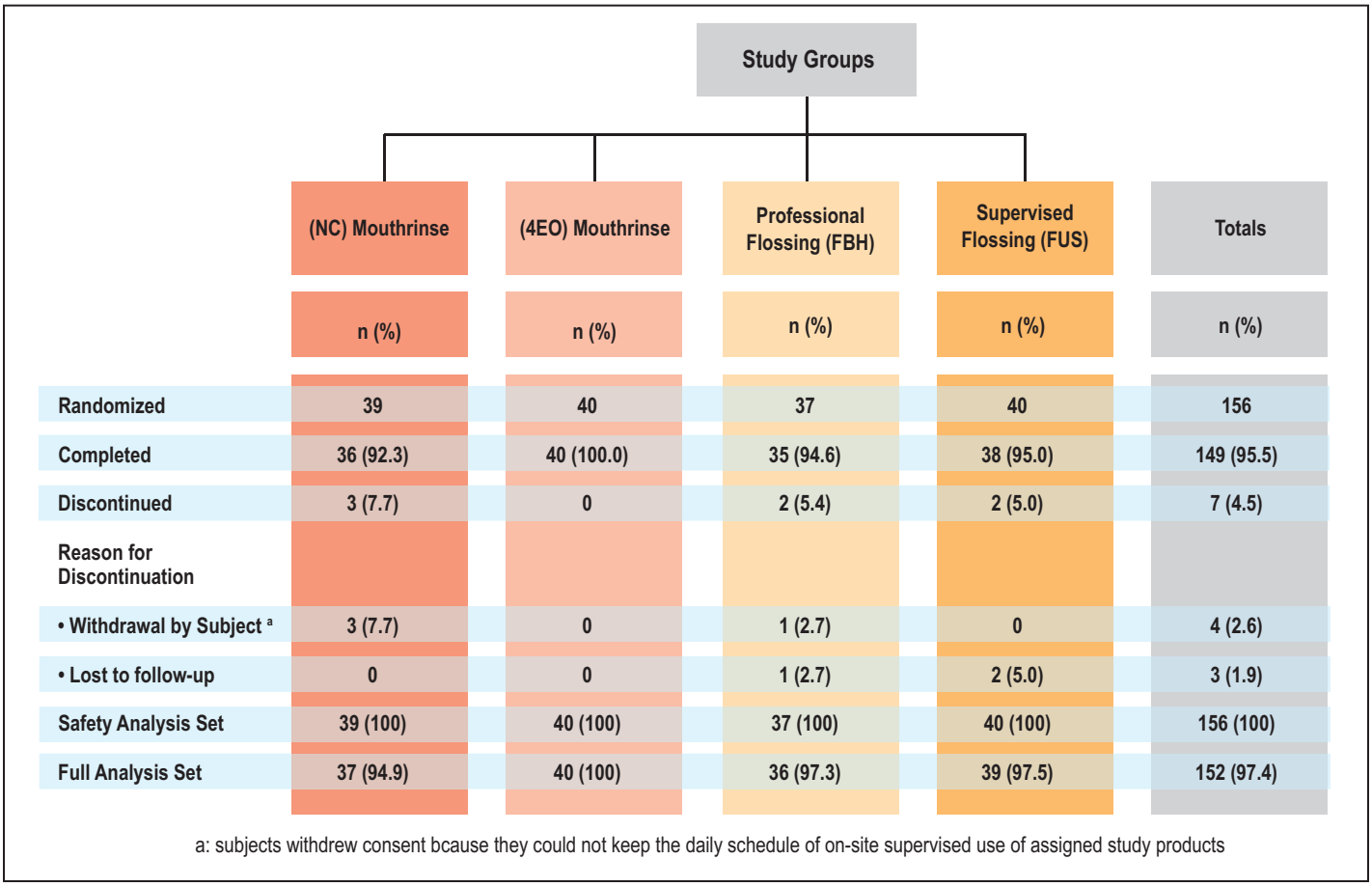
Interproximal Mean TPI and MGI

As compared to the NC rinse group, the interproximal mean TPI was statistically significantly reduced for all treatments at week 4 (4EO: 29.5%; FBH: 11.7%; FUS: 6.73%), and for the 4EO group (22.8% reduction), but not the FBH (4.96%) or FUS (2.41%) groups, at week 12 (Table II). The interproximal mean MGI was statistically significantly reduced for 4EO (50.5% and 46.4%, respectively), FBH (26.0% and 26.4%, respectively) and FUS (18.6% and 21.6%, respectively) groups as compared to NC rinse at week 4 and week 12 (Table III).

Interproximal Mean BI and Percent Bleeding Sites

Interproximal mean BI was statistically significantly reduced for the 4EO group (59.0% and 76.4%, respectively), FBH group (67.8% and 85.6%, respectively) and FUS group

Figure 1. Flow chart of trial group assignments (n=156)



	(NC) Mouthrinse	(4EO) Mouthrinse	Professional Flossing (FBH)	Supervised Flossing (FUS)	Totals
	n (%)	n (%)	n (%)	n (%)	n (%)
Randomized	39	40	37	40	156
Completed	36 (92.3)	40 (100.0)	35 (94.6)	38 (95.0)	149 (95.5)
Discontinued	3 (7.7)	0	2 (5.4)	2 (5.0)	7 (4.5)
Reason for Discontinuation					
• Withdrawal by Subject [a]	3 (7.7)	0	1 (2.7)	0	4 (2.6)
• Lost to follow-up	0	0	1 (2.7)	2 (5.0)	3 (1.9)
Safety Analysis Set	39 (100)	40 (100)	37 (100)	40 (100)	156 (100)
Full Analysis Set	37 (94.9)	40 (100)	36 (97.3)	39 (97.5)	152 (97.4)

a: subjects withdrew consent bcause they could not keep the daily schedule of on-site supervised use of assigned study products

(62.8% and 78.0%, respectively) compared to NC rinse group at weeks 4 and week 12 (Table IV). Likewise, interproximal percent bleeding sites were statistically significantly reduced for the 4EO group (58.4% and 78.5%, respectively), FBH group (68.9% and 86.0%, respectively) and FUS group (63.8% and 78.3%, respectively) as compared to NC rinse group at weeks 4 and 12 (Table V). All other secondary endpoints measured at week 12 are presented in Table IV and Table V.

Interproximal Mean PMI

Interproximal mean PMI at weeks 4 and 12 were largely directionally similar to interproximal mean TPI. At weeks 4 and 12 in comparison to the NC rinse group, the interproximal mean PMI was statistically significantly reduced for 4EO group by 54.9% and 50.0%, respectively, for the FBH group by 25.4% and 12.1%, respectively, and for the FUS group by 12.8% at week 4 only. Exploratory endpoints for whole mouth and interproximal probing depth and BOP at week 12 are presented in Table VI. All three treatment groups statistically significantly reduced probing depth and BOP compared to the NC group.

Interpretation of Differences Between 4EO and Flossing

As noted in the statistical analysis description in the methods, comparisons between 4EO and floss groups were based on CIs, and statistical significance for 4EO versus floss groups can be assessed by whether the CIs contain 0 or not. Statistically significant reductions for the 4EO group vs each of the floss groups was observed for all endpoints based on MGI or TPI. For other endpoints, 4EO was in most cases not statistically significantly different versus either floss group. The only exception in favor of floss was that FBH statistically significantly reduced interproximal BOP at 12 weeks versus 4EO (Tables II-VI).

Clinical safety

The rinses and procedures were well tolerated by trial participants. Nineteen participants experienced at least one treatment-emergent adverse event (TEAE) during the study trial: four participants in the NC group, seven in the 4EO

Table I. Demographics by group assignment (n=156)

	NC Rinse	4EO Rinse	Professional flossing (FBH)	Supervised flossing (FUS)	Total n	*p*-value
n	**39**	**40**	**37**	**40**	**156**	
Mean age (SD)	39.3 (13.58)	38.2 (13.39)	44.6 (14.61)	33.0 (13.28)	38.6 (14.18)	0.004*
Sex	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**0.392****
Male	9 (23.1)	14 (35.0)	9 (24.3)	15 (37.5)	47 (30.1)	
Female	30 (76.9)	26 (65.0)	28 (75.7)	25 (62.5)	109 (69.9)	
Race	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**0.750*****
White	33 (84.6)	33 (82.5)	30 (81.1)	28 (70.0)	124 (79.5)	
Black/African American	3 (7.7)	4 (10.0)	5 (13.5)	6 (15.0)	18 (11.5)	
Asian	1 (2.6)	1 (2.5)	—	2 (5.0)	4 (2.6)	
Native Hawaiian/Other Pacific Islander	—	—	1 (2.7)	—	1 (<1.0)	
American Indian/Alaskan Native	—	1 (2.5)	—	—	1 (<1.0)	
Other	2 (5.1)	1 (2.5)	1 (2.7)	4 (10.0)	8 (5.1)	
Ethnicity	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**0.085*****
Hispanic/Latino	4 (10.3)	3 (7.5)	—	6 (15.0)	13 (8.3)	
Not Hispanic/Latino	35 (89.7)	37 (92.5)	37 (100)	34 (85.0)	143 (91.7)	
Smoker	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**0.792*****
No	36 (92.3)	38 (95.0)	33 (89.2)	37 (92.5)	144 (92.3)	
Yes	3 (7.7)	2 (5.0)	4 (10.8)	3 (7.5)	12 (7.7)	
Whole Mouth Baseline Scores						
Mean MGI (SD)	2.07 (0.562)	2.17 (0.461)	1.99 (0.560)	2.15 (0.553)	2.10 (0.535)	0.433*
Mean TPI (SD)	3.01 (0.545)	3.07 (0.602)	2.83 (0.419)	3.04 (0.565)	2.99 (0.542)	0.208*
Mean BI (SD)	0.302 (0.1745)	0.306 (0.1989)	0.260 (0.1568)	0.343 (0.2496)	0.303 (0.1991)	0.350*
Mean % Bleeding Sites (SD)	21.17 (10.132)	20.64 (10.891)	18.11 (8.058)	23.11 (13.556)	20.81 (10.931)	0.254
Mean Pocket Depth (SD)	1.73 (0.208)	1.70 (0.197)	1.72 (0.275)	1.73 (0.265)	1.72 (0.236)	0.954*
Interproximal Baseline Scores						
Mean MGI (SD)	2.40 (0.491)	2.48 (0.373)	2.31 (0.488)	2.45 (0.467)	2.41 (0.457)	0362*
Mean TPI (SD)	3.16 (0.486)	3.24 (0.543)	3.02 (0.366)	3.19 (0.500)	3.15 (0.482)	0.227*
Mean BI (SD)	0.315 (0.1837)	0.322 (0.2119)	0.276 (0.1975)	0.373 (0.2947)	0.322 (0.2273)	0.313*
Mean % Bleeding Sites (SD)	22.57 (11.057)	21.81 (11.610)	19.20 (11.118)	25.06 (16.166)	22.22 (12.755)	0.250
Mean PMI (SD)	3.20 (0.779)	3.38 (0.791)	3.08 (0.678)	3.26 (0.697)	3.23 (0.740)	0.332*

**p*-values are based on ANOVA model with term for treatment group.

***p*-values are based on Chi-Squares test.

****Twenty percent or more cells with expected cell size <5, Chi-Square test may not be valid test. Fisher's Exact test was used.

Table II. Interproximal mean Turesky Plaque Index (TPI) at baseline, weeks 4 and 12

	NC mouthrinse	4EO mouthrinse	Professional flossing (FBH)	Supervised flossing (FUS)
Baseline				
n	**37**	**40**	**36**	**39**
Mean (SD)	3.13 (0.453)	3.24 (0.543)	3.03 (0.368)	3.19 (0.506)
Week 4				
n	**37**	**40**	**36**	**39**
LSmean (SE)	3.09 (0.058)	2.17 (0.056)	2.72 (0.059)	2.88 (0.057)
Treatment group versus NC rinse				
p-value*		<0.001	<0.001	0.011
Difference (SE)		-0.91 (0.081)	-0.36 (0.083)	-0.21 (0.081)
95% CI		[-1.07, -0.75]	[-0.53, -0.20]	[-0.37, -0.05]
% reduction		29.5	11.7	6.7
Treatment group versus FUS				
Difference (SE)		-0.70 (0.079)		
95% CI		[-0.86, -0.55]		
Treatment group versus FBH				
Difference (SE)		-0.55 (0.082)		
95% CI		[-0.71, -0.39]		
Week 12				
n	**36**	**40**	**35**	**38**
LSmean (SE)	3.04 (0.056)	2.35 (0.053)	2.89 (0.057)	2.97 (0.054)
Treatment group versus NC rinse				
p-value*		<0.001	0.060	0.347
Difference (SE)		-0.69 (0.077)	-0.15 (0.080)	-0.07 (0.078)
95% CI		[-0.85, -0.54]	[-0.31, 0.01]	[-0.23, 0.08]
% reduction		22.8	5.0	2.4
Treatment group versus FUS				
Difference (SE)		-0.62 (0.076)		
95% CI		[-0.77, -0.47]		
Treatment group versus FBH				
Difference (SE)		-0.54 (0.079)		
95% CI		[-0.70, -0.39]		

**p*-values, model-based estimated means (LSmeans), and standard errors were based on a mixed effects model for repeated measures analysis (MMRM), with the fixed effects including treatment, visit, and treatment by visit interaction; baseline as a covariate; and baseline by visit interaction.

group, four in the FBH group and four in the FUS group. The types of TEAEs observed were: coated tongue (two in the NC group, five in the 4EO group, two in the FBH group and one in the FUS group); nausea (one in the NC group, one in the 4EO group and two in the FUS group); plicated tongue (one in the NC group, two in the 4EO group); toothache (one in the FUS group); headache (one each in the FBH and FUS groups) and one respiratory tract infection in the FBH group. Two incidences of coated tongue in the 4EO group were classified by the Investigator as possibly related to trial treatment. All TEAEs were mild to moderate severity and were documented and followed to resolution. No deaths or serious TEAEs were reported. No TEAEs resulted in participant withdrawal from the trial.

Discussion

The purpose of this 12-week supervised clinical trial was to investigate the effects of twice daily rinsing with a mouthrinse containing a fixed combination of four essential oils (4EO) and supervised daily flossing regimens as compared to a negative control 5% hydro-alcohol rinse (NC) on the prevention and reduction of plaque, gingivitis, and gingival bleeding. Participants using the 4EO mouthrinse twice daily as part of their daily oral care regimen experienced statistically significant improvements in gingival health at all measurement points and in all assessments: reductions in plaque, gingivitis and gingival bleeding after four and 12 weeks, and probing depth and bleeding on probing after 12 weeks, as compared to the NC rinse. Investigation of

Table III. Interproximal mean Modified Gingival Index (MGI) at baseline, weeks 4 and 12

	NC mouthrinse	4EO mouthrinse	Professional flossing (FBH)	Supervised flossing (FUS)
Baseline				
n	**37**	**40**	**36**	**39**
Mean (SD)	2.37 (0.484)	2.48 (0.373)	2.31 (0.492)	2.44 (0.464)
Week 4				
n	**37**	**40**	**36**	**39**
LSmean (SE)	2.26 (0.073)	1.12 (0.071)	1.67 (0.075)	1.84 (0.072)
Treatment group versus NC rinse				
p-value*		<0.001	<0.001	<0.001
Difference (SE)		-1.14 (0.102)	-0.59 (0.105)	-0.42 (0.103)
95% CI		[-1.34, -0.94]	[-0.79, -0.38]	[-0.62, -0.22]
% reduction		50.5	26.0	18.6
Treatment group versus FUS				
Difference (SE)		-0.72 (0.100)		
95% CI		[-0.92, -0.52]		
Treatment group versus FBH				
Difference (SE)		-0.55 (0.103)		
95% CI		[-0.76, -0.35]		
Week 12				
n	**36**	**40**	**35**	**38**
LSmean (SE)	2.34 (0.070)	1.26 (0.067)	1.73 (0.071)	1.84 (0.068)
Treatment group versus NC rinse				
p-value		<0.001	<0.001	<0.001
Difference (SE)		-1.09 (0.097)	-0.62 (0.100)	-0.51 (0.098)
95% CI		[-1.28, -0.90]	[-0.82, -0.42]	[-0.70, -0.312]
% reduction		46.4	26.4	21.6
Treatment group versus FUS				
Difference (SE)		-0.58 (0.095)		
95% CI		[-0.77, -0.39]		
Treatment group versus FBH				
Difference (SE)		-0.47 (0.098)		
95% CI		[-0.66, -0.28]		

**p*-values, model-based estimated means (LSmeans), and standard errors were based on a mixed effects model for repeated measures analysis (MMRM), with the fixed effects including treatment, visit, and treatment by visit interaction; baseline as a covariate; and baseline by visit interaction.

plaque accumulation and gingival inflammation employed multiple measures, focusing on interproximal sites as well as the whole mouth using plaque (TPI), gingivitis (MGI) and gingival bleeding indices (EBI). The TPI is a more universally utilized plaque index in clinical trials than the PMI but PMI produced a similar pattern in plaque reduction in comparison to TPI, helping to confirm robustness of the NC rinse findings. In this study, statistically significant reductions for the 4EO group versus each of the floss groups was observed at 4 and 12 weeks for MGI and TPI.

Comparing the mode of action of chemotherapeutic effects of 4EO on plaque and the mechanical disruption of plaque by floss may provide insight to these results. The essential oils of menthol, thymol, eucalyptol, and methyl salicylate have been shown to rapidly disrupt the bacterial cell wall through protein denaturation, bacterial enzyme activity alteration, bacterial endotoxin extraction, and increased bacterial regeneration time, resulting in a sustained reduction in bacteria regrowth over time.[27] Dental floss which is indicated for removal of plaque and food particles between teeth to reduce tooth decay, is able to remove interproximal plaque to some level.[2,12] In a classical clinical study on plaque biofilm growth and development, it was found that as early as 12 hours after rendering all tooth surfaces plaque-free, a consistent pattern of plaque development was evident, starting with the interproximal areas of the premolars and molars.[28] Based on these findings, Lang et al. theorized that the qualitative and quantitative bacterial composition in the saliva

Table IV. Interproximal mean Bleeding Index (BI) at baseline, weeks 4 and 12

	NC mouthrinse	4EO mouthrinse	Professional flossing (FBH)	Supervised flossing (FUS)
Baseline				
n	**37**	**40**	**36**	**39**
Mean (SD)	0.302 (0.1757)	0.322 (0.2119)	0.280 (0.1990)	0.373 (0.2986)
Week 4				
n	**37**	**40**	**36**	**39**
LSmean (SE)	0.316 (0.0204)	0.129 (0.0196)	0.102 (0.0207)	0.117 (0.0200)
Treatment group versus NC rinse				
p-value*		<0.001	<0.001	<0.001
Difference (SE)		-0.186 (0.0283)	-0.214 (0.0290)	-0.198 (0.0286)
95% CI		[-0.242, -0.130]	[-0.271, -0.157]	[-0.255, -0.141]
% reduction		59.0	67.8	62.8
Treatment group versus FUS				
Difference (SE)		0.012 (0.0280)		
95% CI		[-0.044, 0.067]		
Treatment group versus FBH				
Difference (SE)		0.028 (0.0285)		
95% CI		[-0.029, 0.084]		
Week 12				
n	**36**	**40**	**35**	**38**
LSmean (SE)	0.452 (0.0234)	0.107 (0.0223)	0.065 (0.0238)	0.099 (0.0229)
Treatment group versus NC rinse				
p-value*		<0.001	<0.001	<0.001
Difference (SE)		-0.346 (0.0323)	-0.387 (0.0333)	-0.353 (0.0328)
95% CI		[-0.409, -0.282]	[-0.453, -0.321]	[-0.418, -0.288]
% reduction		76.4	85.6	78.0
Treatment group versus FUS				
Difference (SE)		0.007 (0.0319)		
95% CI		[-0.056, 0.070]		
Treatment group versus FBH				
Difference (SE)		0.042 (0.0326)		
95% CI		[-0.023, 0.106]		

**p*-values, model-based estimated means (LSmeans), and standard errors were based on a mixed effects model for repeated measures analysis (MMRM), with the fixed effects including treatment, visit, and treatment by visit interaction; baseline as a covariate; and baseline by visit interaction.

may have changed, subsequently influencing the rate of plaque accumulation.[28]

As discussed previously, the trial design included supervision of the daily use of dental floss as an adjunct to toothbrushing twice a day. Taking the flossing regimen further, it was either performed by a dental hygienist or by the participant who was monitored for proper use to investigate the role that effective flossing plays in reducing plaque and gingivitis. Both flossing intervention groups had statistically significant reductions in interproximal and whole mouth mean plaque scores as compared to the NC rinse group after four weeks, but not at 12 weeks. Participants in both flossing groups were found to have statistically significant improvements in their gingival health at all measurement points and in all assessments as compared to the NC rinse group in gingivitis and gingival bleeding at both four and 12 weeks.

