

Evaluation of the Plaque Removal Efficacy of Two Commercially Available Dental Floss Devices

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Abstract

- **Objective:** This single blind, crossover design, clinical trial provided a comparative assessment of the oral cleaning of two dental devices as demonstrated through the removal of dental plaque when used according to marketed product-use directions.
- **Methodology:** Twenty-six subjects, both male and female between the ages of 19 and 64 years, completed this two-cell crossover study. Subjects were assessed for whole mouth plaque levels, both before and after use of each of the randomly assigned floss devices, by assessing disclosed plaque using the Modified Turesky Plaque Index. The two floss devices were a Mint Floss Pick and a standard rolled floss. Subjects abstained from brushing the night before appearing in the clinic, and based upon meeting the minimum plaque criteria of 1.5 at the first phase of the crossover, used one of the two floss devices according to the directions for use found on the product packaging. Both pre- and post-device use plaque levels were recorded with calculations made of both the actual difference in plaque level, as well as the percent plaque removed. Data were subjected to an analysis of covariance (ANCOVA), and employed a model consistent with crossover design.
- **Results:** Overall results from both phases of the crossover showed the Mint Floss Pick product removed 19.4% of the plaque. The standard rolled floss product removed 15% of the plaque. Both products removed statistically significant plaque when assessed versus pre-treatment levels. Although the ANCOVA identified a statistically significant difference between treatments favoring the Floss Pick product, further statistical examination revealed a significant sequence effect, which led to a conservative product comparison of equivalence. This analysis confirmed that the Floss Pick product was “at least as good as” the standard floss product for plaque removal. Additional analyses of various sites in the mouth, *i.e.*, interproximal, anterior, posterior, etc., also confirmed similarity of performance for both products in this test.
- **Conclusion:** A two-way crossover assessment of the cleaning capability of a Mint Floss Pick product compared to a standard rolled floss product was performed through assessment of the removal of dental plaque. Results of this clinical investigation support the Floss Pick product to be “at least as good as” standard rolled floss in cleaning capability when both products were used according to their product-use directions.

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Introduction

The mechanical removal of dental plaque from the marginal areas of the tooth, as well as from areas between the teeth, has long been understood as an effective means by which to improve and maintain the overall cleanliness and health of the oral soft tissues. Plaque has been identified as the etiological agent leading to the process of inflammation of the soft tissues, which can lead eventually to periodontal disease and caries.¹⁻¹² Soft tissue health returns with the daily removal of plaque.^{13,14} The primary means of daily plaque removal has typically been through the use of a toothbrush and toothpaste.¹⁵ Published reports have shown, however, that tooth brushing can remove somewhere between 65% and 75% of the total plaque load on or around the dentition.¹⁶ Due to the fact that tooth brushing alone does not completely remove the plaque, additional devices have been introduced to assist in the cleaning process.

Interdental cleaning has been part of oral hygiene for over 5000 years.¹⁷ In some cultures, chewing sticks have been established as a daily routine for cleaning teeth.¹⁸ Over the years, a number of newer cleaning devices have been introduced, and dental floss is the most common of them. Studies on the adjunctive use of dental floss have indicated its effectiveness for plaque removal in hard-to-reach areas, such as interproximal spaces and posterior aspects of the teeth.^{7,20-25} The American Dental Association recommends that flossing be part of the daily routine of tooth brushing to remove accumulated plaque.²⁵ It would appear that if the public would use floss regularly in addition to tooth brushing, much of the accumulated plaque would be removed and the development of soft tissue disease largely controlled. However, while some studies have found that 100% of respondents surveyed use toothbrushes, only 40% report any use of floss as a part of their regular oral hygiene.²⁶⁻³⁰

In addition to the lack of use of flossing, there are other considerations surrounding the compliance of more complete oral hygiene. Floss is considered by some people to be “difficult” to use, and requires too much time out of a busy schedule. Thus, even with those people who use floss, it is not often effective or even consistent.³¹⁻³⁶ Alternatives to floss have been developed, and the research on these devices has had mixed results for efficacy of plaque removal. For instance, when wood sticks were compared to floss and a single-tuft toothbrush, none of the devices demonstrated superiority over the others.³⁷ When a rubber tip was compared to floss and a toothbrush, both removed plaque versus tooth brushing alone, but had no effect on the status of gingivitis present.³⁴ Some authors have stated that there is no “consistent” clear picture of the superiority of one interproximal cleaning device over another.^{22,32,33,38-41} The results of this literature have left some dental professionals with an unclear picture of what to recommend to their patients for improved oral hygiene on a regular basis.