Given the results with 4EO mouthrinse compared to the two flossing groups, the change in plaque composition from mechanical removal might not be as effective from a clinical perspective as from chemotherapeutic intervention. This may help explain some of the findings of this paper and warrants further investigation, including at the microbiome level, of a brush/floss/rinse routine in comparison to brushing alone, brush/floss, and brush/rinse routines.

There were improvements in probing depth and BOP after 12 weeks in the flossing groups. Two previous six-month unsupervised

Table V. Interproximal percent gingival bleeding sites at baseline, weeks 4 and 12

	NC mouthrinse	4EO mouthrinse	Professional flossing (FBH)	Supervised flossing (FUS)
Baseline				
n	**37**	**40**	**36**	**39**
Mean (SD)	21.83 (10.547)	21.81 (11.610)	19.39 (11.217)	24.96 (16.363)
Week 4				
n	**37**	**40**	**36**	**39**
LSmean (SE)	23.60 (1.374)	9.82 (1.321)	7.35 (1.400)	8.54 (1.348)
Treatment group versus NC rinse				
p-value*		<0.001	<0.001	<0.001
Difference (SE)		-13.78 (1.906)	-16.25 (1.961)	-15.06 (1.925)
95% CI		[-17.55, -10.02]	[-20.12, -12.37]	[-18.86, -11.25]
% reduction		58.4	68.9	63.8
Treatment group versus FUS				
Difference (SE)		1.27 (1.888)		
95% CI		[-2.46, 5.01]		
Treatment group versus FBH				
Difference (SE)		2.47 (1.924)		
95% CI		[-1.34, 6.27]		
Week 12				
n	**36**	**40**	**35**	**38**
LSmean (SE)	35.19 (1.478)	7.57 (1.406)	4.92 (1.506)	7.63 (1.445)
Treatment group versus NC rinse				
p-value*		<0.001	<0.001	<0.001
Difference (SE)		-27.62 (2.040)	-30.26 (2.110)	-27.55 (2.068)
95% CI		[-31.65, -23.59]	[-34.44, -26.09]	[-31.64, -23.47]
% reduction		78.5	86.0	78.3
Treatment group versus FUS				
Difference (SE)		-0.070 (2.017)		
95% CI		[-4.06, 3.92]		
Treatment group versus FBH				
Difference (SE)		2.64 (2.060)		
95% CI		[-1.43, 6.71]		

**p*-values, model-based estimated means (LSmeans), and standard errors were based on a mixed effects model for repeated measures analysis (MMRM), with the fixed effects including treatment, visit, and treatment by visit interaction; baseline as a covariate; and baseline by visit interaction.

studies also found that the flossing groups had smaller observed reductions in interproximal plaque and gingivitis compared to the mouthrinse groups.[13,14] Similarly, a Cochrane review reported a very low certainty of evidence for the ability of flossing, when added to toothbrushing, to reduce gingivitis over a one to six-month time frame.[12] In the current trial, neither flossing group demonstrated a reduction in interproximal plaque compared to NC after 12 weeks indicating that flossing fails to prevent plaque build-up throughout the day.

An interesting finding was the BOP measurements in the FBH group which indicated that flossing by a dental hygienist resulted in a significantly greater mean reduction in interproximal BOP compared to the 4EO mouthrinse group. Additionally, the supervised flossing group also had directionally lower, but not statistically significant, mean interproximal BOP measurements as compared to the 4EO group. A potential explanation for this could be the deeper subgingival access and more thorough mechanical subgingival plaque disruption that effective flossing may provide as compared to the use of a 4EO mouthrinse. This study attempts to demonstrate the importance of technique in performing dental flossing for optimal results.

Oral health care providers are challenged with making patient care recommendations based on the unique needs of each individual. Results from this trial provide data-driven evidence to assist oral health care providers in recommending

Table VI. Whole-mouth, interproximal mean probing depth and bleeding on probing, week 12

	NC mouthrinse	4EO mouthrinse	Professional flossing (FBH)	Supervised flossing (FUS)
Whole Mouth Mean Probing Depth – Baseline				
n	**37**	**40**	**36**	**39**
Mean (SD)	1.73 (0.202)	1.70 (0.197)	1.73 (0.276)	1.72 (0.268)
Week 12				
n	**36**	**40**	**35**	**38**
LSmean (SE)	1.72 (0.012)	1.57 (0.012)	1.56 (0.012)	1.62 (0.012)
Treatment group versus NC rinse				
p-value*		<0.001	<0.001	<0.001
Difference (SE)		-0.15 (0.017)	-0.17 (0.017)	-0.11 (0.017)
95% CI		[-0.19, -0.12]	[-0.20, -0.13]	[-0.14, -0.07]
% reduction		8.9	9.6	6.1
Treatment group versus FUS				**1**
Difference (SE)		-0.05 (0.017)		
95% CI		[-0.08, -0.02]		
Treatment group versus FBH				
Difference (SE)		0.01 (0.02)		
95% CI		[-0.02, 0.05]		
Whole Mouth Mean Bleeding on Probing – Baseline				
n	**37**	**40**	**36**	**39**
Mean (SD)	0.314 (0.1475)	0.324 (0.1712)	0.303 (0.1391)	0.347 (0.1827)
Week 12				
n	**36**	**40**	**35**	**38**
LSmean (SE)	0.349 (0.0168)	0.224 (0.0159)	0.182 (0.0170)	0.218 (0.0163)
Treatment group versus NC rinse				
p-value*		<0.001	<0.001	<0.001
Difference (SE)		-0.125 (0.0231)	-0.168 (0.0239)	-0.131 (0.0234)
95% CI		[-0.171, -0.079]	[-0.215, -0.120]	[-0.177, -0.085]
% reduction		35.8	48.0	37.5
Treatment group versus FUS				
Difference (SE)		0.006 (0.0228)		
95% CI		[-0.039, 0.051]		
Treatment group versus FBH				
Difference (SE)		0.043 (0.0233)		
95% CI		[-0.003, 0.089]		

	NC mouthrinse	4EO mouthrinse	Professional flossing (FBH)	Supervised flossing (FUS)
Interproximal Mean Probing Depth – Baseline				
n	**37**	**40**	**36**	**39**
Mean (SD)	1.97 (0.238)	1.93 (0.231)	1.95 (0.320)	1.95 (0.304)
Week 12				
n	**36**	**40**	**35**	**38**
LSmean (SE)	1.97 (0.014)	1.78 (0.014)	1.76 (0.015)	1.83 (0.014)
Treatment group versus NC rinse				
p-value*		<0.001	<0.001	<0.001
Difference (SE)		-0.18 (0.020)	-0.21 (0.021)	-0.13 (0.020)
95% CI		[-0.22, -0.14]	[-0.25, -0.17]	[-0.17, -0.09]
% reduction		9.35	10.6	6.7
Treatment group versus FUS				
Difference (SE)		-0.05 (0.020)		
95% CI		[-0.09, -0.01]		
Treatment group versus FBH				
Difference (SE)		0.02 (0.020)		
95% CI		[-0.01, 0.06]		
Interproximal Mean Bleeding on Probing – Baseline				
n	**37**	**40**	**36**	**39**
Mean (SD)	0.352 (0.1778)	0.361 (0.1931)	0.346 (0.1564)	0.386 (0.1983)
Week 12				
n	**36**	**40**	**35**	**38**
LSmean (SE)	0.389 (0.0196)	0.261(0.0186)	0.182 (0.0199)	0.228 (0.0191)
Treatment group versus NC rinse				
p-value*		<0.001	<0.001	<0.001
Difference (SE)		-0.128 (0.0270)	-0.207 (0.0279)	-0.161 (0.0273)
95% CI		[-0.181, -0.074]	[-0.262, -0.152]	[-0.215, -0.107]
% reduction		32.9	53.2	41.5
Treatment group versus. FUS				
Difference (SE)		0.033 (0.0266)		
95% CI		[-0.019, 0.086]		
Treatment group versus FBH				
Difference (SE)		0.079 (0.0272)		
95% CI		[0.025, 0.133]		

*p-values, model-based estimated means (LSmeans), and standard errors were based on analysis of covariate with term for treatment and baseline as a covariate.

effective plaque and gingivitis control methods as part of their patients' customized oral care regimens. Adding an easy-to-use intervention such as a 4EO mouthrinse to a patient's oral care routine provides an effective option to manage gingivitis and supragingival plaque accumulation.

Limitations

The sample population was limited to people who volunteered to be part of a clinical trial at a research center in the Midwest and may not be representative of the general population. The inclusion criteria specifically recruited people with evidence of gingivitis and without evidence of severe periodontitis and the results may not be generalizable to a population with more optimal oral health or with greater disease. This trial did not address the possible differences in efficacy of a three-step routine of brushing, flossing, and rinsing as compared to a two-step routine of brushing and rinsing under supervision nor did it evaluate the toothbrushing technique. The trial only investigated flossing once a day rather than multiple occasions daily. Furthermore, floss was the only interdental cleaning device that was investigated in this trial. Future research should include various combinations of mechanical and chemotherapeutic agents.

Conclusions

Twice daily use of a mouthrinse containing four essential oils, menthol, thymol, eucalyptol and methyl salicylate, combined with twice daily toothbrushing statistically significantly reduced plaque, gingivitis and gingival bleeding at 4 and 12 weeks as compared to a 5% hydroalcohol negative control rinse. Both the professional flossing (FBH) and the supervised self-flossing (FUS) groups demonstrated improved gingival health measures as compared to the negative control rinse group. Statistically significant plaque reduction in the flossing groups was attained at week 4 but not at week 12.

Disclosures

Johnson & Johnson Consumer Inc., (JJCI; Skillman, NJ, USA) sponsored this clinical trial and was responsible for the trial design and the collection, analysis, and interpretation of the data. Mary Lynn Bosma, James McGuire, Anusha Sunkara, and Pamela Sullivan are employees of JJCI. Jeffery Milleman and Kimberly Milleman are principals at Salus Research, Inc, Fort Wayne, IN, USA and received grants from JJCI and conducted the trial on behalf of JJCI. Abbie Yoder is an employee of Salus Research, Inc.

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Research

Comparative Effectiveness of Toothbrushing, Flossing and Mouthrinse Regimens on Plaque and Gingivitis: A 12-week virtually supervised clinical trial

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Abstract

Purpose: Various mechanical and chemotherapeutic methods are used to control dental plaque accumulation and prevent or reduce gingivitis. The purpose of this 12-week clinical trial was to investigate the effects of various combinations of supervised mechanical and chemotherapeutic regimens on the prevention and reduction of plaque, gingivitis, and gingival bleeding.

Methods: Volunteers presenting with some evidence of gingivitis and no severe periodontitis were randomized into four groups: brush only (BO); brush/rinse (BR); brush/floss (BF); brush/floss/rinse (BFR) for this examiner-blinded clinical trial. Toothbrush, toothpaste, floss and a mouthrinse containing a fixed combination of four essential oils (EO) and training/instructions were provided to participants as per their assigned group. Participants performed their regimen at home, under virtual supervision, once each weekday; the second daily and weekend uses were unsupervised. Assessments included oral hard and soft tissue, plaque, gingivitis, and gingival bleeding (weeks 4, 12); probing depth and bleeding on probing (week 12).

Results: Of 213 enrolled participants, 209 completed the study. After 12 weeks, plaque, gingivitis, and gingival bleeding were significantly reduced in groups BR (35.8%, 50.8%, and 71.0% respectively, $p<0.001$) and BFR (32.8%, 54.1%, and 78.2% respectively, $p<0.001$) compared to BO. After 12 weeks, gingivitis and gingival bleeding were significantly reduced in the BF group (9.2%, $p=0.013$ and 17.5%, $p=0.003$, respectively), however there were no significant reductions in plaque in the BF group as compared to the BO group ($p=0.935$).

Conclusions: Oral care regimens that included a mouthrinse containing a fixed combination of four EOs (BR and BFR), demonstrated statistically significantly reduced plaque, gingivitis, and gingival bleeding as compared to BO and BF after 12 weeks. The BF regimen statistically significantly reduced gingivitis and gingival bleeding but did not statistically significantly reduce plaque compared to BO after 12 weeks.

Keywords: dental plaque, gingivitis, flossing, toothbrushing, essential oils, mouthrinses

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Introduction

Dental biofilm (plaque) is a primary etiologic factor in the two most widely prevalent dental diseases, caries and gingivitis, and is regarded as an underlying cause of gingival inflammation.[1] A variety of mechanical methods including toothbrushing, flossing and the use of other interdental cleaning devices are recommended for controlling the accumulation of plaque biofilm. Dental floss is classified by the Food and Drug Administration as a Class I medical device for removal of plaque and food particles between teeth to reduce tooth decay.[2] Historically, the use of a silk thread for interdental cleaning was first documented by a dental surgeon in the early 1800's.[3] While the materials used to manufacture dental floss have advanced significantly, patient adoption of flossing as a regular component of an oral hygiene regimen has not conformed to professional recommendations.

In a cross-sectional study using the National Health and Nutrition Examination Survey (NHANES) 2011-2014 data, 35% of participating adults (n=6939) reported having used dental floss, or any other interdental cleaning device, no more than once in the previous seven days.[4] Results from the nationwide NHANES study reflect that compliance with commonly recommended oral hygiene regimens for interdental cleaning is low.[4] In a systematic review of the home use of interdental cleaning devices on preventing and controlling periodontal diseases and caries, Worthington and colleagues reported low certainty of evidence for flossing to reduce gingivitis over one to six-month time frames.[5] Studies examining the proportion of bleeding sites and plaque were found to be inconsistent in the review, leading to a very low certainty of evidence for the benefits of flossing and these clinical outcomes.[5] Worthington et al. also discussed a study showing that individuals have difficulty mastering flossing techniques and lack the motivation to do so.[5]

Chemotherapeutic agents, such as various toothpastes and mouthrinses, provide an additional means to control plaque and reduce gingivitis. Adjunctive chemotherapeutic agents have been studied extensively and numerous systematic reviews have been published. In one systematic review and meta-analysis of the efficacy of these agents in managing gingivitis, Serrano et al. found that toothpaste and mouthrinse formulations with specific plaque control agents provided significant improvements in oral health outcomes as measured by plaque and gingivitis indices, including gingival bleeding.[6] Mouthrinses containing a fixed combination of four essential oils (EO) (LISTERINE® Antiseptic, Johnson & Johnson Consumer Inc., Skillman, NJ, USA) have been studied extensively in clinical trials of six months or longer.[7-16]

Mechanical (medical) devices such as toothbrushes and dental floss and chemotherapeutic (drug) products such as toothpastes and mouthrinses have different functional characteristics and are considered under separate categories (manual interdental cleaners and chemotherapeutic products for control of gingivitis) within the American Dental Association's (ADA) Council on Scientific Affairs Seal of Acceptance Program.[17,18] In 2016, the ADA's Council on Scientific Affairs modified the Seal of Acceptance program guidelines for both product categories. Under the revisions, both product categories have similar efficacy criteria requirements to fulfill for the Seal of Acceptance.[18] Combined results for a product must demonstrate an average reduction in gingivitis of ≥10% (using the Modified Gingival Index (MGI)) or ≥ 15% (using the Löe and Silness gingival index) compared to the control group.[19,20] Plaque measurements only require reductions that are statistically significantly different from the control group. The main difference between the categories is the required duration of clinical trials; interdental cleaning devices require two 30-day studies, whereas chemotherapeutic agents require two 3-month studies (prior to 2016, a six-month duration was required).[18]

When taking the chemotherapeutics guidelines into consideration and testing a combination of mechanical and chemotherapeutic agents, previous trials have had short durations (ie, two weeks evaluating EO mouthrinse vs flossing twice daily),[21] intermediate durations (ie, eight weeks assessing cetylpyridinium chloride (CPC) and chlorhexidine (CHX) rinses vs flossing)[22] and would not fulfill the more rigorous requirements (ie, longer duration) for chemotherapeutic agents. Bosma et al. report the comparative effectiveness of flossing or rinsing on plaque and gingivitis using a three-month timepoint in their examiner-blind, randomized, controlled clinical trial.[23] Additionally, three studies of six-month duration conducted prior to the 2016 ADA guideline revisions demonstrated the benefits of EO mouthrinse and floss in combination.[24-26] The lack of published studies of at least three months duration combining chemotherapeutic with mechanical interventions, confirms the need for studies that meet the longer term duration requirements (ie, the chemotherapeutic study requirement) according to current ADA guidelines.

The studies discussed above, with the exception of Bosma et al.,[23] were unsupervised and did not monitor daily technique and product use. A search of the literature failed to identify supervised studies that were conducted for at least three months for both mouthrinse and floss. Within the context of a home-use study, including virtual supervision is a reasonable and sufficient method to help ensure use of product. In addition, to answer questions regarding the effectiveness of technique-sensitive practices such as dental flossing, virtual supervision also provides insights into study participants abilities and practices. The purpose of this 12-week clinical trial was to investigate the effects of various combinations of supervised mechanical and chemotherapeutic regimens on the prevention and reduction of plaque, gingivitis, and gingival bleeding.

Methods

This examiner-blind, randomized, parallel group, controlled clinical trial was conducted at Salus Research, Inc. (Fort Wayne, IN, USA), an American Dental Association

(ADA) qualified site,[27] from October 2020 to February 2021. The principles of the International Council on Harmonisation (ICH) Guidance for Good Clinical Practice (ICH E6 (R2)) were applied and the study protocol was approved by the Institutional Ethics Committee on research involving humans (IntegReview IRB, Austin, TX, USA). After receiving a thorough explanation of the study and the opportunity to ask questions in private, all participants provided written informed consent on a form which complied with the requirements of the Health Insurance Portability and Accountability Act. The study was registered on clinicaltrials.gov (registration number NCT04750005).

The randomization schedule was generated using a validated program created by the Biostatistics Department at Johnson & Johnson Consumer Inc. (JJCI, Skillman, NJ, USA). Participants were assigned in equal allocation to each treatment using a block randomization with block size of four; participants were assigned a unique randomization number that determined treatment assignment. The principal investigator (PI) and examiners were blinded to the treatments administered to participants. Personnel dispensing the test products or supervising their use did not participate in the examination of participants to minimize potential bias. During supervised use other staff members, including the PI /examiners, did not have access to the area where the product was being administered.

Sample

Participants were from the Fort Wayne, IN area and were selected for screening from the clinical site's database on the basis of the trial's inclusion and exclusion criteria, which included such items as gingivitis, bleeding, and periodontal involvement. Participants were males and females aged 18-60 years (age limited to 60 years by sponsor due to Covid-19 risk factors at the time of the study), in good general and oral health, without known allergies to commercial dental products, with at least 20 teeth with scorable facial and lingual surfaces. All participants had evidence of some gingivitis (although no minimum score on the MGI was required), were without evidence of advanced periodontitis, and had at least 10 percent bleeding sites based on the Expanded Bleeding Index (EBI) as determined by the screening/baseline examination.[19,28] Participants were eligible for the study if they had no sites with >5 mm probing depth, and a maximum of three sites with 5 mm probing depths. Participants agreed to attend virtual smart-phone video daily sessions on weekdays for study procedures. Other inclusion criteria included the absence of fixed or removable orthodontic appliances or removable partial dentures; the absence of significant oral soft tissue pathology excluding plaque-induced gingivitis, (at the discretion of the PI). Female participants of childbearing potential had negative pregnancy tests (baseline and week 12) and agreed to use medically acceptable methods of birth control for one month prior to baseline and throughout the study. Participants were not permitted to have dental procedures unless needed as emergency treatment during the study.

The following conditions excluded participants from participation: having had a dental prophylaxis within four weeks prior to screening/baseline; needing antibiotics prior to dental treatment; use of certain medications within last month (antibiotics, anti-inflammatory or anticoagulant therapy within one month); use of chemotherapeutic oral care products within two weeks; being pregnant or lactating; use of smokeless tobacco, vaping or e-cigarettes or suspected substance abuse; and any other medical or psychiatric condition that would make the volunteer inappropriate for the study in the judgment of the PI.

Interventions

At baseline, all participants had a complete dental prophylaxis before being assigned to study products. Qualified participants were randomized into one of four treatment groups: 1) brush only (BO); 2) brush and rinse with fixed combination of four essential oils (4EO) (Listerine® Cool Mint® Antiseptic Mouthwash; JJCI, Skillman, NJ, USA) mouthrinse (BR); 3) brush and floss (BF); 4) brush, floss, and rinse with 4EO mouthrinse (BFR). Each participant received a soft-bristled manual toothbrush (ADA soft, flat-trim reference toothbrush, sourced through the ADA) and toothpaste (Colgate® Cavity Protection; Colgate-Palmolive, New York, NY, USA). Participants assigned to the flossing groups received an unflavored waxed dental floss (REACH® Waxed Unflavored Dental Floss; JJCI, Skillman, NJ, USA). Participants in rinsing groups received blinded bottles of 4EO mouthrinse and marked dosage cups. Instructions for use were provided at screening/baseline session. Participants assigned to a flossing group received specific instruction on flossing technique by a dental hygienist and had to demonstrate competency to them. All participants performed the first use of their regimen under supervision at the test site.

For the 12-week duration of the study, all participants performed their oral hygiene regimens at the beginning of each weekday under virtual supervision (smartphone) by study personnel. The second weekday use and the twice-daily usage on weekends/holidays were unsupervised. All participants

were instructed to brush for one minute (timed) with a full ribbon of study dentifrice twice daily. The BR group brushed then rinsed with 20 mL of 4EO rinse for 30 seconds (timed) twice daily. The BF group brushed, then flossed as directed during the first daily oral hygiene session. In the evenings, these participants brushed but did not floss. The BFR group brushed, flossed as directed, then rinsed with 20 mL of 4EO rinse for 30 seconds (timed) during the first oral hygiene session. In the evenings, these participants brushed and rinsed but did not floss. Participants maintained diaries to document product use and brought all materials to the test site at weeks 4 and 12; diaries were checked, and floss and mouthrinse materials were weighed for compliance.

Assessments

Assessments were conducted at baseline, weeks 4 and 12. Prior to each visit, participants refrained from their product use for at least eight (but not more than 18) hours and did not eat for at least four hours before the visit. All assessment visits included review of the inclusion/exclusion criteria and concomitant medications, oral examination of hard and soft tissues, and adverse event monitoring before other measurements were taken. Each clinical assessment was performed consistently throughout the study by one trained and calibrated clinical examiner. Calibration of the examiner included an intra-examiner repeatability exercise performed yearly according to the site's standard operating procedures for the specific assessment.

Clinical assessments were conducted in the following order: oral examination of hard and soft tissue for safety, MGI, six-site EBI, probing depth, bleeding on probing (BOP) (baseline and week 12 only), six-site Turesky modification of the Quigley-Hein Plaque Index (TPI), and Proximal Marginal Plaque Index (PMI).[19,28-32] All plaque assessments for this trial were supragingival measures and probing depth and BOP were measured at six sites. Measurements were made at six-sites for each graded tooth (mesiofacial, facial, distofacial, mesiolingual, lingual, distolingual). Bleeding on probing measures were based on 1 = yes bleeding, 0 = no bleeding.

The primary efficacy endpoints were whole mouth mean MGI and TPI at week 12. Additional secondary efficacy endpoints at week 4 were whole mouth mean TPI, MGI, and EBI; marginal mean TPI, MGI and EBI at weeks 4 and 12; interproximal mean TPI, MGI, EBI at weeks 4 and 12; interproximal percent bleeding sites at weeks 4 and 12; interproximal mean PMI at weeks 4 and 12. Exploratory endpoints at week 12 were whole mouth and interproximal mean probing depth and bleeding on probing (BOP).

Statistical analyses

A sample size of 200 participants (50 per treatment group) was estimated to provide greater than 95% power to detect a population difference of 0.46 between BR and BF in mean MGI, assuming a population standard deviation of 0.44; and greater than 95% power to detect a population difference of 0.54 between BR and BF in mean TPI, assuming a population standard deviation (SD) of 0.37. The population within-treatment SD and differences between population means were based on results from studies using the same examiners as the current study.[23] This sample size also provides 95% power for detecting a standardized effect size (difference between treatment means divided by SD) of 0.78 (MGI) for BFR versus BF and greater than 99% power to detect a standardized effect size of 1.5 (TPI) for BFR versus BF. These standardized effect size estimates were based on the study sponsor's historical database for MGI and TPI clinical trial data. Sample sizes were estimated using PASS version 14.0.4 (NCSS, LLC, Kaysville, UT, USA).

Treatments were compared using a mixed effects model for repeated measures (MMRM) approach, considering within-participant correlation as unstructured and with model terms for baseline as a covariate, treatment, visit, treatment by visit interaction, and baseline by visit interaction.[33,34] For key comparisons of BR versus BF and BFR versus BF at 12 weeks, the familywise type I error rate was strongly controlled at one-sided 2.5% by separately applying a fixed sequence approach for BR versus BF and BFR versus BF comparisons, and testing at the one-sided 1.25% significance level at each step within those sequences. For BR versus BF, non-inferiority with respect to MGI and TPI was assessed first. Provided that non-inferiority was demonstrated with respect to both MGI and TPI, superiority of BR versus BF was tested with respect to TPI and then MGI, and subsequently non-inferiority of BR versus BF was tested with respect to EBI. If the null hypothesis was not rejected at any step in the sequence, any further testing was considered exploratory. For BFR versus BF, superiority was similarly tested with respect to TPI, followed by MGI, and then by EBI. All comparisons outside the fixed-sequence procedure were tested at the 2.5% significance level, one-sided.

Non-inferiority for BR versus BF, within the fixed sequence referenced above, was assessed by testing the null hypothesis H_0 $((\mu_{BR}- \mu_B) \geq (1/2)\ (\mu_{BF}- \mu_B))$ versus alternative (one-sided) hypothesis H_1 $((\mu_{BR}- \mu_B) < (1/2)\ (\mu_{BF}- \mu_B))$. Rejection of H_0 in favor of H_1 demonstrates statistically that BR maintains a majority of the effect of BF, where the effect of BR is $\mu_{BR}- \mu_B$, and the effect of BF is $\mu_F- \mu_B$. The ratio $(\mu_{BR}- \mu_B)/(\mu_{BF}-$

μ_B) was further explored using Fieller confidence intervals if μ_{BF}- μ_B was significantly different from 0. (Fieller intervals are not presented in this paper, as superiority testing revealed superiority for BR versus BF, and therefore further exploration of the ratio (μ_{BR}- μ_B) / (μ_{BF}- μ_B) was not necessary.)

Demographic and baseline characteristics were compared across treatment groups using analysis of variance (ANOVA), Chi-square test, or Fisher's exact test. SAS version 9.4 software (SAS Institute, Cary, NC, USA) was used for statistical analyses.

Results

Of the 213 randomized participants, 209 completed the study. Participants were randomized into four treatment groups: BO (n=53), BR (n=53), BF (n=53), and BFR (n=54). Two participants withdrew and two were lost to follow up. The sample distribution is shown in Figure 1. Demographic and baseline characteristics are presented in Table I. There were no statistically significant differences in baseline measurements among the groups, with the exception of mean whole mouth TPI. Variation in baseline index scores was accounted for by using the prespecified covariate adjustment in the statistical model.

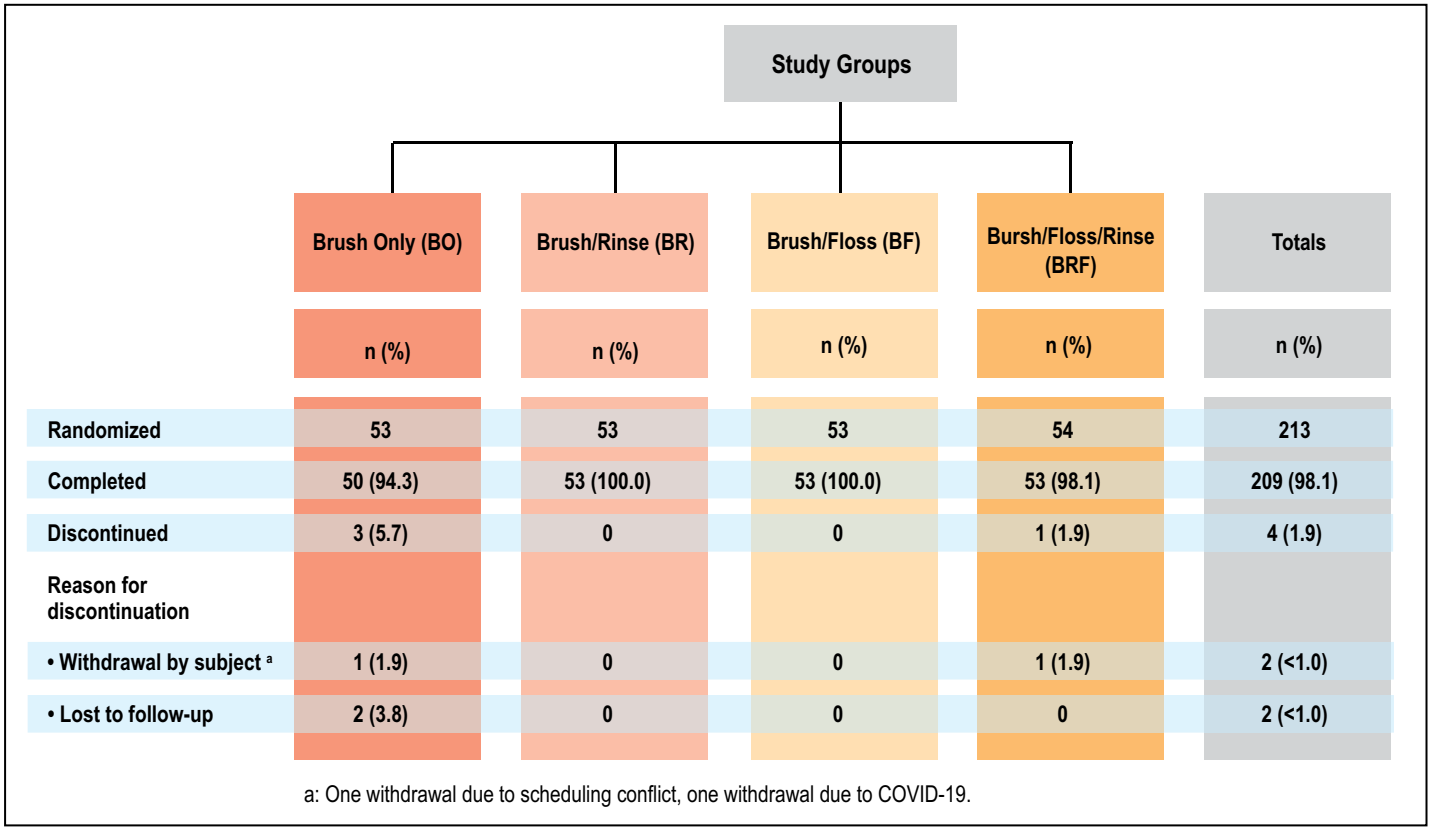
Efficacy: Primary endpoints

Whole Mouth Mean TPI and MGI at Week 12

At week 12, the BR and BFR groups demonstrated significantly reduced whole mouth mean TPI compared to the BO group (35.8% reduction and 32.8% reduction, respectively, $p<0.001$). The whole mouth mean TPI in the BF group was not significantly different from the BO group ($p=0.935$). In addition, compared to the BF group, the BR and BFR groups demonstrated significantly reduced whole mouth mean TPI (38.3% and 35.5%, $p<0.001$). The whole mouth mean TPI was not significantly different between the BR and BFR groups ($p=0.861$) (Table II).

As compared to the BO group, all three groups had significantly reduced whole mouth mean MGI at week 12; BR group reduced by 50.8%, ($p<0.001$); BF group by 9.2% ($p=0.013$); BFR group by 54.1% ($p<0.001$). In addition, compared to the BF group, the BR and BFR groups demonstrated significantly reduced whole mouth mean MGI by 45.8% and 49.5%, respectively ($p<0.001$). The whole mouth mean MGI was not significantly different between the BR and BFR groups ($p=0.203$) (Table III). As described in the methods, the whole mouth mean TPI and whole mouth mean MGI non-inferiority and superiority comparisons

Figure 1. Participant distribution (n= 213)



a: One withdrawal due to scheduling conflict, one withdrawal due to COVID-19.

between BR and BF were performed sequentially, first non-inferiority then superiority. Because both non-inferiority and superiority were demonstrated, only superiority is discussed to avoid redundancy.

Efficacy: Secondary endpoints

Whole Mouth Mean EBI and Percent Bleeding Sites at Week 12

Compared to the BO group, all three groups demonstrated significantly reduced whole mouth mean EBI at week 12: BR group by 71.0% ($p<0.001$); BF group by 17.5% ($p=0.003$);

Table I. Participant demographics and baseline characteristics (n=213)

	Brush Only	Brush/Rinse	Brush/Floss	Brush/Floss/Rinse	Total	Overall *p*-value
n	53	53	53	54	213	
Mean Age, years (SD)	42.2 (9.77)	43.8 (9.84)	41.4 (10.03)	40.8 (12.43)	42.0 (10.57)	0.500 *
Sex, n (%)						0.982 **
Male	12 (22.6)	12 (22.6)	11 (20.8)	13 (24.1)	48 (22.5)	
Female	41 (77.4)	41 (77.4)	42 (79.2)	41 (75.9)	165 (77.5)	
Race, n (%)						
White	44 (83.0)	42 (79.2)	43 (81.1)	45 (83.3)	174 (81.7)	0.536 ***
Black/African American	5 (9.4)	7 (13.2)	7 (13.2)	4 (7.4)	23 (10.8)	
Asian	3 (5.7)	0 (0)	0 (0)	1 (1.9)	4 (1.9)	
Other	1 (1.9)	4 (7.5)	3 (5.7)	4 (7.4)	12 (5.6)	
Ethnicity, n (%)						
Hispanic/Latino	2 (3.8)	2 (3.8)	2 (3.8)	2 (3.7)	8 (3.8)	>0.999 ***
Not Hispanic/Latino	51 (96.2)	51 (96.2)	51 (96.2)	52 (96.3)	205 (96.2)	
Smoker, n (%)						
No	52 (98.1)	52 (98.1)	52 (98.1)	54 (100)	210 (98.6)	0.713 ***
Yes	1 (1.9)	1 (1.9)	1 (1.9)	0 (0)	3 (1.4)	
Whole Mouth Baseline Scores						
Mean TPI (SD)	2.98 (0.386)	3.00 (0.359)	2.94 (0.324)	3.13 (0.340)	3.01 (0.358)	0.042*
Mean MGI (SD)	2.19 (0.475)	2.23 (0.459)	2.26 (0.388)	2.25 (0.371)	2.23 (0.423)	0.866*
Mean EBI (SD)	0.289 (0.1879)	0.319 (0.1775)	0.307 (0.2007)	0.294 (0.1390)	0.302 (0.1767)	0.834*
Mean Percent Bleeding Sites	22.30 (10.570)	24.07 (10.383)	23.12 (12.082)	22.22 (8.010)	22.92 (10.308)	0.774*
Interproximal Baseline Scores						
Mean TPI (SD)	3.13 (0.364)	3.15 (0.335)	3.09 (0.316)	3.26 (0.332)	3.16 (0.341)	0.056*
Mean MGI (SD)	2.48 (0.401)	2.54 (0.384)	2.56 (0.327)	2.53 (0.323)	2.53 (0.359)	0.664*
Mean EBI (SD)	0.293 (0.1907)	0.315 (0.1760)	0.305 (0.1955)	0.290 (0.1403)	0.300 (0.1758)	0.882*
Mean Percent Bleeding Sites	23.05 (10.826)	23.73 (10.203)	23.28 (12.193)	22.10 (8.415)	23.04 (10.431)	0.874 *

* p-values are based on ANOVA model with term for treatment group.

** p-values are based on Chi-Squares test.

*** 20% or more cells with expected cell size <5, Chi-Square test may not be valid test. Fisher's Exact test was used.

Table II. Whole Mouth Mean TPI after 4 and 12 Weeks: Full analysis set

	Brush Only	Brush/Rinse	Brush/Floss	Brush/Floss/ Rinse
Baseline				
n	51	53	53	53
Mean	2.99	3.00	2.94	3.13
SD	0.378	0.359	0.324	0.338
Week 4				
n	51	52	53	53
LSmean	2.83	1.86	2.90	1.77
SE	0.053	0.053	0.053	0.053
% reduction (p-value) versus Brush Only*	—	34.2 (p<0.001)	-2.5 (p=0.826)	37.4 (p<0.001)
% reduction (p-value) versus Brush/Floss*	—	35.8 (p<0.001)	—	38.9 (p<0.001)
% reduction (p value) versus Brush/Rinse*	—	—	—	4.9 (p=0.113)
Week 12				
n	50	53	53	53
LSmean	2.81	1.80	2.92	1.89
SE	0.055	0.054	0.054	0.054
% reduction (p-value) versus Brush Only*	—	35.8 (p<0.001)	-4.2 (p=0.935)	32.8 (p<0.001)
Non-inferiority p-value versus Brush/Floss**	—	p<0.001	—	—
% reduction (Superiority p-value) versus Brush/Floss*	—	38.3 (p<0.001)	—	35.5 (p<0.001)
% reduction (p-value) versus Brush/Rinse	—	—	—	-4.6 (p=0.861)

* p-values are one-sided based on mixed effects model for repeated measures with terms for treatment, visit, baseline by visit, and treatment by visit and corresponding baseline as covariate. Estimated means (LSmeans) and standard errors were based on the same model.

** p-values are one-sided based on mixed effects model for repeated measures and non-inferiority test comparing Brush/Rinse vs 0.5 Brush/Floss + 0.5 Brushing only.

BFR group by 78.2% (p<0.001). The BR was demonstrated as non-inferior to the BF (p<0.001). In addition, compared to the BF group, the BR and BFR groups significantly reduced whole mouth mean EBI (64.9% and 73.6%, respectively, p<0.001). The whole mouth mean EBI did not differ significantly between the BR and BFR groups (p=0.127).

Regarding gingival bleeding, when compared to the BO group, all three groups demonstrated significantly reduced whole mouth percent bleeding sites at week 12; BR group by 68.9% (p<0.001); BF group by 14.0% (p=0.006); BFR group by 75.5% (p<0.001). In addition, as compared to the BF group, the BR and BFR groups demonstrated significantly reduced whole mouth percent bleeding sites (63.8% and 71.5%, respectively, p<0.001). Whole mouth percent bleeding sites did not differ significantly between the BR and BFR groups (p=0.112).

While it appears redundant to present non-inferiority comparisons as well as superiority comparisons of BR with BF for whole mouth mean EBI, both results are presented because this non-inferiority comparison (but not the corresponding superiority comparisons) was one of the set of key comparisons controlled strongly at the one-sided 2.5% familywise error rate.

Interproximal TPI, MGI, EBI, Percent Bleeding Sites at Week 12

The BR and BFR groups demonstrated significantly reduced interproximal mean TPI as compared to the BO group (26.9% reduction and 24.9% reduction, respectively, p<0.001). The BF group did not differ significantly from the BO group (p=0.976). In addition, compared to the BF group, the BR and BFR groups showed significantly reduced interproximal mean TPI (30.3% reduction and 28.4% reduction, respectively, p<0.001). The interproximal mean TPI did not significantly differ between the BR and BFR groups (p=0.793) (Table II).

All three groups demonstrated significantly reduced interproximal mean MGI as compared to the BO group at week 12: BR group by 42.7% (p<0.001); BF group by 8.9% (p=0.006); BFR group by 44.0%

Table III. Whole Mouth Mean MGI after 4 and 12 weeks: Full analysis set

	Brush Only	Brush/Rinse	Brush/Floss	Brush/Floss/ Rinse
Baseline				
n	51	53	53	53
Mean	2.21	2.23	2.26	2.25
S.D.	0.471	0.459	0.388	0.374
Week 4				
n	51	52	53	53
LSmean	2.04	1.15	1.84	0.92
SE	0.059	0.058	0.057	0.057
% reduction (p-value) versus Brush Only*	—	43.7 (p<0.001)	9.7 (p=0.008)	55.1 (p<0.001)
% reduction (p-value) versus Brush/Floss*	—	37.6 (p<0.001)	—	50.2 (p<0.001)
% reduction (p-value) versus Brush/Rinse*	—	—	—	20.3 (p=0.002)
Week 12				
n	50	53	53	53
LSmean	2.00	0.98	1.81	0.92
SE	0.059	0.057	0.057	0.057
% reduction (p-value) versus Brush Only*	—	50.8 (p<0.001)	9.2 (p=0.013)	54.1 (p<0.001)
Non-inferiority (p-value) versus Brush/Floss**	—	(p<0.001)	—	—
% reduction (Superiority p-value) versus Brush/Floss*	—	45.8 (p<0.001)	—	49.5 (p<0.001)
% reduction (p-value) versus Brush/Rinse*	—	—	—	6.8 (p=0.203)

* p-values are one-sided based on mixed effects model for repeated measures with terms for treatment, visit, baseline by visit, and treatment by visit and corresponding baseline as covariate. Estimated means (LSmeans) and standard errors were based on the same model.

** p-values are one-sided based on mixed effects model for repeated measures and non-inferiority test comparing Brush/Rinse vs 0.5 Brush/Floss + 0.5 Brushing only.