In spite of the mixed findings in the literature, it is generally agreed by the dental profession that the regular use of dental floss has allowed for more complete daily plaque removal, and is demonstrably better than tooth brushing alone.^{8,20-22} The addition of daily flossing to the regular oral hygiene regimen can be an effective mechanism for the removal of dental plaque from interproximal surfaces, which can be missed through toothbrush action.⁴² It would appear that if people would use something in addition to tooth brushing, and they found it convenient to use, the compliance for usage would increase.

A device has been developed which would provide both flossing and interproximal dental pick cleaning, and could make performing both procedures convenient, and at the same time vastly improve compliance to an enhanced mechanical cleaning regimen. This study was designed to examine the comparative effectiveness of such a combination device versus that of standard dental floss when used according to product labeling instructions.

Materials and Methods

This study was designed to directly compare the cleaning efficacy of the DenTek® Mint Floss Pick (DenTek® Oral Care, Inc., Maryville, TN, USA; Figure 1) to that of Johnson & Johnson Reach® Mint Waxed Rolled Floss (Johnson & Johnson Co., Skillman, NJ, USA) for the removal of dental plaque. Both products were assessed when used according to package directions.

Subjects

Approximately 40 subjects were recruited from the general West Palm Beach, FL, USA area. Subjects were in good general

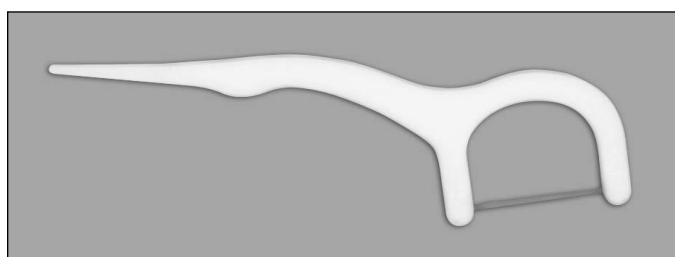


Figure 1. Mint Floss Pick.

health, and met the following inclusion/exclusion criteria: Male and female adults age 18 years or older who possessed 20 or more natural teeth, with at least 16 acceptable for scoring plaque, willing to use the assigned products according to instructions, be available for all appointments, be likely to complete the study, agree to brush their teeth twice daily as instructed, and exhibit no oral neglect. Grossly carious, fully crowned or restored, orthodontically banded abutment teeth, and third molars were not included in the tooth count. Twenty-nine volunteers read and signed the Informed Consent statement after the study was fully explained. Subjects were excluded if they were taking any medications which might interfere with the outcome of the study by affecting tissue condition, salivation, plaque formation (*e.g.*, antibiotics, anticoagulants, and other medications that would compromise the data), had a history of infectious disease (*e.g.*, AIDS, hepatitis, tuberculosis), had drug allergies, idiosyncrasies, or significant adverse effects following the use of oral hygiene products, had any condition that required prophylactic antibiotic coverage prior to subgingival cleaning and other invasive dental procedures, had any serious medical condition requiring control with medication (*e.g.*, asthma, diabetes, hepatic or renal disease), or drug abuse. The examiner also screened for significant oral soft tissue pathology, systemically related gingival enlargement, gross caries based on a visual examination, or tissue damage. Screening was also used to exclude moderate/advanced periodontitis (ADA Class III or IV). Pregnant or lactating females, as determined by medical history, were excluded from the study.

Twenty-six subjects were enrolled and completed the test phases of the clinical trial based upon meeting all protocol inclusion/exclusion criteria, and meeting the plaque level entrance criterion of a mean 1.5 per tooth score for overnight plaque level as measured via the Modified Turesky Plaque Index.⁴³

All subjects were asked to refrain from the use of any other methods of oral hygiene, except for the standard toothbrush (Oral-B® 40 Indicator, Procter & Gamble Co., Cincinnati, OH, USA) and standard toothpaste (AIM® Toothpaste, Church & Dwight Co., Inc., Princeton, NJ, USA), issued at the screening visit, for twice-daily use for one week prior to study initiation. This two-cell crossover study design required that subjects use one of the two test products during each test visit.

Screening Visit

During this visit, subjects were screened for medical and dental history to ensure they could safely and effectively participate in the trial. Subjects were asked if they had previously used dental floss, and if they would be willing to do so as part of this trial. Only subjects willing to use dental floss were entered into the trial. Subjects were also shown the test product. They were asked if they had used such a device in the past. If they had not, they were shown the device and asked to use the device at the clinic according to the package instructions. They were to use as many floss pick devices as was necessary to successfully floss and pick their entire dentition. Upon completion, those incapable of using the device, or those unwilling to do so, were excused from the trial. The remaining subjects were given a full rubber cup dental polishing prior to leaving the clinic, and an appointment for the first visit of the test phase of the trial one week following their

screening visit. They were also reminded to refrain from brushing the night before and the day of that trial visit.

Study Trial Visits

During the first of two study trial periods, subjects were first given an oral soft tissue examination. Once completed, they were administered a plaque disclosing solution and then evaluated for the level of plaque. At least 16 scorable teeth were examined on each subject. Subjects who averaged at least 1.5 on the Modified Turesky Plaque Index continued participation through to the remainder of the trial. Subjects who did not meet the specified plaque criteria were excused from the study. Qualified subjects were allowed to use the test product in front of a typical wall-mounted bathroom mirror until they had completed use of the assigned product throughout their entire mouth. Upon completion of product usage, the subjects returned to the examination room, were re-disclosed, and examined for plaque by the same examiner. This procedure was followed for the second test visit as well.

Subject assignment to one of the two treatments was randomized during the first phase of the study crossover. Subjects were given the alternate treatment for use during the second phase of the trial, one week after the first phase ended. Neither the examiner nor recorders were made aware of the product being used by subjects during either phase of the trial. Product assignment and use was performed in a separate section of the clinical facility. Subjects were provided with written instructions based upon the instructions provided with the product as sold at their point of marketing, and advised to read them thoroughly. A study technician was present to answer questions regarding the instructions. At the second test visit, subjects were provided with the alternate test product.

Blinding of Test Products

Since these two test products differed in appearance, blinding of the identity of the test product to the subjects could not be achieved.

Data Handling

Data were recorded on clinical recording forms and identified by subject number, trial phase, and as either pre- or post-test product usage. Data were transferred to an electronic spreadsheet and sent for statistical analyses. Statistical analyses included an analysis of covariance (ANCOVA), which employed a model consistent with a crossover design with the pre-treatment score employed as the appropriate covariable. Post-test means are reported as adjusted. Assessments for interactions due to sequence order of product presentation to subjects, along with consideration of model fixed effects, including sequence group, treatment, and period and baseline preliminary tests, were also assessed.

Results

The study results are based upon 26 qualified subjects who completed all phases of the crossover design trial. Of the subjects completing the trial, three were male while 23 were female. The average age of the population was 43.58 years, with a range in age from 19 to 64 years (Table I).

Table I
Study Population Demographics

Mean Age/Range	43.58	19–64
Sex (M/F)	Male—3	Female—23

The mean plaque scores before product use (baseline) are found in Table II. There were no significant statistical differences between the two groups on these measures.

Table II
Summary of Pre-Flossing Plaque Index Scores
Combined Period 1 and Period 2 Data
For Subjects Who Completed Both Treatment Periods

Subset	Treatment			
	Test Product		Standard Floss	
	n	Mean ± SD	n	Mean ± SD
Whole-Mouth	26	2.32 ± 0.22	26	2.32 ± 0.23
Interproximal	26	2.37 ± 0.23	26	2.37 ± 0.24
Facial	26	2.45 ± 0.28	26	2.50 ± 0.35
Lingual	26	2.19 ± 0.25	26	2.14 ± 0.20
Anterior	26	2.19 ± 0.25	26	2.21 ± 0.26
Posterior	26	2.42 ± 0.25	26	2.40 ± 0.26
Anterior/Facial	26	2.22 ± 0.32	26	2.32 ± 0.44
Posterior/Facial	26	2.63 ± 0.34	26	2.65 ± 0.38
Anterior/Lingual	26	2.16 ± 0.30	26	2.11 ± 0.17
Posterior/Lingual	26	2.21 ± 0.24	26	2.16 ± 0.26
Posterior/Interproximal	26	2.47 ± 0.26	26	2.46 ± 0.27