(p<0.001). In addition, compared to the BF group, the BR and BFR groups demonstrated significantly reduced interproximal mean MGI (37.1% reduction and 38.5% reduction, respectively, p<0.001). The interproximal mean MGI did not differ significantly between the BR and BFR groups (p=0.357) (Table III).

As compared to the BO group, all three groups demonstrated significantly reduced interproximal mean EBI at week 12: BR group by 71.5% (p<0.001); BF group by 19.2% (p=0.002); BFR group by 81.4% (p<0.001). In addition, the BR and BFR groups significantly reduced interproximal mean EBI compared to the BF group (64.7% reduction and 77.0% reduction, respectively, p<0.001). The interproximal mean EBI did not differ significantly between the BR and BFR groups (p=0.068) (Table IV).

Compared to the BO group, all three groups demonstrated significantly reduced interproximal percent bleeding sites at week 12: BR group by 68.7% (p<0.001); BF group by 16.1% (p=0.004); BFR group by 79.3% (p<0.001). The BR group demonstrated significantly reduced interproximal percent bleeding sites as compared to the BF group (62.8% reduction, p<0.001). In addition, the BFR group demonstrated significantly reduced interproximal percent bleeding sites as compared to the BF group (75.4% reduction, p<0.001), but not compared to the BR group (33.8% reduction, p=0.04) (Table IV).

Interproximal Mean PMI at Week 12

The BR and BFR groups demonstrated significantly reduced interproximal mean PMI as com-pared to the BO group (29.6% reduction and 24.9% reduction, respectively, p<0.001). The BF group did not differ significantly from the BO group (p=0.894). In addition, as compared to the BF group, the BR and BFR groups demonstrated significantly reduced interproximal mean PMI (31.9% reduction and 27.5% reduction, respectively, p<0.001). The interproximal PMI did not differ significantly between the BR and BFR groups (p=0.953) (Table III).

All other secondary endpoints measured at weeks 4 and 12 are presented in Tables II-IV. The exploratory endpoints of whole mouth and interproximal mean probing

Table IV. Secondary efficacy endpoints

	Brush/Rinse	Brush/ Floss	Brush/Floss/Rinse
Whole Mouth Mean EBI – 4 Weeks / 12 Weeks			
% reduction (p-value) versus Brush Only	59.3 / 71.0 (p<0.001)*	12.0 / 17.5 (p=0.048)* / (p=0.003)*	72.8 / 78.2 (p<0.001)*
% reduction (p-value) versus Brush/Floss	53.8 / 64.9 (p <0.001) * (p <0.001) **	—	69.1 / 73.6 (p <0.001) *
% reduction (p-value) versus Brush/Rinse	—	—	33.1 / 24.9 (p=0.030)* / (p=0.127)*
Whole Mouth % Bleeding Sites Based on EBI – 4 Weeks / 12 Weeks			
% reduction (p-value) versus Brush Only *	59.1 / 68.9 (p<0.001)	9.6 / 14.0 (p=0.065) / (p=0.006)	72.1 / 75.5 (p<0.001)
% reduction (p-value) versus Brush/Floss *	54.7 / 63.8 (p<0.001)	—	69.1 / 71.5 (p<0.001)
% reduction (p-value) versus Brush/Rinse*	—	—	31.8 / 21.3 (p=0.021) / (p=0.112)
Interproximal Mean TPI - 4 Weeks / 12 Weeks			
% reduction (p-value) versus Brush Only*	26.2 / 26.9 (p<0.001)	-2.6 / -4.9 (p=0.853) / (p=0.976)	29.5 / 24.9 (p<0.001)
% reduction (p-value) versus Brush/Floss*	28.1 / 30.3 (p<0.001)	—	31.3 / 28.4 (p<0.001)
% reduction (p-value) versus Brush/Rinse*	—	—	4.5 / -2.7 (p=0.091) / (p=0.793)
Interproximal Mean MGI - 4 Weeks / 12 Weeks			
% reduction (p-value) versus Brush Only *	33.3 / 42.7 (p<0.001)	8.1 / 8.9 (p=0.007) / (p=0.006)	41.9 / 44.0 (p<0.001)
% reduction (p-value) versus Brush/Floss*	27.4 / 37.1 (p<0.001)	—	36.8 / 38.5 (p<0.001)
% reduction (p-value) versus Brush/Rinse*	—	—	12.9 / 2.2 (p=0.004) / (p=0.357)
Interproximal Mean EBI - 4 Weeks / 12 Weeks			
% reduction (p-value) versus Brush Only*	62.1 / 71.5 (p<0.001)	12.1 / 19.2 (p=0.047) / (p=0.002)	78.0 / 81.4 (p<0.001)
% reduction (p-value) versus Brush/Floss*	56.9 / 64.7 (p<0.001)	—	74.9 / 77.0 (p<0.001)
% reduction (p-value) versus Brush/Rinse*	—	—	41.9 / 34.7 (p=0.014) / (p=0.068)

	Brush/Rinse	Brush/ Floss	Brush/Floss/Rinse
Interproximal % Bleeding Sites Based on EBI - 4 Weeks / 12 Weeks			
% reduction (p-value) versus Brush Only*	61.1 / 68.7 (p<0.001)	9.2 / 16.1 (p=0.082) / (p=0.004)	77.1 / 79.3 (p<0.001)
% reduction (p-value) versus Brush/Floss*	57.1 / 62.8 (p<0.001)	—	74.8 / 75.4 (p<0.001)
% reduction (p-value) versus Brush/Rinse*	—	—	41.3 / 33.8 (p=0.008) / (p=0.040)
Interproximal PMI - 4 Weeks / 12 Weeks			
% reduction (p-value) versus Brush Only*	27.3 / 29.6 (p<0.001)	-3.1 / -3.5 (p=0.859) / (p=0.894)	28.1 / 24.9 (p<0.001)
% reduction (p-value) versus Brush/Floss*	29.4 / 31.9 (p<0.001)	—	30.3 / 27.5 (p<0.001)
% reduction (p-value) versus Brush/Rinse*	—	—	1.2 / -6.6 (p=0.378) / (p=0.953)
Marginal Mean TPI - 4 Weeks / 12 Weeks			
% reduction (p-value) versus Brush Only*	52.8 / 56.1 (p<0.001)	-2.2 / -2.5 (p=0.739) / (p=0.741)	55.6 / 50.8 (p<0.001)
% reduction (p-value) versus Brush/Floss*	53.8 / 57.2 (p<0.001)	—	56.6 / 52.0 (p<0.001)
% reduction (p-value) versus Brush/Rinse*	—	—	6.0 / -12.1 (p=0.209 / (p=0.916)
Marginal Mean MGI - 4 Weeks / 12 Weeks			
% reduction (p-value) versus Brush Only*	56.1 / 60.6 (p<0.001)	11.8 / 9.5 (p=0.012) / (p=0.035)	70.6 / 66.4 (p<0.001)
% reduction (p-value) versus Brush/Floss*	50.2 / 56.5 (p<0.001)	—	66.7 / 62.9 (p<0.001)
% reduction (p-value) versus Brush/Rinse*	—	—	33.2 / 14.8 (p=0.003) / (p=0.128)
Marginal Mean EBI - 4 Weeks / 12 Weeks			
% reduction (p-value) versus Brush Only*	54.1 / 69.8 (p<0.001)	12.1 / 13.7 (p=0.083) / (p=0.031)	63.2 / 71.6 (p<0.001)
% reduction (p-value) versus Brush/Floss*	47.8 / 65.0 (p<0.001)	—	58.1 / 67.1 (p<0.001)
% reduction (p-value) versus Brush/Rinse*	—	—	19.7 / 5.9 (p=0.148) / (p=0.403)

* p-values are one-sided based on mixed effects model for repeated measures with terms for treatment, visit, baseline by visit, and treatment by visit and corresponding baseline as covariate. Percent reductions were based on estimated means (LSmeans) from the same model.

** p-values are one-sided based on mixed effects model for repeated measures and non-inferiority test comparing Brush/Rinse vs 0.5 Brush/Floss + 0.5 Brushing only.

depth and mean BOP at week 12 are presented in Table V. All statistical tests comparing the BR and BFR groups to the BF group in this study, apart from the non-inferiority tests for BR and BF, were one-sided assessing the benefit of BR or BFR to BF. Using the one-sided approach, interproximal mean BOP for the BR group as compared to the BF group did not show statistically significant reductions in favor of BR (p=0.976) after 12 weeks. To more completely evaluate the relative benefits of flossing given the magnitude and direction of the observed difference, a two-sided test was applied for this comparison. Based on this statistical test, the BF group had a significantly lower mean interproximal BOP than the BR group (p=0.049) after 12 weeks.

Safety

Of the treatment-emergent adverse events (TEAE) the PI classified as "probable" or "very likely" caused by the study product, one participant experienced moderate lip mucosa desquamation, and two participants in the BR group experienced mild oral mucosal desquamation. Four participants in the BFR group experienced mild oral mucosal desquamation. All were single episodes that required no treatment and resolved. All other TEAEs (angular cheilitis, coated tongue, ulcer, and mouth ulceration due to food burn) were also single events, either mild or moderate in severity, that resolved without treatment. No participants discontinued participation in the study due to adverse events. No deaths and no serious AEs were reported.

Discussion

The purpose of this long-term (12-week) clinical trial was to investigate the effects of various combinations of supervised mechanical and chemotherapeutic regimens on the prevention and reduction of plaque, gingivitis, and gingival bleeding. Participants using a mouthrinse containing a fixed combination of four essential oils, in combination with toothbrushing or with toothbrushing and flossing, demonstrated statistically significant reductions in supragingival plaque, gingivitis, and gingival bleeding as compared to toothbrushing only and compared to toothbrushing and flossing at the end of 12 weeks. Furthermore, using dental floss in addition to toothbrushing (BF) provided no measurable plaque reduction as compared to toothbrushing alone (BO) but did provide reductions in gingivitis and gingival bleeding when compared to BO at 12 weeks. Although the Turesky modification of the Quigley-Hein Plaque Index (TPI) is a more widely utilized supragingival plaque index in clinical trials, use of the Proximal Marginal Plaque Index (PMI) in this study produced a similar pattern in plaque reduction in comparison to TPI, helping to confirm the robustness of the findings.

While the use of dental floss was not shown to reduce supragingival plaque in this study, it was shown to statistically significantly reduce several whole mouth and interproximal measures (i.e. mean MGI, mean EBI, marginal gingival bleeding, and percent of bleeding sites based on EBI) compared to brushing alone, but not as effectively as the EO mouthrinsing regimens. This finding suggests that while the mechanical action of flossing may affect the plaque mass for a short period of time that was long enough to have an impact on gingival health, its effect was not long enough to measure significant plaque reduction at 8-18 hours. These results are consistent with findings of a 12-week clinical trial conducted by Bosma et al.[23]

Although it was an exploratory outcome measure in this supervised clinical trial, the BOP results had clinical implications. Participants assigned to flossing as part of their oral care regimen (BFR and BF) had statistically significant reductions in whole mouth and interproximal mean BOP at 12 weeks compared to toothbrushing only (BO). Compared to BR at 12 weeks, the BFR and BF groups demonstrated statistically significantly reduced interproximal mean BOP and only the BFR group demonstrated statistically significantly reduced whole mouth mean BOP. These findings were consistent with the supervised flossing groups in a study by Bosma et al.[23] A potential explanation for this could be the deeper interproximal subgingival access and the mechanical plaque disruption that flossing may provide compared to rinsing with a 4EO mouthrinse.

Periodontal diseases are a result of complex interactions of multiple factors. Evaluating an individual's periodontal health should take into consideration more than plaque and bacterial control.[35] In a review of the histological and clinical determinants of periodontal health, Lang and Bartold provide a definition for both the intact and reduced periodontium and state that BOP is the best parameter for monitoring health or inflammation of the gingival tissue.[35] Although the severity of the gingival bleeding and the amount of plaque accumulation are associated with one another, it has been suggested that BOP may be an earlier sign of gingivitis than erythema and edema.[35] In the presence of BOP, it is impossible to have pristine periodontal health.[35]

To determine the best adjunctive routine in addition to brushing only, multiple disease measures (MGI, bleeding, probing depth, BOP) were considered at the 12-week

Table V. Exploratory endpoints: Whole mouth and interproximal probing depth and bleeding on probing at week 12.

	Brush Only	Brush/Rinse	Brush/Floss	Brush/Floss/ Rinse
Whole Mouth Mean Probing Depth				
Baseline				
n	51	53	53	53
Mean	1.88	1.88	1.910	1.95
SD	0.307	0.194	0.262	0.304
Week 12				
n	50	53	53	53
LSmean	1.81	1.76	1.80	1.74
SE	0.017	0.016	0.016	0.016
% reduction (p-value*) versus Brush Only	—	3.0 (p=0.011)	0.9 (p=0.247)	3.8 (p=0.002)
% reduction (p-value*) Brush/Rinse versus Brush/Floss	—	2.1 (p=0.051)	—	2.9 (p=0.012)
% reduction (p-value*) Brush/Floss/Rinse versus Brush/Rinse	—	—	—	0.8 (p=0.268)
Whole Mouth Mean Bleeding on Probing				
Baseline				
n	51	53	53	53
Mean	0.171	0.155	0.189	0.153
SD	0.1921	0.1392	0.1721	0.1460
Week 12				
n	50	53	53	53
LSmean	0.143	0.124	0.095	0.071
SE	0.0121	0.0117	0.0117	0.0117
% reduction (p-value*) versus Brush Only	—	13.2 (p=0.131)	34.0 (p=0.002)	50.4 (p<0.001)
% reduction (p-value*) Brush/Rinse versus Brush/Floss	—	31.4 (p=0.963)	—	24.9 (p=0.079)
% reduction (p-value*) Brush/Floss/Rinse versus Brush/Rinse	—	—	—	42.9 (p<0.001)

	Brush Only	Brush/Rinse	Brush/Floss	Brush/Floss/ Rinse
Interproximal Mean Probing Depth				
Baseline				
n	51	53	53	53
Mean	2.21	2.21	2.25	2.29
SD	0.323	0.215	0.288	0.312
Week 12				
n	50	53	53	53
LSmean	2.14	2.06	2.12	2.06
SE	0.020	0.019	0.019	0.019
% reduction (p-value*) versus Brush Only	—	3.5 (p=0.004)	1.1 (p=0.209)	3.8 (p=0.002)
% reduction (p-value*) Brush/Rinse versus Brush/Floss	—	2.5 (p=0.029)	—	2.7 (p=0.017)
% reduction (p-value*) Brush/Floss/Rinse versus Brush/Rinse	—	—	—	0.3 (p<0.415)
Interproximal Mean Bleeding on Probing				
Baseline				
n	51	53	53	53
Mean	0.233	0.206	0.250	0.207
SD	0.2549	0.1823	0.2166	0.1965
Week 12				
n	50	53	53	53
LSmean	0.190	0.171	0.127	0.093
SE	0.0161	0.0157	0.0157	0.0157
% reduction (p-value*) versus Brush Only	—	10.1 (p=0.196)	33.2 (p=0.003)	51.4 (p<0.001)
% reduction (p-value*) Brush/Rinse versus Brush/Floss	—	34.6 (p=0.976**)	—	27.2 (p=0.060)
% reduction (p-value*) Brush/Floss/Rinse versus Brush/Rinse	—	—	—	45.9 (p<0.001)

* p-values are one-sided based on ANCOVA model with terms for treatment as factor and corresponding baseline as covariate. Estimated means (LSmeans) and standard errors were based on the same model.

** If assessed based on two-sided statistically test rather than one-sided as planned for this study, BF shows significant reduction compared to BR (two-sided p=0.049).

timepoint of this study. When comparing BR versus BF for these endpoints at week 12, BR was statistically significantly better than BF for reducing interproximal MGI and percent bleeding sites but BF was significantly better than BR for reducing interproximal BOP. When comparing BFR to BR, BFR was statistically significantly better than BR for reducing interproximal BOP but not for other interproximal measures. Moreover, BFR provided statistically significant reductions in interproximal MGI, percent bleeding sites, and probing depth compared to BF. Whole mouth results followed a similar pattern.

Considering the evidence generated in this study and evidence from an earlier study,[26] twice daily brushing, daily flossing, and twice daily rinsing with an essential oil mouthrinse should be considered when advising patients on the management of plaque, gingivitis and gingival bleeding. The current clinical study provides additional data-driven evidence to assist healthcare providers in recommending plaque and gingivitis control methods as part of their patients' oral care regimens.

Recognizing that effective flossing can be a difficult task that requires functional bilateral dexterity and skill, a component of the current study explored the relationship between manual dexterity and clinical outcomes.[36] Another component of the current study surveyed participants regarding their oral hygiene habits at baseline.[37] Results of all components of this study provide dental professionals with information and insights to better counsel patients about daily oral hygiene regimens.

Limitations and future research

The study was conducted from October 2020 to February 2021, during the COVID-19 pandemic and this may have influenced the volunteers and their mindset (e.g. age, risk tolerance) for participation in this study. Fear, risk aversion, or other concerns, perhaps related to medical status, during this time may have discouraged certain types of individuals from participating in the study. The sample was limited to individuals who volunteered to be part of a clinical study and may not be representative of the general population. The clinical site specifically recruited participants with evidence of some gingivitis and without evidence of severe periodontitis. Thus, the results would not be generalizable to individuals who are on either end of the periodontal health/disease spectrum.

Differences between supervised two (brushing and rinsing) versus three (brushing, flossing, rinsing) step oral care routines, once versus multiple daily occasions of flossing, and dental floss versus other interdental aids were not explored. Evidence is lacking for the long-term clinical benefit of flossing multiple times a day. Additionally, there are multiple aids for interdental cleaning which include interdental brushes. A 2014 workshop of internationally recognized dental experts sponsored by the European Federation of Periodontology concluded that flossing should only be recommended for sites where interdental brushes would not be able to pass through the interproximal areas without causing trauma, eg, sites where attachment loss is not present.[38] Considering the positive effect on BOP by flossing shown in this study, future research exploring the benefits of flossing on this measure is indicated. Future studies should also investigate the combination of interproximal brushes and mouthrinses as related to gingival health and the parameters investigated in this trial.

Conclusions

Virtually supervised oral care regimens that included a mouthrinse containing a combination of four essential oils (BR and BFR), significantly reduced plaque, gingivitis, and gingival bleeding as compared to toothbrushing only (BO) and brushing and flossing (BF) after 12 weeks. Gingivitis and gingival bleeding were significantly reduced in the BF group; however, plaque levels were not reduced after 12 weeks. The BF regimen was not significantly different from BO after 12 weeks. These data provide evidence for dental healthcare professionals to recommend a three-part oral hygiene regimen of brushing, flossing and mouthrinsing to their patients.

Disclosures

Johnson & Johnson Consumer Inc. (JJCI; Skillman, NJ, USA) sponsored this clinical trial and was responsible for the study design and the collection, analysis, and interpretation of the data. Mary Lynn Bosma, James A. McGuire, Kathleen McAdoo, and Alicia DelSasso are employees of JJCI. Jeffery Milleman and Kimberly Milleman are principals at Salus Research, Inc., Fort Wayne, IN, USA and received grants from JJCI and conducted the study on behalf of JJCI. Kaylie Wills is an employee of Salus Research, Inc.

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Research

Role of Manual Dexterity on Mechanical and Chemotherapeutic Oral Hygiene Regimens

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Abstract

Purpose: Effective use of mechanical plaque control devices can depend on individual manual dexterity levels. The purpose of this component of a 12-week, virtually-supervised clinical trial was to investigate the role of manual dexterity on clinical outcomes for gingivitis, as measured by the relationship between manual dexterity scores on the Purdue Pegboard Test (PPT) and the effects of various mechanical and chemotherapeutic oral hygiene regimens.

Methods: This was a single-center, examiner blinded, randomized, four-treatment arm, parallel group, 12-week plaque and gingivitis study. At baseline, healthy adult volunteers with evidence of gingivitis were assessed for manual dexterity and were then examined for plaque, gingivitis and bleeding. After a dental prophylaxis, participants were randomized into four treatment groups: brush only (BO); brush/rinse (BR); brush/floss (BF); and brush/floss/rinse (BFR). The flossing groups received instruction in flossing. The PPT was used to assess manual dexterity and was performed by a licensed occupational therapist. Virtual supervision was required once each weekday and the oral hygiene regimen was unsupervised on evenings and weekends.

Results: Of the 213 subjects enrolled, 209 completed the trial. Improvements from baseline to week 12 in interproximal percent nonbleeding healthy sites (Expanded Bleeding Index (EBI)=0 and Modified Gingival Index (MGI)=0 or 1) were dependent on the participant's dexterity score. Participants with the lowest dexterity scores (9 or lower) in the BFR treatment group demonstrated the greatest improvement interproximally based on the indices (EBI and MGI). In comparison, the BF test group subjects with dexterity scores 9 or lower had limited change in improvement interproximally. There was a direct correlation between flossing effectiveness and dexterity scores.

Conclusions: Less manual dexterity can limit dental flossing effectiveness. Flossing is a difficult daily task that requires functional bilateral dexterity to be perform correctly. Individuals with lower levels of manual dexterity were shown to benefit from the addition of an essential oil mouthrinse to a regimen of toothbrushing and flossing in this clinical trial. The addition of an essential oil mouthrinse improved interproximal gingival health and mitigated the manual dexterity variable.

Keywords: manual dexterity, Purdue Pegboard Test, plaque control, flossing, toothbrushing, mouthrinses, essential oils

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Introduction

Oral disease is a global health challenge with significant health and economic burdens on populations across the lifespan.[1] Dental caries and periodontal disease are among the most prevalent and consequential diseases of the oral cavity worldwide.[1,2] Dental biofilm (plaque) is a complex community of microbial cells embedded in an extracellular matrix that attaches to the tooth surface. Changes in the structure of the microbial communities within biofilm (plaque) serve as a primary etiologic factor for dental caries and periodontal diseases.[3] Means of plaque control include the use of mechanical and chemotherapeutic methods. Chemotherapeutic agents include toothpastes and

mouthrinses with active ingredients indicated for the control, reduction, or prevention of plaque and gingivitis. The wealth of evidence available in systematic reviews, meta-analyses, along with two recent clinical trials, reinforce the clinical relevance of adding an essential oil mouthrinse to the oral care regimen to control plaque and gingivitis.[4-14] The daily removal and disruption of this biofilm has also traditionally included mechanical methods such as toothbrushing and flossing. Unfortunately, many individuals lack sufficient manual dexterity to perform proper oral hygiene methods such as daily flossing between their teeth.[15,16]

There has been limited research exploring the relationship between dexterity and oral hygiene efficacy with mechanical devices. Niederman and Sullivan developed and validated the Oral Hygiene Skill Achievement Index (S.A.I) as a method for evaluating an oral hygiene skill. The S.A.I. evaluates a person's ability to position and manipulate an oral device (toothbrush, dental floss) and provides a format for oral hygiene instruction.[17] Doherty et al. developed the Oral Hygiene Performance Test (OHPT) as a screening instrument to measure oral hygiene skills in the elderly and disabled.[18]

In a recent study on the clinical relevance of dexterity in oral hygiene, Barouch et al. evaluated 80 subjects ranging in age from 18 to 60 on their ability to use chopsticks to transfer 50 peas in water from one box to another within a period of one minute.[19] The participants then had their plaque index score recorded before and after receiving oral hygiene instructions. Comparisons were made based on age, sex, dominant hand and the results of the chopstick dexterity test. Based on their findings, Barouch et al. concluded that dexterity might be a good predictor of improved oral hygiene and should be included as an assessment for customized education.[19]

The Purdue Pegboard Test (PPT) was first developed in 1948 and has been used for different ages across the lifespan in a variety of settings. The PPT takes 15 minutes to administer and involves completing a series of four subsets consisting of placing small pins into holes on a pegboard and assembling pins with collars and washers. First standardized on adult employees requiring fine and gross motor dexterity in the workplace, normative data has been collected from the PPT for children and adolescents from 5 to 19 years of age, as well.[20,21] Additionally, the PPT has been shown to be a reliable measure of hand dexterity in individuals with multiple sclerosis, Parkinson's disease and intellectual disabilities.[22-24] The PPT has also been used to establish validity for other hand dexterity assessments, such as the Jebsen Hand Function Test in adults with schizophrenia and the Functional Dexterity Test for traumatic hand injury.[25,26] The PPT was used in a study by Kenney et al. on the relationship of manual dexterity to performance of oral hygiene among university students.[27]

The PPT is a validated instrument and considered the gold standard for measuring hand dexterity when correlated with new and existing measures in populations with and without hand function impairments.[18,19,28-34] The PPT is also an assessment instrument because it provides separate dexterity scores for both preferred (dominant) and nonpreferred hands. Moreover, the PPT also measures small finger movements to assemble pins and washers requiring the use of both hands working together. Given its ease of use and brief administration time, the PPT was selected to further analyze manual dexterity and dental flossing skills. The purpose of this component of a 12-week, virtually-supervised clinical trial, was to investigate the role of manual dexterity on clinical outcomes for gingivitis, as measured by the relationship between manual dexterity scores on the Purdue Pegboard Test (PPT) and the effects of various mechanical and chemotherapeutic oral hygiene regimens.

Methods

This component of a randomized, controlled clinical trial was conducted from October 2020 to February 2021 at Salus Research, Inc. (Fort Wayne, IN, USA), an American Dental Association (ADA) qualified research site.[35] The principles of the International Council on Harmonisation Guidance for Good Clinical Practice (ICH E6 (R2)) were applied to this study. The study protocol was approved by the Institutional Ethics Committee on research involving humans (IntegReview Institutional Review Board, Austin, TX, USA) and was registered on clinicaltrials.gov (NCT04750005). Written informed consent was obtained from all subjects in accordance with the Declaration of Helsinki. Screening and baseline assessments were conducted at the same visit.

Sample

Participants were from the Fort Wayne, Indiana area and were selected for screening from the clinical test site's database. Due to COVID-19 risk at the time of the study, the age range of the sample was limited to males and females between the ages of 18 to 60 years. Participants needed to meet the following inclusion criteria: good general and oral health, no known allergies to commercial dental products, a minimum of 20 teeth with scorable facial and lingual surfaces, evidence of some gingivitis (although no minimum

score on the Modified Gingival Index (MGI) was required), absence of advanced periodontitis, and a minimum of 10 percent bleeding sites based on the Expanded Bleeding Index (EBI).[36,37] Participants were eligible for the study if they had no sites with >5 mm probing depth, a maximum of three sites at 5 mm probing depth, and needed to be available to attend daily virtual smart-phone video sessions on weekdays for study procedures. Other inclusion criteria included absence of fixed or removable orthodontic appliance or removable partial dentures, significant oral soft tissue pathology excluding plaque-induced gingivitis, at the discretion of the principal investigator/dental examiner (PI). Participants were excluded for a variety of reasons including: dental prophylaxis within four weeks prior to baseline, requiring antibiotics prior to dental treatment, use of antibiotics, anti-inflammatory or anticoagulant therapy during the study or within one month prior to baseline, use of chemotherapeutic oral care products within the last two weeks, pregnancy or lactating, use of smokeless tobacco, vaping or e-cigarettes or suspected substance abuse, any medical or psychiatric condition that would make the participant inappropriate for the study in the judgment of the PI.

The randomization was generated using a validated program created by the Biostatistics Department at Johnson & Johnson Consumer Inc. (JJCI, Skillman, NJ, USA). Participants were assigned in equal allocation to each treatment using a block randomization with block size of four. Each participant was assigned a unique randomization number that determined treatment assignment. The PI and examiners were blinded to the treatment regimens of the subject groups. The personnel dispensing the test products or supervising their use did not participate in the examination of subjects to minimize potential bias. Other staff members, including the PI and examiners, did not have access to the area where the product was being used. Eligible subjects with evidence of gingivitis were randomized into four equal treatment groups: brush only (BO); brush/rinse (BR); brush/floss (BF); and brush/floss/rinse (BFR).

Assessments

The PPT was administered to all randomized subjects participating in a plaque and gingivitis clinical trial prior to baseline clinical examinations.[14] The test was administered by a licensed occupational therapist to determine a manual dexterity score at the time of the baseline examination visit. The PPT uses a pegboard consisting of multiple holes arranged in rows. The first part of the assessment requires the subject to place as many pins as possible into the holes using each hand separately followed by both hands together. Participants were allowed 30 seconds for each task. The last assessment requires the subject to assemble a pin, washer, collar, and additional washer and place the assembly into the holes over a 60 second period. Dexterity scores were determined by combinations of the various executions.[20] As the variable being examined for dexterity (dental flossing) requires the use of both hands simultaneously, pin placement using both hands was chosen as the score for analysis. Higher numerical scores on the PPT correlate with greater dexterity.

The intraoral assessments included oral hard and soft tissue safety assessment, MGI, six-site EBI, six-site probing depth, six-site bleeding on probing, six-site Turesky modification of the Quigley-Hein Plaque Index (TPI), and Proximal Marginal Plaque Index (PMI).[36-41] Each clinical assessment was performed consistently throughout the study by the same trained and calibrated clinical examiner. This calibration included an intra-examiner repeatability exercise performed yearly according to the site's standard operating procedures for the specific assessment.

Interventions

All subjects received a manual toothbrush (ADA soft, flat-trim reference toothbrush, sourced through the ADA). Subjects received toothpaste, dental floss and a mouthrinse containing a fixed combination of four essential oils (4EO) according to their assigned regimen. Instructions on product use were provided at screening/baseline; participants assigned to the flossing group received specific instructions on flossing technique and demonstrated competency. No specific toothbrushing instructions were provided except to brush for one timed minute. Similarly, participants assigned to the rinse group were instructed to rinse with 20 mL of mouthrinse for a timed 30 seconds.

Statistical analyses

A sample size of 200 completed subjects (50 per treatment group) was estimated to provide sufficient power to detect differences between BR and BF and between BFR and BF.[14]

The dexterity component of the clinical trial focused on the relationship between the PPT scores and the improvements from baseline to week 12 in interproximal percent nonbleeding healthy sites.[14] The impact of dexterity on treatment effects was assessed using a linear model that fits regression lines with change from baseline to week 12 as the response variable, and dexterity as an explanatory variable. This model allowed for different intercepts and different slopes for the four treatment groups. Specifically,

the following linear model was applied: $y_{ij} = \mu + \mu_i + (\beta + \beta_i)x_{ij} + \varepsilon_{ij,}$ where y_{ij} = change from baseline to week 12 in efficacy variable (week 12 minus baseline) for treatment i and subject j; x_{ij} = both hands dexterity score for treatment i and subject j; $\mu + \mu_i$ = intercept for treatment I; $\beta + \beta_i$ = slope for treatment I; and ε_{ij} = random error for treatment i and subject j, independently distributed as normal with mean 0 and variance σ^2.

Treatment by dexterity interaction was assessed by testing the null hypothesis H_0: $\beta_i=0$ for all i, vs. the alternative hypothesis H_1: $\beta_i\neq0$ for some i. H_0 describes a scenario where intercepts could be different among treatments, but the regression lines are parallel. In other words, the various treatments could have different effects on the outcome measure, but the differences among treatment effects are not dependent on dexterity of the subjects using those products. Rejection of H_0, based on the appropriate F test, demonstrates that differences in treatment effects are dependent on dexterity. Each statistical test was performed at the 5% significance level, two-sided.

Percent nonbleeding healthy sites were calculated by taking the total number of sites with EBI=0 and MGI=0 or 1, divided by the total number of sites assessed for each subject. No imputation of missing data was performed. All other details about the statistical analysis of the clinical trial are reported separately.[14] Data from all subjects at baseline and week 12 (i.e., completed subjects) were included in this analysis. SAS version 9.4 (SAS Institute, Cary, NC, USA) was used for statistical analyses.

Results

Demographics

Of the 213 randomized participants, 209 completed the study; 2 withdrew their consent and 2 were lost to follow-up (Figure 1). Participants had a mean age of 42.0 (SD 10.57) years (ranging from 18 to 59 years); means ages by group were similar (Table I). The majority of subjects were female (77.5%, n=41), Caucasian (81.7%, n=174), and non-smokers (98.6%, n=210). A summary of baseline characteristics (age, sex, PPT dexterity scores, MGI, and EBI) is shown in Table I. Most subjects (91.5%, n=195) reported right hand

Figure 1. Participant distribution (n=213)

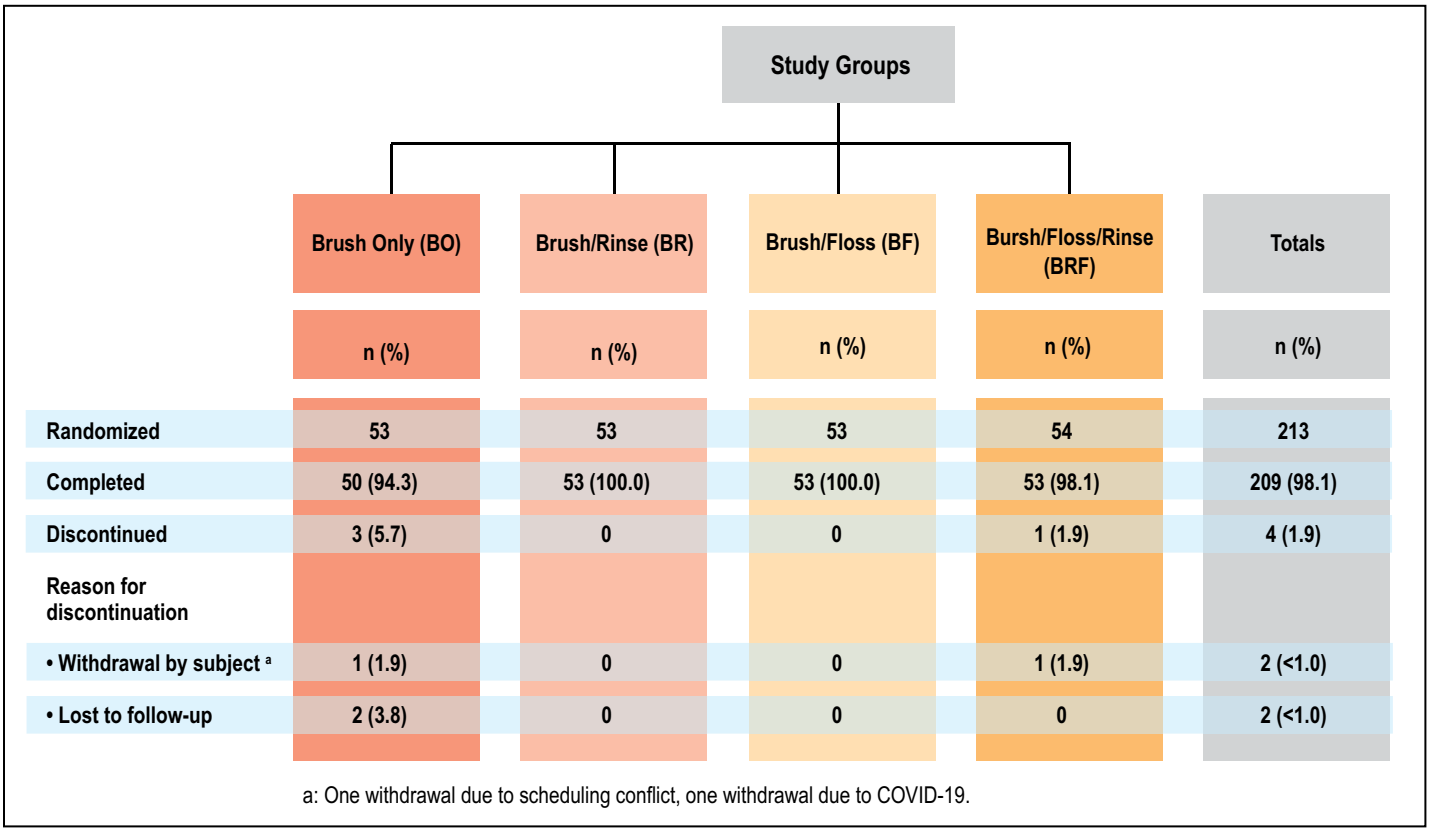


Table I. Sample demographics at baseline (n= 213)

Group	Brush only (n=53)	Brush/rinse (n=53)	Brush/floss (n=53)	Brush/floss/rinse (n=54)	Total (n=213)
Mean age, years (SD)	42.2 (9.77)	43.8 (9.84)	41.4 (10.03)	40.8 (12.43)	42.0 (10.57)
Sex, n (%)					
Male	12 (22.6)	12 (22.6)	11 (20.8)	13 (24.1)	48 (22.5)
Female	41 (77.4)	41 (77.4)	42 (79.2)	41 (75.9)	165 (77.5)
Mean baseline of interproximal % EBI=0 and MGI=0 or 1 (SD)	3.91 (6.757)	3.28 (7.670)	2.31 (4.843)	1.71 (3.498)	2.80 (5.931)
PPT dexterity scores – Mean (%)					
Declared dominant hand – Right	47 (88.7)	48 (90.6)	48 (90.6)	52 (96.3)	195 (91.5)
Declared dominant hand – Left	6 (11.3)	5 (9.4)	5 (9.4)	2 (3.7)	18 (8.5)
Mean right hand score (SD)	13.7 (2.02)	14.1 (2.05)	14.0 (1.76)	13.1 (2.52)	13.7 (2.13)
Mean left hand score (SD)	13.3 (1.80)	13.2 (2.14)	13.7 (2.14)	12.8 (2.07)	13.3 (2.05)
Mean both hand score (SD)	11.2 (1.82)	10.9 (1.77)	11.4 (2.05)	10.7 (2.03)	11.0 (1.93)
Mean right + left + both (SD)	38.2 (4.88)	38.1 (5.17)	39.1 (5.24)	36.6 (6.04)	38.0 (5.39)
Mean assembly score (SD)	34.8 (6.80)	35.1 (7.23)	33.4 (9.37)	33.9 (8.54)	34.3 (8.02)

dominance; while only 8.5% (n=18) reported left hand dominance. There were no significant differences among treatment groups for any of the demographic data.

Efficacy and dexterity

At the conclusion of 12 weeks, statistically significant treatment regimen-by-dexterity score interaction was observed for percent nonbleeding healthy sites (EBI=0 and MGI=0 or 1) (p=0.005). This p-value reflects differences in comparisons between treatment groups among dexterity scores. Regression line estimates for change from baseline showed greater than 60% increase from baseline (greater than 60% improvement) in the BFR treatment group in test subjects with both hands dexterity scores 9 or lower and 45-50% improvement for subjects with both hands dexterity scores 12 or higher (Fgure 2). In comparison, the BF test group had slight worsening to 5% improvement from baseline to 12 weeks for interproximal percent nonbleeding healthy sites in subjects with both hands dexterity scores 9 or lower. However, the subjects in the BF treatment group with dexterity scores 12 or higher had 10-20% increase in interproximal percent nonbleeding healthy sites (EBI=0 and MGI=0 or 1).

Figures 3–6 show changes from baseline for interproximal percent nonbleeding healthy sites (EBI=0 and MGI=0 or 1) for the four treatment groups versus PPT scores for interproximal soft tissue of individual regions of the mouth (posterior, anterior, maxillary and mandibular regions). In all regions of the mouth, the same relationships between percent nonbleeding healthy sites and dexterity were observed.

Discussion

The purpose of this component of a 12-week, virtually-supervised clinical trial was to investigate the role of manual dexterity on clinical outcomes for gingivitis, as measured by the relationship between manual dexterity scores on the Purdue Pegboard Test (PPT) and the effects of various mechanical and chemotherapeutic oral hygiene regimens. Findings from this study demonstrated significant evidence of the correlation between dexterity scores and the effectiveness of various oral hygiene regimens in reducing gingival inflammation.

Dexterity is defined as a neuromotor function that combines sensation and hand strength to produce fine, voluntary movements that can be used to manipulate small objects during a specific task.[28] Manual dexterity allows an individual to manipulate objects with the hand, and fine dexterity is the intricate, in-hand or digit manipulation of everyday objects. This study compared the use of various daily oral hygiene regimens to dexterity test scores. The

Figure 2. Change from baseline in the interproximal percent of nonbleeding healthy sites (%) (EBI=0 and MGI=0 or 1) versus dexterity scores by group

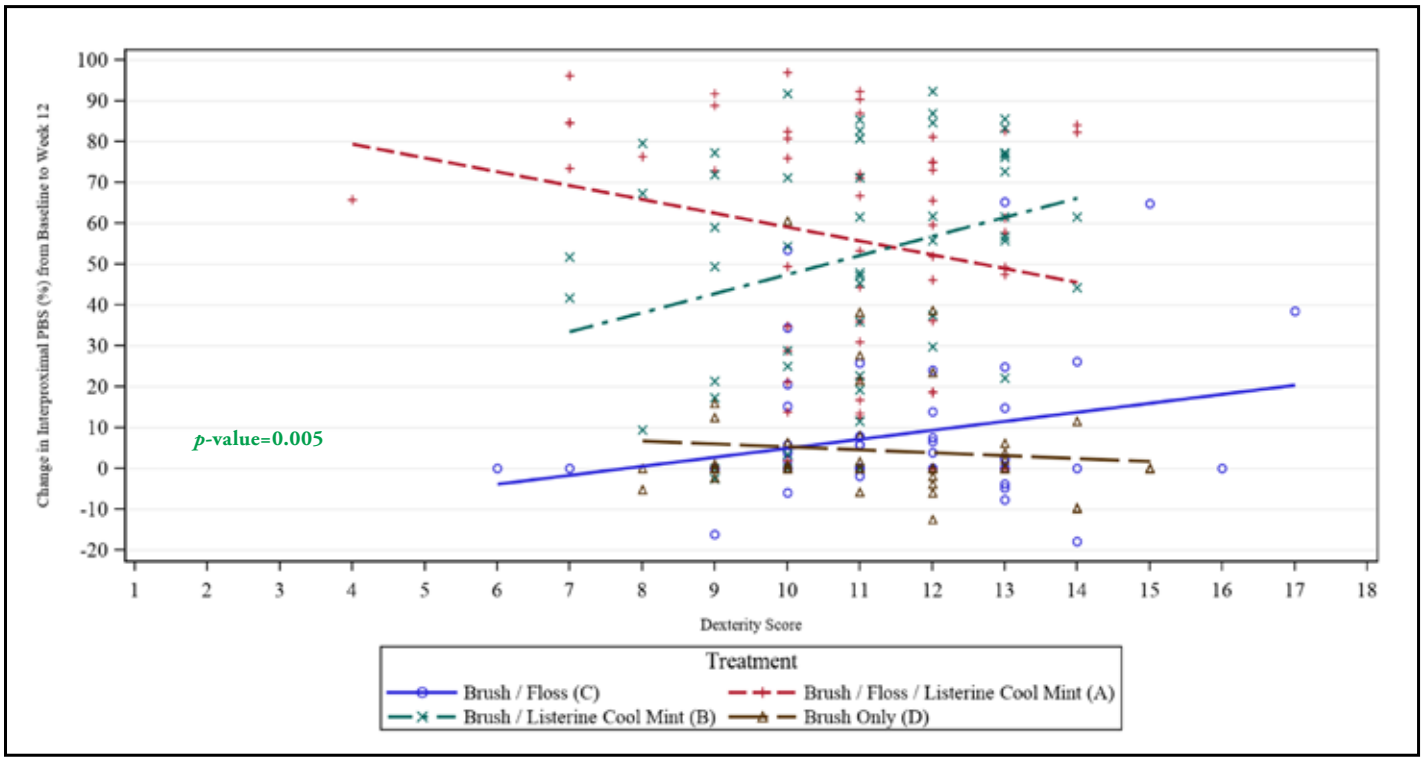


Figure 3. Change from baseline for posterior interproximal percent nonbleeding healthy sites (%) with EBI=0 and MGI=0 or 1 vs. dexterity score

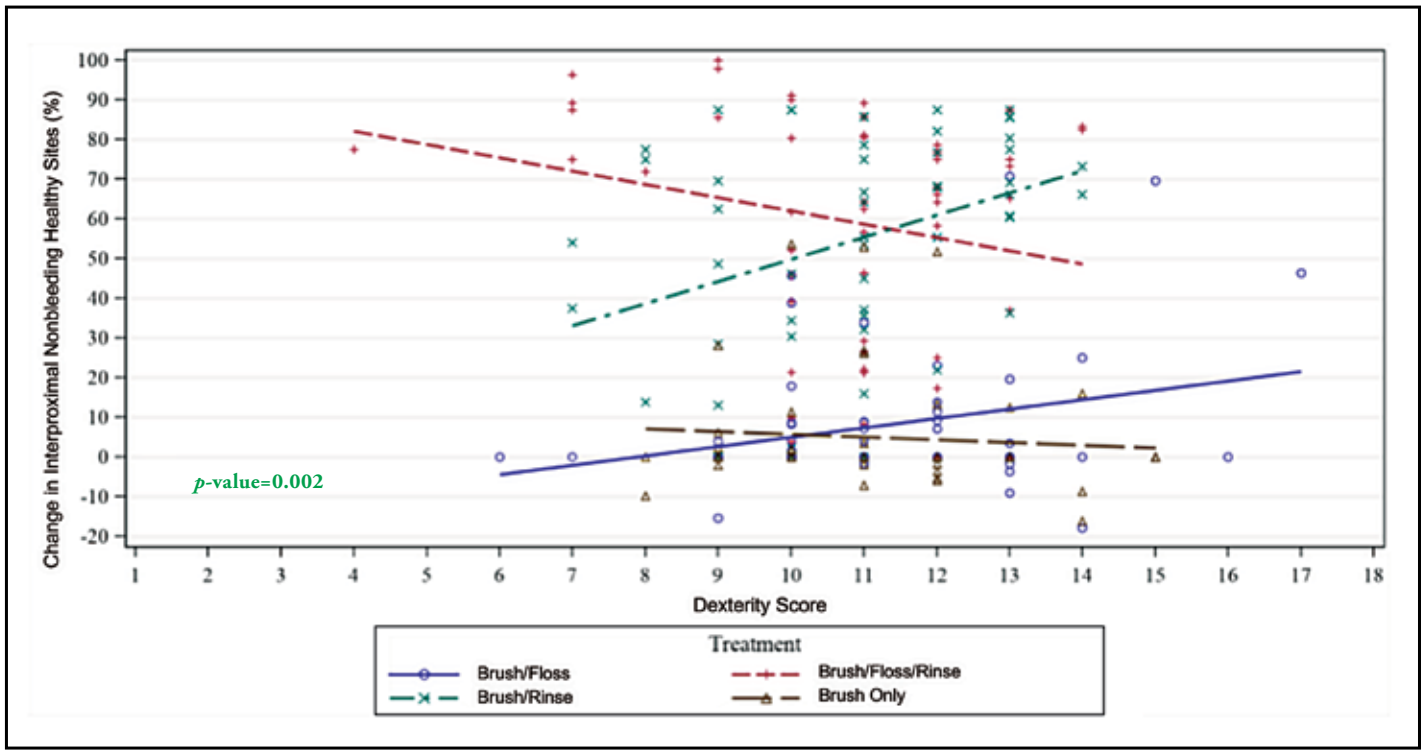


Figure 4. Change from baseline for anterior interproximal percent nonbleeding healthy sites (%) with EBI=0 and MGI=0 or 1 vs. dexterity score

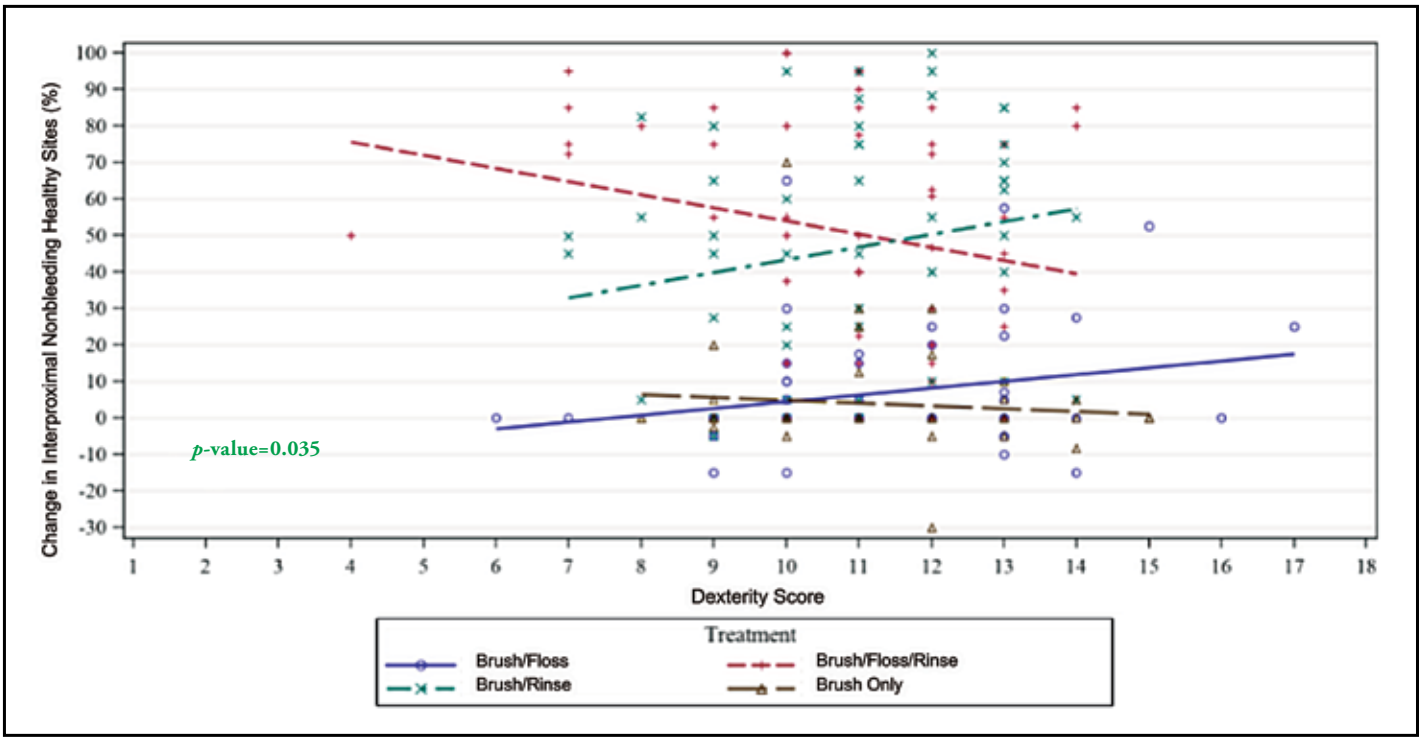


Figure 5. Change from baseline for maxillary interproximal percent nonbleeding healthy sites (%) with EBI=0 and MGI=0 or 1 vs. dexterity score

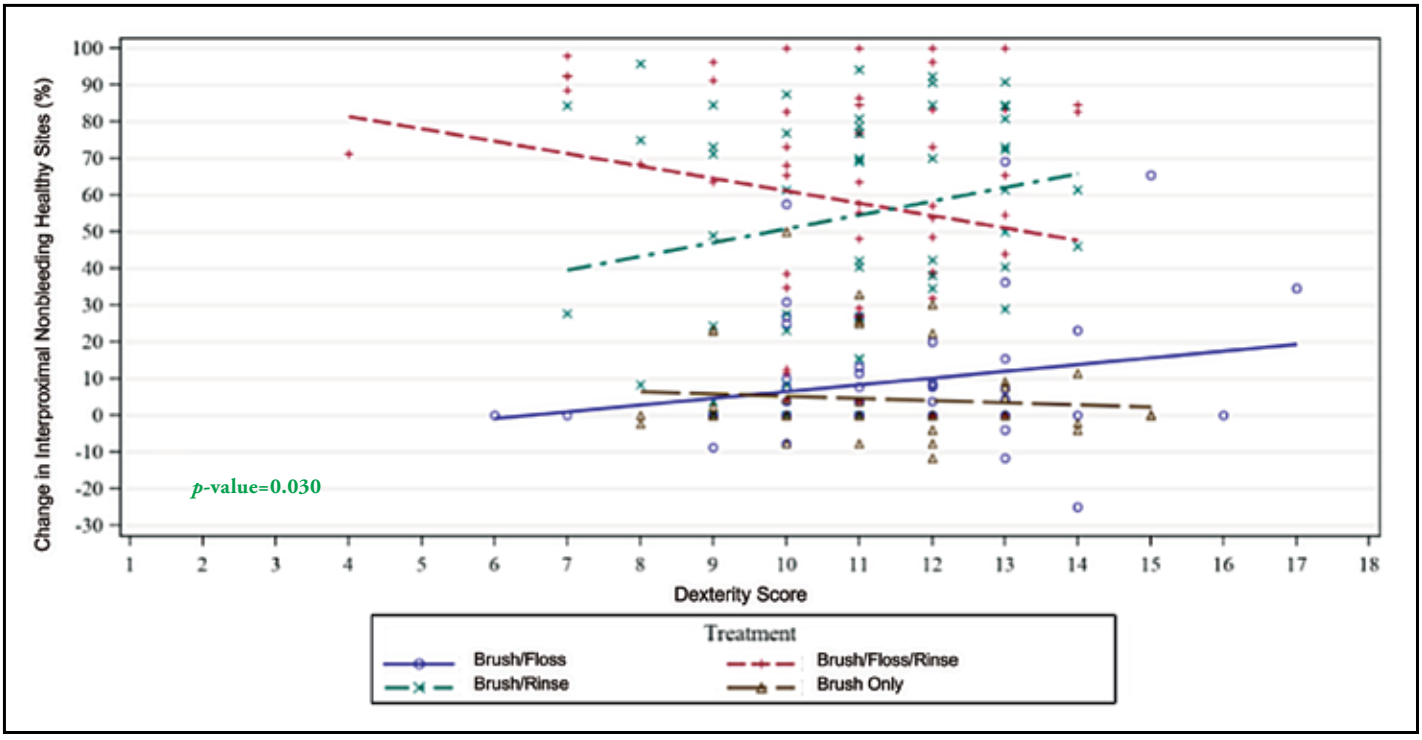
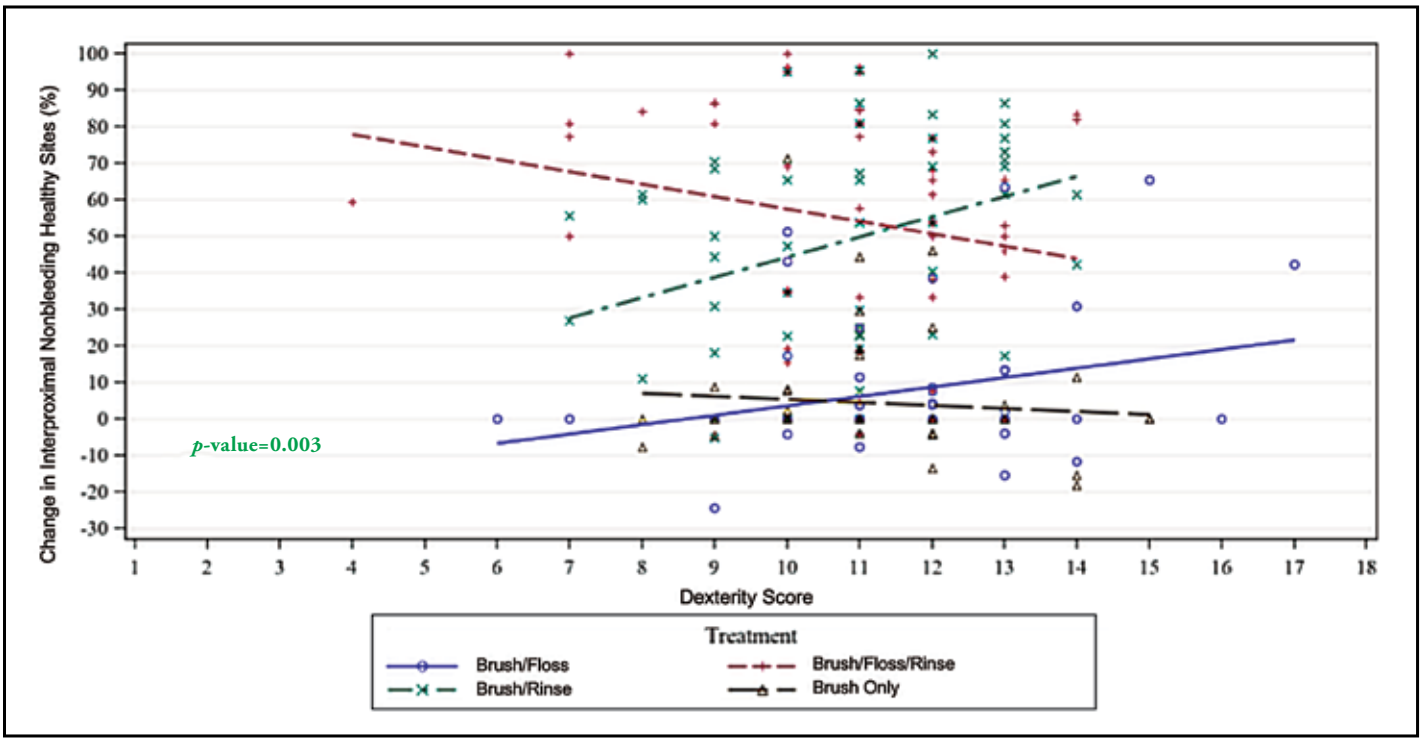


Figure 6. Change from baseline for mandibular interproximal percent nonbleeding healthy sites (%) with EBI=0 and MGI=0 or 1 vs. dexterity score



correct use of dental floss requires functional bilateral dexterity. Consider the process of extracting floss from the dispenser which requires unilateral or bilateral gross motor movement of the shoulder, elbow, forearm, wrist, and digits to obtain the product from the container. The actual flossing phase requires fine dexterity coupled with manual dexterity of the bilateral upper extremities. To be successful with this mechanical regimen, an individual must possess a certain level of bilateral gross and fine motor dexterity. Approximately 20% of participants had a both hand dexterity score ≤9 and approximately 22% had a both hand dexterity score ≥13. In spite of being supervised daily, Monday through Friday, in this clinical trial participants in the BF group with lower dexterity scores had little or no improvement in interproximal gingivitis (EBI=0 and MGI=0 or 1). It was of interest that participants in the BFR group with lower dexterity scores demonstrated the most improvement in interproximal gingival health (>60% for participants having dexterity no higher than 9) after 12 weeks of supervised usage. The addition of a chemotherapeutic mouthrinse to a brushing/flossing regimen contributed to the improved gingival health in this group. Moreover, the participants with the highest dexterity scores in the BF group, even under supervision, demonstrated no greater than 20% improvement in their interproximal gingival health. In all regions of the mouth, the same relationships between change in percent nonbleeding healthy sites and dexterity was observed. A mouthrinse is able to reach all areas of the mouth thus mitigating the effect that dexterity could potentially have as with dental flossing.

The BO group demonstrated little or no change during the 12-week treatment period irrespective of dexterity scores. These results were anticipated as this group was only instructed to brush for one minute using their normal toothbrushing technique. As the technique was not observed and the subjects were not instructed in a specific toothbrushing method, no changes were expected. Subjects with higher relative dexterity scores in the BR group demonstrated greater improvement in their interproximal gingival health. This result could have been due to the Hawthorne effect of being in a clinical trial. According to the findings in a systematic review by McCambridge et al., positive consequences for behaviors being investigated due to research participation have been found to exist in most studies.[42]

Limitations

The study was conducted during the COVID-19 pandemic (October 2020 to February 2021) and restrictions may have influenced those who volunteered to participate (e.g. age, risk tolerance). The sample was restricted to people between the ages of 18 to 60 years who volunteered to be part of a

clinical study conducted at a single test site in the midwestern United States and may not be representative of the general population. Future research of interest would be to expand the age range and geographic area to be more representative of the population, to assess responses immediately following oral hygiene, and to assess plaque reduction immediately following oral hygiene, versus dexterity.

Conclusion

Findings from this component of a supervised clinical trial demonstrate that lower levels of manual dexterity, as measured by a validated assessment tool, can limit the effectiveness of dental flossing. The daily use of dental floss as a mechanical interdental cleaning device requires functional bilateral manual dexterity to perform correctly. The addition of a chemotherapeutic essential oil mouthrinse was shown to improve interproximal gingival health and mitigated the variable of manual dexterity.

Disclosures

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Research

Habits, Practices and Beliefs Regarding Floss and Mouthrinse among Habitual and Non-Habitual Users

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Abstract

Purpose: The purpose of this survey was to investigate how flossing and rinsing behaviors impact individual beliefs about oral disease risk, the efficacy of floss and mouthrinse, and the perceived benefits and barriers of floss and mouthrinse.

Methods: Participants in this required component of a 12-week plaque and gingivitis randomized clinical trial on flossing and rinsing regimens completed a paper questionnaire prior to randomization and baseline/screening measurements.

Results: All of the clinical trial participants (n=213) completed the questionnaire. Respondents were grouped as habitual or non-habitual users of floss or mouthrinse if the product was used at least once daily; 16% (n=34) were habitual users of floss and 17% (n=36) were habitual users of mouthrinse. Perceived barriers included fear of gingival bleeding and pain, forgetting, and not including flossing or rinsing as part of the daily oral care routine. Non-habitual users were less likely to believe in the intangible benefits of flossing or rinsing and much more likely to perceive barriers to using floss or mouthrinse. Risk perception of developing oral disease was not shown to predict product usage. Respondents viewed their risk of developing gingivitis as relatively low despite this diagnosis being confirmed clinically among the participants.

Conclusion: While respondents strongly believed that brushing, flossing, and mouthrinse use carry unique benefits and that combining all three methods would be optimal, these respondents still had high perceived barriers to using floss and mouthrinse regularly and consequently these habits were not included in their daily oral hygiene regimen. Understanding the perceptions regarding oral health behaviors may help drive more effective interventions and assist practitioners in improving their patients' oral health outcomes.

Keywords: dental floss, mouthrinse, oral hygiene habits, health behaviors, gingivitis

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Introduction

Dental floss is one of the most commonly recommended interdental cleaners because of its ability to reach between the teeth, where toothbrush bristles are not able to easily access, and effectively remove interproximal food, debris and dental biofilm.[1] The Food and Drug Administration (FDA) has classified dental floss as a Class I medical device for removal of plaque and food particles between teeth to reduce tooth decay.[2] A 2019 Cochrane review of the literature found that the use of interdental brushes or dental floss in conjunction with toothbrushing may reduce gingivitis or plaque or both, when compared to toothbrushing alone.[3] Another Cochrane review on the use of dental floss for the management of periodontal disease and dental caries in adults, identified evidence supporting the use of flossing plus toothbrushing with a small reduction in plaque over the short term (one to three months). Currently, major dental professional associations post information for the public on their websites relating to various oral hygiene routines.[4-7]

Chemotherapeutic mouthrinses have been shown to access areas in the oral cavity that are difficult to reach with a toothbrush and can help to control plaque, gingivitis, dental caries, and oral malodor depending on the specific formulation of the rinse. The benefits of chemotherapeutic mouthrinses have been consistently demonstrated in a wide range of clinical studies and in subsequent systematic reviews and meta-analyses.[8-16] Two recent clinical trials comparing various levels of supervised

oral hygiene regimens including flossing and rinsing with an essential oil mouthrinse further reinforced the clinical relevance of adding a chemotherapeutic rinse to the oral care regimen.[17,18] However, daily recommendations for mouthrinse use are inconsistent across professional organizations.[5,19] The American Dental Association's (ADA) Council on Scientific Affairs has issued advice on the benefits of ADA Accepted antimicrobial mouthrinses to help prevent and reduce plaque and gingivitis dating back to May 2007,[20] and dental hygienists have been identified as key sources of information regarding the evidence supporting antimicrobial rinsing as part of oral hygiene practice.[21] Yet, despite the published evidence supporting the efficacy of adding a chemotherapeutic mouthrinse to the oral care regimen, reasons as to why the daily use of floss and mouthrinse have not been widely adopted by the general public are not fully understood.

The Delta Dental Oral Health and Well-Being Survey conducted in 2014 found that 35% of the adults surveyed reported flossing at least once daily while 19% reported never using dental floss.[22] In a study analyzing two years' worth of data from the National Health and Nutrition Examination Survey (NHANES), Fleming et al. found that 32% of respondents reported they had not used floss at all in the previous week, while an equal number reported using floss daily, and the remaining third reported flossing their teeth only on some days of the previous week.[23] Certain demographic factors seem to influence dental floss use. Women were more likely to floss daily than men; Asian, non-Hispanic and Hispanic adults were more likely than white, non-Hispanic adults to use floss; those who do not use tobacco more likely than current tobacco users to use floss.[23]

In a study focused on mouthrinse use patterns in Scotland, daily mouthrinsing was only practiced by 25% of the respondents, while 38% reported never using it and 17% used it less than once a month.[24] Again, women were more likely to use mouthrinse than men, and never-smokers more likely to use a mouthrinse than both current and former smokers; usage decreased with age and lower socioeconomic status.[24] Results from this study also identified that people experiencing periodontal disease, ulcers, oral infections/swelling and other problems were all more likely than healthy people to report using mouthrinse.[24]

While it is helpful to know which types of patients might be less likely to use dental floss or mouthrinse, these demographic differences do not necessarily indicate how interventions for promoting better oral health might be best designed. There are a limited number of published studies that have investigated how individual beliefs and perceptions might influence flossing or mouthrinsing behaviors. Identifying these beliefs might help clarify the most effective methods for health care practitioners to open conversations with patients or for public health outreach programs to encourage specific strategies and product use. Previous research suggests that attitudes and beliefs about oral health, including feelings of self-efficacy, predict intentions to improve oral care behaviors, while current behavior and subjective norms do not.[25] In a study by Buglar et al., self-efficacy, or the confidence in one's ability to perform oral self-care, significantly predicted brushing and flossing behavior, in addition to the perceived barriers to these behaviors.[26] Ronis et al. similarly found that flossing habits were best predicted by self-efficacy and perceived barriers, but only looked at a small number (fewer than five) of potential barriers.[27]

The opportunity to survey the beliefs and perceptions of a larger number of individuals enrolling in a clinical trial focused on various toothbrushing, flossing and mouthrinsing regimens, could provide new insight into these attitudes and provide insight on how to better promote effective oral health regimens. The purpose of this survey was to investigate how flossing and rinsing behaviors impact beliefs about oral disease risk, the efficacy of floss and mouthrinse in patients with gingivitis, and the perceived benefits and barriers of floss and mouthrinse. It further sought to examine the differences that exist between habitual and non-habitual users of dental floss and mouthrinse.

Methods

An original, ten-part survey was administered once at the start of a 12-week clinical trial prior to examination and randomization. The purpose of the clinical trial was to evaluate the efficacy of brushing, flossing, and mouthrinsing regimens in the prevention and reduction of plaque and gingivitis. The clinical trial took place at Salus Research, Inc., an American Dental Association (ADA) qualified clinical research site[28] located in Fort Wayne, Indiana, USA. The trial received institutional review board approval from IntegReview (Austin, TX, USA) and was registered on clinicaltrials.gov (NCT04750005). After receiving a thorough explanation of the trial and the opportunity to ask questions in private, all participants provided written informed consent on a document which complied with the requirements of the Health Insurance Portability and Accountability Act.

Sample

Participants were from the Fort Wayne, Indiana area and were selected for screening from the clinical test site's database. Males and females between the ages of 18 to 60 years (age limited by the sponsor due to Covid-19 risks at the time of the trial) in good general and oral health, without known allergies to commercial dental products, and with at least 20 teeth with scorable facial and lingual surfaces, were eligible for consideration. All participants needed to present with evidence of gingivitis (although no minimum score on the MGI was required) and be without evidence of advanced periodontitis. Participants needed to have at least 10% bleeding sites based on the Expanded Bleeding Index (EBI), a maximum of three sites of 5mm probing depth and no sites greater than 5mm at the

baseline/screening clinical examination. Participants agreed to attend virtual smart-phone video daily sessions on weekdays for trial procedures. Other inclusion criteria included absence of fixed or removable orthodontic appliances, removable partial dentures, significant oral soft tissue pathology excluding plaque-induced gingivitis, at the discretion of the investigator/dental examiner. Participants were excluded for a variety of reasons, including: dental prophylaxis within four weeks prior to baseline/screening; needing antibiotics prior to dental treatment; use of certain medications within last month (antibiotics, anti-inflammatory or anticoagulant therapy within one month); use of chemotherapeutic oral care products within two weeks; being pregnant or lactating; use of smokeless tobacco, vaping or e-cigarettes or suspected substance abuse; and any other medical or psychiatric condition that would make the volunteer inappropriate for the trial in the judgment of the principal investigator (PI).

Survey instrument

A quantitative recall questionnaire was developed by members of a cross-functional team with more than 20 years expertise in clinical and consumer research studies and product development and followed consumer product industry practices. The ten-part questionnaire consisted of core items previously developed by the sponsor for oral care products to which new items that focused on specific elements of the clinical trial were added. Overall, the questionnaire was designed to identify specific lifestyle measures of the respondents. The questionnaire utilized multiple-choice (habits) and scaled responses (perceptions, beliefs). Table I presents the structure of the questionnaire and description of the items. Individual questions are provided on Tables III, IV, and V. For the purpose of this questionnaire, the term mouthwash was used and may be considered interchangeable with mouthrinse.

Oral care habits and practices

Respondents reported how frequently they brushed their teeth, used mouthrinse, and flossed, with options of "never," "occasionally," "once daily," "at least twice daily," and "more than twice daily." Given current recommendations for the use of floss and mouthrinse, respondents were considered 'habitual users' of floss or mouthrinse if they used the respective product at least once daily.

Risk perception

Respondents used a 7-point Likert scale (1=strongly disagree to 7=strongly agree) to rate their own perceived risk of developing oral health problems to three items, specifically, "I think my risk of developing gingivitis (red or bleeding gums) is relatively low," "I think my risk of developing dental cavities is low," and "I think my risk of losing my teeth as I get older is relatively low."

Efficacy beliefs of floss and mouthrinse

Responding to ten items, respondents rated the perceived necessity and relative importance of brushing, flossing, and rinsing with mouthrinse on oral health using a 7-point Likert scale (1=strongly disagree to 7=strongly agree). Items included "I think that flossing is as necessary as brushing," "rinsing with mouthrinse is a necessary part of protecting oral health," "flossing and using mouthrinse are equally good at accomplishing the goal of reaching hard to reach places in the mouth," and "brushing, flossing, and rinsing with mouthrinse each add unique and necessary benefits to oral care."

Table I. Survey structure and item descriptions

Part I: 5 multiple choice items regarding respondent's oral hygiene habits (ie, toothbrushing, use of mouthwash, use of floss); 4 items and 1 open ended question for individuals to quantify time to complete flossing
Part II: 2 multiple choice items about respondent's self-perception about flossing and use of mouthwash
Part III: 3 items inquiring about respondent's belief about their risk for specific oral diseases with responses on a 7-point Likert scale (strongly agree to strongly disagree)
Part IV: 10 items inquiring about respondent's belief regarding the importance of specific oral hygiene habits (flossing, mouthwash, brushing) with responses on a 7-point Likert scale (strongly agree to strongly disagree)
Part V: 1 item asking respondents to characterize use of dental floss by 7 descriptors with responses on a 7-point Likert scale (good to bad; pleasant to unpleasant)
Part VI: 1 item asking respondents to characterize, on a 7-point Likert scale (easy to difficult), daily use of floss
Part VII: 20 items asking respondents to qualify how daily flossing would impact their oral health, self-perception, and others' perception of them, with responses on a 7-point Likert scale (strongly agree to strongly disagree)
Part VIII: 6 items asking respondents about their capability to floss under specific circumstances with responses on a 7-point Likert scale (strongly agree to strongly disagree)
Part IX: 18 items inquiring about respondent's beliefs regarding flossing with responses on a 7-point Likert scale (strongly agree to strongly disagree)
Part X: 11 items inquiring about respondent's beliefs regarding mouthwash with responses on a 7-point Likert scale (strongly agree to strongly disagree)

Perceived benefits of daily flossing and rinsing

Respondents rated the potential benefits of flossing and rinsing daily as recommended by responding to 20 items using a 7-point Likert scale (1=strongly disagree to 7=strongly agree). Items included benefits related to physical health "my gums would be healthier" and "I would get fewer cavities", cosmetic concerns "my appearance and smile would be improved" and "I

would be less likely to have bad breath", and less tangible, emotional benefits "I would feel more confident" and "I would feel good about my oral care routine".

Perceived barriers to using floss and mouthrinse

To understand how difficult or easy maintaining a daily flossing habit is perceived, six items assessed respondents' self-efficacy beliefs about their own capability to floss using a 7-point Likert scale (1=strongly disagree to 7=strongly agree). Items included "If I wanted to, I could floss even on days that I am busy and overloaded" and "I could floss even while I am on vacation."

To assess which barriers may make flossing less likely, 18 items asked about a variety of potential factors that make flossing more difficult or undesired and used a 7-point Likert scale (1=strongly disagree to 7=strongly agree). Items included "flossing is painful for me," "flossing takes too much time," "my gums bleed if I floss," and "I find it physically difficult to floss." Similarly, 11 items assessed barriers to using mouthrinse, most of which overlapped those for floss. Items included "mouthwash is overpriced," "I just forget to rinse with mouthwash sometimes," "my dentist/dental hygienist has not told me to rinse with mouthwash," and "I think I brush well enough that rinsing with mouthwash just won't add much."

Procedure

Respondents completed the paper questionnaire regarding their beliefs, habits, and behavior regarding their oral health, including their floss and mouthrinse usage (not brand-specific) at the baseline/screening visit, prior to randomization into the clinical trial.[18] After completing informed consent documents, all participants had their medical and dental histories, and inclusion and exclusion criteria reviewed, then completed the questionnaire. Only one questionnaire was completed by each participant.

Statistical Analysis

Habitual floss users included those who responded that they used dental floss at least once daily and non-habitual floss users included those who did not floss and those who flossed occasionally. Likewise, habitual mouthrinse users included those who responded that they used mouthrinse at least once daily and non-habitual mouthrinse users included those who did not use mouthrinse and those who used mouthrinse occasionally. Survey questions with Likert scale responses had responses collapsed into two categories: agree responses (ie, strongly agree, agree, somewhat agree) and disagree responses (ie, strongly disagree, disagree, somewhat disagree). Responses to one item included a visual analog scale of responses (e.g., good to bad; beneficial to harmful).

Means for habitual users and non-habitual users for floss and mouthrinse were performed using two-sample t-tests, using a 5% significance level, two-sided. The t-tests used a pooled variance approach if the equal variances assumption was not rejected, or Satterthwaite's method if the equal variances assumption was rejected. A folded F-test was used for comparing the variances between habitual and non-habitual users. SAS version 9.4 (SAS Institute, Cary, NC, USA) was used for statistical analyses.

Results

All the participants enrolled in the clinical trial (n=213) completed the survey. The sample included 165 females (77.5%) and 48 males (22.5%) ranging from 18 to 59 years of age with an average age of 42 years. Participants self-identified their race, with 81.7% (n=174) White/Caucasian, 10.8% (n=23) Black/African American, 1.9% (n=4) Asian, 3.8% Hispanic (n=8) and 5.6% (n= 12) other. Only 1.4% (n=3) identified as using tobacco products (smokers). Sample demographics are shown in Table II.

Oral Care Habits and Practices

All respondents brushed at least daily as per the trial eligibility criteria, with 25.8% (n= 55) brushing once daily, 71.4% (n=152) brushing twice daily, and 2.8% (n=6) brushing three or more times. Of particular note, few respondents were habitual users (at least once daily) of either dental floss (16.0%, n=34) or mouthrinse (16.9%, n=36) and 4.2% (n=9) reported using floss or mouthrinse twice daily. By comparison, 29.6% (n=63) reported never using mouthrinse and 10.8% (n=23) reported never using floss. Overall, 6.6% (n=14) were habitual users of both dental floss and mouthrinse.

Efficacy Beliefs for Floss and Mouthrinse

There was high agreement (somewhat agree, agree, or strongly agree) with statements such as "brushing, flossing, and rinsing with mouthwash each add unique and necessary benefits to oral care" (89.7%, n=191) and that "combining brushing, flossing, rinsing is the superior oral

Table II. Sample demographics and baseline characteristics (n=213)

Characteristic	Total
n	213
Mean Age, y (SD)	42.0 (10.57)
Sex	**n (%)**
Male	48 (22.5)
Female	165 (77.5)
Race	**n (%)**
White	174 (81.7)
Black/African American	23 (10.8)
Asian	4 (1.9)
Other	12 (5.6)
Ethnicity	**n (%)**
Hispanic/Latino	8 (3.8)
Not Hispanic/Latino	205 (96.2)
Smoker	**n (%)**
No	210 (98.6)
Yes	3 (1.4)

care routine" (91.1%, n=194), indicating participants' stronger endorsement of floss and mouthrinse as essential. While most agreed that flossing is as necessary as brushing (77.9%, n=166) less than half (46.9%, n=100) believed this to be true for mouthrinse, and while most agreed flossing is necessary to protect oral health (88.3%, n=188) only 65.7% (n=140) agreed mouthrinsing is necessary to protect oral health. This positive perception of the unique place that dental floss holds in the oral care routine was further reflected in responses to the statements "electric toothbrushes do the same job as floss" with only 16.4% (n=35) of the respondents indicating any agreement as compared to 61.5% (n=131) indicating any level of disagreement (somewhat disagree, disagree, strongly disagree). Similarly, in response to the item "I think flossing adds little benefit to good brushing habits," most participants (53.5%, n=114) disagreed, suggesting participants understand the importance of flossing. However, most (70.4%, n=150) agreed with the item "flossing and mouthwash are equally good at accomplishing the goal of reaching hard to reach places in the mouth" with only 17.4% (n=37) in disagreement.

Perceived Benefits of Daily Flossing and Rinsing

Overall, most of the 20 potential benefits of flossing and rinsing daily were strongly endorsed by the respondents (Table III). The two potential benefits that received the highest endorsement were "my gums would be healthier" and "I would be protecting my teeth from plaque and decay" (91.1%, n=194; for both statements). Seventeen of the items had over 70% (n=149) of respondents agreeing that daily flossing and rinsing provided a benefit, with physical health benefits generally being agreed with the most. Items that received the least agreement were the belief that daily flossing and rinsing would improve appearance and smiles (61%, n=130 agreeing; 12.2%, n=26 disagreeing), make one feel better about oneself (57.7%, n=123 agreeing; 8.5%, n=18, disagreeing), and that others would notice an improvement (40.4%, n=86 agreeing; 17.8%, n=38 disagreeing). Even for these items, the rates of disagreement were still rather low, suggesting respondents either endorsed them or were unsure, and none of these items centered on the physical health benefits of flossing and rinsing.

Perceived Barriers to Using Floss and Mouthrinse

Many of the potential barriers to flossing were endorsed as personal challenges of the respondents (Table IV). Interestingly, the barriers with the greatest levels of agreement were routine-based such as "flossing is not a habit of mine" (66.7%, n=142), "I just forget to floss sometimes" (65.3%, n=139), and "flossing is not part of my oral care routine" (64.3%, n=137). The next highest levels of agreement concerned practical matters of flossing, including "my gums bleed when I floss" (46.9%, n=100) and "I have trouble physically getting the floss in some parts of my mouth" (39.4%, n=84).

Similar to the perceived barriers to flossing, the barriers that received the greatest levels of agreement for rinsing were "rinsing with mouthwash is not part of my oral care routine" (67.1%, n=143 agreeing) and "I just forget to rinse with mouthwash sometimes" (51.6%, n=110 agreeing). Perceived barriers to rinsing are shown in Table V. However, unlike with flossing, the next highest items were "mouthwash is overpriced" (27.2%, n=58) and "my dentist/hygienist has not told me to rinse with mouthwash" (26.3%, n=56). Results for all items are presented in Table V.

Perceived Oral Health Risk

In general, respondents believed that their risk of oral health problems was relatively low. In terms of developing dental caries, over half (58.2%, n=124) agreed their risk was relatively low compared to 29.1% (n=62) who disagreed. Most (65.7%, n=140) also believed their risk of losing their teeth with age was low compared to 22.5% (n=48) who disagreed. Interestingly, over half (56.8%, n=121) also believed that their risk for gingivitis was low, while 29.6% (n=63) indicated disagreement to gingivitis risk. This is particularly noteworthy given that, due to the inclusion criteria, all participants had at least mild gingivitis and a minimum gingival bleeding site requirement of 10% or more.

Respondents were divided into habitual and non-habitual users of dental floss and mouthrinse to better understand the underlying difference between the users and non-users of these products. Habitual floss users (floss at least once daily, n=34) and non-habitual floss users (n=179), and habitual mouthrinse users (rinse at least once daily, n=36) and non-habitual mouthrinse users (n=177) were compared on their perceived oral health risks. Independent t-tests showed that these groups did not differ on risk perception depending on whether they flossed or rinsed regularly ($p>0.05$). Habitual and non-habitual floss and mouthrinse user groups perceived themselves to be at similarly low risk for oral health diseases.

Perceived Benefits and Barriers by Product Usage

Perceptions regarding the benefits of daily flossing and rinsing were compared across habitual and non-habitual users. Habitual floss and rinse users were shown to be more likely to agree that daily usage would lead to their mouths feeling more pleasant, improve their smile and appearance, and feel better about themselves, compared to non-habitual users of floss or mouthrinse ($p<0.05$). Additionally, habitual flossers agreed more strongly than non-habitual flossers that they feel they are doing the right thing for their oral health ($p=0.015$), they are protecting their teeth from plaque and decay ($p=0.024$), they feel good about their oral care routine ($p=0.001$), and that their mouths feel totally clean ($p=0.010$). Habitual users of mouthrinse also agreed more strongly than non-habitual mouthrinse users that their teeth would last a lifetime ($p=0.024$), they would feel more confident ($p=0.018$), others would notice an improvement ($p\leq0.050$), and their teeth would be healthier ($p=0.003$). No other comparisons were significant ($p<0.05$). The perceived benefits and barriers of floss and mouthrinse by habitual and non-habitual users are shown in Table VI.

Table III. Perceived benefits of daily flossing and rinsing (n=213)

	1 = Strongly Disagree (%)	2 = Disagree (%)	3 = Somewhat Disagree (%)	4 = Neither Agree nor Disagee (%)	5 = Somewhat Agree (%)	6 = Agree (%)	7= Strongly Agree (%)
My mouth would be cleaner	1.4	1.9	<1.0	6.6	17.8	46.9	24.9
My mouth would feel more pleasant	1.4	1.4	1.9	11.7	19.7	39.9	23.9
I would be less likely to have bad breath	1.4	1.4	1.4	17.4	25.4	31.5	21.6
I would be less likely to develop oral disease	<1.0	<1.0	1.4	9.4	17.8	39.9	29.6
I would get fewer cavities	<1.0	<1.0	3.8	14.1	21.6	32.9	25.8
My appearance and smile would be improved	2.3	3.8	6.1	26.8	23.0	24.9	13.1
I would feel better about myself	2.8	2.8	2.8	33.8	13.1	30.0	14.6
My teeth would last a lifetime	1.4	1.4	7.0	19.2	34.7	24.4	11.7
I would feel like I did the right thing for my oral health	<1.0	0.0	1.4	7.0	19.2	39.9	31.5
My gums would be healthier	<1.0	0.0	<1.0	7.0	16.9	39.9	34.3
I would be protecting my teeth from plaque and decay	<1.0	0.0	1.4	6.6	19.2	43.7	28.2
I would feel good about my oral care routine	<1.0	0.0	1.9	9.4	18.3	39.9	29.6
I would be proud of myself for my oral care routine	<1.0	0.0	<1.0	12.7	18.8	36.6	30.5
I would worry less about my oral health	<1.0	2.3	1.9	21.1	20.2	35.7	17.8
I would feel like my oral care routine is more complete	<1.0	<1.0	<1.0	8.0	19.7	42.3	27.2
My mouth would feel totally clean	<1.0	1.4	2.8	9.9	29.1	35.2	21.1
If I used mouthwash in addition to brushing and flossing, then the feeling of a clean mouth would last longer	<1.0	<1.0	1.4	11.7	23.5	40.4	21.1
I would feel more confident	1.9	1.9	1.9	23.9	21.6	33.8	15.0
I think other people would notice an improvement	3.3	5.6	8.9	41.8	19.2	15.0	6.1
My teeth would be healthier	<1.0	<1.0	1.4	10.3	20.7	40.8	25.8

Table IV. Perceived barriers to flossing (n=213)

	1 = Strongly Disagree (%)	2 = Disagree (%)	3 = Somewhat Disagree (%)	4 = Neither Agree nor Disagee (%)	5 = Somewhat Agree (%)	6 = Agree (%)	7= Strongly Agree (%)
Flossing is painful for me	13.1	33.8	8.5	13.6	23.9	4.7	2.3
Flossing takes too much time	14.1	24.4	12.7	18.8	22.1	6.6	1.4
I cannot find the time to floss	18.8	33.8	12.7	20.2	12.7	1.9	0.0
I find it physically difficult to floss	29.6	35.7	8.5	11.7	8.9	5.2	<1.0
I have trouble physically getting the floss in some parts of my mouth	18.8	28.2	6.6	7.0	22.1	12.7	4.7
My gums bleed if I floss	8.9	21.6	7.0	15.5	31.0	11.3	4.7
Flossing is not a habit of mine	8.9	11.3	8.0	5.2	21.6	29.6	15.5
Flossing is not part of my oral care routine	9.9	11.7	9.4	4.7	25.8	25.4	13.1
Floss is overpriced	26.3	34.7	7.5	27.2	3.3	<1.0	<1.0
I just forget to floss sometimes	7.0	8.0	1.9	17.8	26.8	27.2	11.3
I think I brush well enough that flossing won't add much	16.9	25.4	16.9	19.2	14.6	5.6	1.4
My flossing technique isn't very good	8.5	20.2	9.4	23.9	21.6	13.6	2.8
I would need to floss for at least two minutes to get the benefits of flossing	5.2	7.0	13.6	36.2	14.6	20.2	3.3
I do not like the feeling of flossing	16.0	32.4	5.6	19.2	16.4	8.0	2.3
I do not like the taste of flossing	20.2	39.0	8.0	24.4	4.2	4.2	0.0
I'm not sure that flossing really helps remove plaque	20.7	37.1	15.0	16.9	7.0	2.8	<1.0
Flossing is just too much trouble	20.2	27.7	8.0	21.1	16.9	4.7	1.4
My dentist/hygienist has not shown me how to floss	32.4	36.6	7.5	12.7	2.3	6.6	1.9

Table V. Perceived barriers to mouthrinse use (n=213)

	1 = Strongly Disagree (%)	2 = Disagree (%)	3 = Somewhat Disagree (%)	4 = Neither Agree nor Disagee (%)	5 = Somewhat Agree (%)	6 = Agree (%)	7= Strongly Agree (%)
Rinsing with mouthwash takes too much time	21.6	42.7	14.6	14.1	6.1	<1.0	0.0
I cannot find the time to use mouthwash	22.5	44.6	14.6	12.7	4.2	<1.0	<1.0
Rinsing with mouthwash is not part of my oral care routine	7.5	9.4	9.9	6.1	20.7	33.3	13.1
Mouthwash is overpriced	14.6	20.7	8.0	29.6	15.5	7.0	4.7
I just forget to rinse with mouthwash sometimes	8.9	13.1	3.8	22.5	23.5	22.1	6.1
I think I brush well enough that rinsing with mouthwash won't add much	12.2	25.4	17.8	22.5	10.3	11.3	<1.0
I do not like the feeling of rinsing with mouthwash	17.4	36.6	13.1	11.7	13.1	5.2	2.8
I do not like the taste of rinsing with mouthwash	16.4	35.7	12.2	11.7	14.1	5.2	4.7
I'm not sure that rinsing with mouthwash really helps remove plaque	16.9	28.6	16.4	18.8	12.2	5.2	1.9
Rinsing with mouthwash is just too much trouble	18.3	41.8	9.9	20.2	7.0	1.9	<1.0
My dentist/hygienist has not told me to rinse with mouthwash	23.9	30.5	3.8	15.5	9.4	13.6	3.3

Habitual and non-habitual flossers were further compared regarding their perceptions of barriers to flossing. Although self-efficacy was relatively high overall, habitual flossers perceived flossing adoption to be easier as compared to non-habitual users across all items ($p<0.01$). Habitual flossers agreed more strongly that they could floss daily, even under emotional distress, busy times, or while on vacation. The groups also differed significantly on most potential barriers, with the exceptions being perceptions that floss is overpriced and that they have not been shown how to floss by a dentist/dental hygienist (both $p>0.05$). Both statements received very low endorsements from the habitual and non-habitual groups. However, non-habitual users were significantly more likely to endorse the other barriers. Most notably, non-habitual users were more likely to agree that their gums bleed if they floss (M=4.2 vs 2.6, $p<0.001$), flossing is not a habit of theirs (M=5.2 vs 2.3, $p<0.001$), flossing is not part of their oral care routine (M=5.0 vs 2.1, $p<0.001$), and that they just forget to floss sometimes (M=5.0 vs 3.4, $p<0.001$). These findings accounted for the most strongly endorsed barriers to flossing. Results for the perceived barriers to flossing by habitual and non-habitual users are presented in Table VII.

Similarly, habitual and non-habitual mouthrinse users were compared in their perceptions of barriers to using mouthrinse (Table VIII). Notably, habitual and non-habitual users did not differ in beliefs about mouthrinse use taking too much time, which had fairly low levels of agreement (M=2.3 and 2.5, respectively, $p>0.05$), however, the groups differed on all other items. Interestingly, given the higher levels of endorsement, non-habitual mouthrinse users were more likely to say mouthrinse is just not a part of their routine (M=5.3 vs 2.3, $p<0.001$), and that they just forget to rinse sometimes (M=4.5 vs 3.2, $p<0.001$).

Table VI. Perceived benefits and risks of daily flossing and rinsing by habitual and non-habitual users (n=213)*

	Habitual Floss Users (n=34)	Non-Habitual Floss Users (n=179)		Habitual Mouthrinse Users (n=36)	Non-Habitual Mouthrinse Users (n=177)	
	Mean (SD)	Mean (SD)	*p*-value**	Mean (SD)	Mean (SD)	*p*-value***
My mouth would be cleaner	6.0 (1.00)	5.7 (1.18)	0.170	5.9 (1.04)	5.8 (1.18)	0.535
My mouth would feel more pleasant	6.1 (0.78)	5.5 (1.29)	0.002	5.9 (0.79)	5.6 (1.30)	0.021
I would be less likely to have bad breath	5.6 (1.33)	5.4 (1.24)	0.568	5.6 (1.36)	5.4 (1.23)	0.312
I would be less likely to develop oral disease	6.1 (1.10)	5.8 (1.16)	0.158	5.9 (1.13)	5.8 (1.16)	0.740
I would get fewer cavities	5.8 (0.95)	5.5 (1.30)	0.152	5.8 (1.02)	5.5 (1.30)	0.329
My appearance and smile would be improved	5.6 (0.92)	4.8 (1.46)	<0.001	5.4 (0.96)	4.8 (1.48)	0.007
I would feel better about myself	5.5 (1.31)	4.9 (1.43)	0.018	5.4 (1.05)	4.9 (1.48)	0.019
My teeth would last a lifetime	5.4 (1.31)	5.0 (1.22)	0.062	5.5 (1.06)	5.0 (1.26)	0.024
I would feel like I did the right thing for my oral health	6.2 (0.73)	5.8 (1.11)	0.015	6.1 (0.78)	5.8 (1.12)	0.094
My gums would be healthier	6.1 (0.74)	5.9 (1.10)	0.143	6.1 (0.81)	5.9 (1.10)	0.342
I would be protecting my teeth from plaque and decay	6.2 (0.80)	5.8 (1.07)	0.024	5.9 (0.87)	5.9 (1.08)	0.963
I would feel good about my oral care routine	6.2 (0.70)	5.7 (1.16)	0.001	5.9 (0.83)	5.8 (1.16)	0.368
I would be proud of myself for my oral care routine	6.0 (0.95)	5.8 1.14)	0.262	6.0 (0.79)	5.8 (1.17)	0.139
I would worry less about my oral health	5.5 (1.02)	5.3 (1.31)	0.568	5.5 (1.03)	5.3 (1.31)	0.549
I would feel like my oral care routine is more complete	6.1 (0.74)	5.8 (1.16)	0.051	6.0 (0.81)	5.8 (1.15)	0.096
My mouth would feel totally clean	5.9 (0.85)	5.5 (1.18)	0.010	5.7 (1.14)	5.5 (1.14)	0.347
Using mouthwash in addition to brushing and flossing, the feeling of a clean mouth would last longer	5.8 (0.82)	5.6 (1.18)	0.287	5.9 (0.94)	5.6 (1.16)	0.080
I would feel more confident	5.6 (1.02)	5.2 (1.33)	0.107	5.6 (0.96)	5.2 (1.34)	0.018
I think other people would notice an improvement	4.6 (1.33)	4.3 (1.35)	0.255	4.8 (1.24)	4.3 (1.36)	0.050*
My teeth would be healthier	5.9 (0.90)	5.7 (1.10)	0.370	6.1 (0.72)	5.7 (1.11)	0.003

* Mean responses are on a Likert scale, 1 (strongly disagree) to 7 (strongly agree)

**p<0.050; ***p=0.0495

Discussion

Results from this survey help to illuminate reasons for low adoption rates of using both dental floss and mouthrinse as part of the daily oral care routine. Respondents of this survey reported that they are not flossing or using mouthrinse as frequently as generally recommended by oral health care professionals. Interestingly, results from this survey indicate that practices of daily flossing were lower than those reported in previously published studies.[22,23] In general, respondents believed their risk for gingivitis, tooth loss, or dental caries was relatively low. This was notable given that all the participants in this trial were previously screened from the trial site's database as having some gingivitis. All individuals accepted for participation in the trial met the inclusion criteria to have a minimum gingival bleeding site requirement of ≥10% as assessed by a dental examiner at baseline/screening. An assumption might be that non-habitual users of dental floss and/or mouthrinse may not do so because they perceive their risk is lower than habitual users. However, this low level of perceived risk did not differ between habitual and non-habitual users, suggesting that there may be another component influencing perceived risk for oral disease.

Overall, participants indicated understanding that brushing, flossing, and mouthrinsing provide unique and valuable benefits to oral health. Respondents indicated stronger endorsement for the essential role of dental floss in oral care regimens as compared with mouthrinse. However, there was very strong agreement that both daily flossing and rinsing provide clear and broad benefits for oral health. This is perhaps not surprising given the recommendations made by dental professionals and organizations regarding interdental cleaning and the use of mouthrinses.[4-7,19]

Table VII. Perceived barriers to flossing by habitual and non-habitual users (n=213)*

	Habitual Floss Users (n=34)	Non-Habitual Floss Users (n=179)	
	Mean (SD)	Mean (SD)	*p*-value
I can start flossing immediately on a regular basis	6.2 (0.70)	5.6 (1.21)	<0.001
I could floss even on days when I feel busy and overloaded	6.1 (0.74)	5.7 (1.18)	0.002
I could floss even on days when I am feeling tired	6.2 (0.65)	5.6 (1.18)	<0.001
I could floss even on days when I am feeling down in the dumps	6.2 (0.61)	5.7 (1.22)	<0.001
I could floss even when I am feeling anxious or nervous	6.2 (0.65)	5.7 (1.13)	<0.001
I could floss even while I am on vacation	6.3 (0.68)	5.9 (1.04)	0.006
Flossing is painful for me	2.4 (1.40)	3.4 (1.64)	0.001
Flossing takes too much time	2.1 (0.95)	3.6 (1.59)	<0.001
I cannot find the time to floss	1.9 (0.99)	3.0 (1.39)	<0.001
I find it physically difficult to floss	1.9 (1.12)	2.6 (1.57)	0.001
I have trouble physically getting the floss in some parts of my mouth	2.8 (1.81)	3.5 (1.93)	0.038
My gums bleed if I floss	2.6 (1.52)	4.2 (1.64)	<0.001
Flossing is not a habit of mine	2.3 (1.49)	5.2 (1.63)	<0.001
Flossing is not part of my oral care routine	2.1 (1.32)	5.0 (1.62)	<0.001
Floss is overpriced	2.3 (1.22)	2.5 (1.29)	0.324
I just forget to floss sometimes	3.4 (1.97)	5.0 (1.48)	<0.001
I think I brush well enough that flossing won't add much	2.0 (1.10)	3.3 (1.55)	<0.001
My flossing technique isn't very good	2.6 (1.45)	4.0 (1.57)	<0.001
I would need to floss for at least two minutes to get the benefits of flossing	3.6 (1.76)	4.3 (1.35)	0.018
I do not like the feeling of flossing	2.3 (1.40)	3.4 (1.69)	<0.001
I do not like the taste of flossing	2.1 (1.31)	2.8 (1.37)	0.017
I am not sure that flossing really helps remove plaque	2.1 (0.98)	2.7 (1.40)	0.003
Flossing is just too much trouble	2.1 (1.37)	3.3 (1.60)	<0.001
My dentist/hygienist has not shown me how to floss	2.2 (1.32)	2.5 (1.61)	0.361

*Mean responses are on a Likert scale, 1 (strongly disagree) to 7 (strongly agree).

Table VIII. Perceived barriers to mouthrinse use by habitual and non-habitual users (n=213)*

	Habitual Mouthrinse Users (n=36)	Non-Habitual Mouthrinse Users (n=177)	
	Mean (SD)	Mean (SD)	*p*-value
Rinsing with mouthwash takes too much time	2.3 (1.33)	2.5 (1.18)	0.490
I cannot find the time to use mouthwash	1.9 (1.04)	2.4 (1.20)	0.020
Rinsing with mouthwash is not part of my oral care routine	2.3 (1.43)	5.3 (1.45)	<0.001
Mouthwash is overpriced	2.4 (1.29)	3.7 (1.67)	<0.001
I just forget to rinse with mouthwash sometimes	3.2 (1.81)	4.5 (1.61)	<0.001
I think I brush well enough that rinsing with mouthwash won't add much	2.2 (0.98)	3.5 (1.55)	<0.001
I do not like the feeling of rinsing with mouthwash	2.1 (1.12)	3.1 (1.65)	<0.001
I do not like the taste of rinsing with mouthwash	2.2 (1.27)	3.2 (1.74)	≤0.001
I'm not sure that rinsing with mouthwash really helps remove plaque	2.3 (1.23)	3.2 (1.57)	0.001
Rinsing with mouthwash is just too much trouble	1.9 (0.79)	2.8 (1.40)	<0.001
My dentist/hygienist has not told me to rinse with mouthwash	2.3 (1.60)	3.3 (1.90)	0.004

* Mean responses are on a Likert scale, 1 (strongly disagree) to 7 (strongly agree)

Over 90% of the respondents agreed that daily flossing and rinsing practices would result in healthier gums and protect their teeth from plaque and decay. However, despite the beliefs that flossing and rinsing will improve oral health in an at-risk population, only 16% reported flossing daily and only 17% reported using a mouthrinse at least once daily. There were areas identified where increased education might encourage individuals to adopt good oral care behaviors. Non-habitual users were significantly less likely to believe that flossing or mouthrinse use could provide psychosocial benefits such as improving their appearance and smile, suggesting that these may be more useful points of discussion for oral health professionals attempting to persuade patients to adopt these habits. Also, as non-habitual flossers were more likely to say that their gums would bleed if they flossed, it would be important for oral health professionals to explain that bleeding is a sign of inflammation indicating that an individual needs to floss more frequently and that habitual interdental cleaning would reduce these symptoms.[29]

Professional and supervised daily dental flossing and mouthrinsing have been shown to be beneficial in reducing gingival bleeding.[17,18] Results from Milleman et al. suggest that the addition of flossing to brushing and mouthrinsing regimens contributed incrementally to the reduction of whole mouth and interproximal percent bleeding sites after 4 weeks, but not at 12 weeks, as compared to brushing and rinsing alone.[18] In spite of the research to support the incorporation of mouthrinsing into daily oral health regimens,[8-16] one of the barriers cited by more than one quarter of the respondents in this survey was that their dental professionals had not recommended mouthrinsing to them. Receiving the endorsement from their oral health care professional to use mouthrinse may provide the motivation to incorporate it into their daily oral hygiene routine. Habit formation is a means to promote healthy behaviors such as flossing and mouthrinsing.[30,31] The goal should be to achieve optimal oral health for patients. Mouthrinses are an effective option to offer patients as an adjunct to brushing, flossing or other types of interdental cleaning.

Results from this survey suggest that it may be the perceived barriers to flossing and rinsing, rather than beliefs about efficacy or benefits, that are the strongest differentiators in habitual flossing and mouthrinsing. People often forget to use these products, do not like the way they feel or taste, and do not include them as part of their current oral care routines. Oral health care providers may find that discussing strategies for healthy habit formation, promoting self-efficacy in developing these habits, and addressing the specific patient perceived barriers are more likely to lead to healthy oral care behaviors rather than discussing benefits or efficacy of these products. Research suggests applying the theory of planned behavior and motivational habit formation approaches may increase individuals' intentions towards incorporating new oral health behaviors.[30,31]

Given that the main barriers to habitual use of floss and mouthrinse were not due to lack of knowledge regarding their benefits, but rather

due to forgetfulness, incorporation of behavior change theory for habit formation may be particularly useful in future research. Future studies should support the development of effective interventions to increase the daily use of mouthrinse and interdental cleaners such as dental floss.

Limitations

This survey used self-reported information and did not capture actual flossing and mouthrinsing behaviors. Moreover, the sample was limited to volunteers for a clinical trial and may not be representative of the general population. The clinical trial also specifically recruited people with some gingivitis and the results may not generalize to a population with higher or lower levels of gingival inflammation. The trial was also conducted during the COVID-19 pandemic, which may have further influenced who volunteered (e.g., age, risk tolerance) for the trial and the mindset of the participants.

Conclusion

While a majority of the participants in this survey strongly endorsed the belief that brushing, flossing, and using a mouthrinse carry unique benefits and that combining all three methods would be optimal for oral health, results suggest that the perceived barriers to using floss and mouthrinse regularly limited the adoption of these self-care routines. Dental professionals should consider assisting patients with strategies to build habits for effective interdental cleaning. Understanding the perceptions and barriers regarding oral health behaviors may help drive more effective interventions and support practitioners in improving their patients' oral health outcomes.

Disclosures

Johnson & Johnson Consumer Inc. (JJCI; Skillman, NJ, USA) sponsored this clinical trial and was responsible for the trial design and the collection, analysis, and interpretation of the data. Katie Rotella, Mary Lynn Bosma, James McGuire, Anusha Sunkara, and Alicia DelSasso are employees of JJCI. Jeffery Milleman and Kimberly Milleman are principals at Salus Research, Inc., and have received grants from JJCI to conduct this trial. Megan Gaff is employee at Salus Research, Inc.

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