Combined results for the mean plaque scores after test product or standard floss use for all subjects from both phases of the crossover can be seen in Table III. Subjects using either the Floss Pick test product or the standard floss product exhibited statistically significant ($p < 0.001$) removal of plaque for whole mouth, based upon comparison of pre-treatment plaque scores versus post-treatment plaque scores. When all scores were combined, subjects using the test product experienced a mean 19.4% reduction in plaque, while the subjects using the standard floss product experienced a 15.0% reduction (Table IV).

The between-treatment comparisons (Table V), performed according to a crossover ANCOVA statistical procedure, compared the test group to the standard floss control. This analysis indicated a statistically significant difference in plaque

Table III
Summary of Post-Flossing Adjusted Plaque Index Scores
Combined Period 1 and Period 2 Data
For Subjects Who Completed Both Treatment Periods

Subset	Treatment			
	Test Product		Standard Floss	
	n	Mean ± SD	n	Mean ± SD
Whole-Mouth	26	1.87 ± 0.28	26	1.97 ± 0.32
Interproximal	26	1.86 ± 0.30	26	1.98 ± 0.33
Facial	26	1.90 ± 0.32	26	2.05 ± 0.41
Lingual	26	1.83 ± 0.29	26	1.90 ± 0.28
Anterior	26	1.75 ± 0.28	26	1.85 ± 0.33
Posterior	26	1.96 ± 0.32	26	2.07 ± 0.34
Anterior/Facial	26	1.66 ± 0.28	26	1.82 ± 0.44
Posterior/Facial	26	2.10 ± 0.40	26	2.23 ± 0.44
Anterior/Lingual	26	1.84 ± 0.35	26	1.87 ± 0.29
Posterior/Lingual	26	1.82 ± 0.29	26	1.91 ± 0.31
Posterior/Interproximal	26	1.94 ± 0.34	26	2.08 ± 0.35

Table IV
Combined Results for Both Crossover Phases
Whole Mouth Plaque

	Floss Pick	Standard Floss
Pre-treatment Plaque Score	2.32	2.32
Post-treatment Plaque Score	1.87	1.97
Percent Plaque Reductions	19.4%	15.0%
Sig. Level	p < 0.0001	p < 0.0001

Table VII
Results for Phase 2 of Crossover
Whole Mouth Plaque

	Floss Pick	Standard Floss
Pre-treatment Plaque Score	2.29 ± 0.29	2.34 ± 0.18
Post-treatment Plaque Score	1.84 ± 0.34	2.12 ± 0.24
Percent Plaque Reductions	19.5%	9.5%
Sig. Level	p < 0.0001	p < 0.0001

Table V
Pre- to Post-Flossing Reductions in Plaque Index Scores and Between-Treatment Comparisons
Combined Period 1 and Period 2 Data For Subjects Who Completed Both Treatment Periods

Subset	Treatment				Comparisons	
	Test Product		Standard Floss		Between-Treatment ¹	Sequence Group ²
	n	Mean ± SD	n	Mean ± SD	p-value	p-value
Whole-Mouth	26	0.45 ± 0.15	26	0.35 ± 0.19	0.0029	0.0553
Interproximal	26	0.52 ± 0.18	26	0.39 ± 0.20	0.0012	0.0641
Facial	26	0.55 ± 0.22	26	0.45 ± 0.26	0.0400	0.1806
Lingual	26	0.36 ± 0.13	26	0.24 ± 0.16	0.0014	0.0099
Anterior	26	0.44 ± 0.16	26	0.36 ± 0.22	0.0339	0.1350
Posterior	26	0.46 ± 0.18	26	0.33 ± 0.17	0.0019	0.0228
Anterior/Facial	26	0.56 ± 0.29	26	0.50 ± 0.32	0.1774	0.2625
Posterior/Facial	26	0.54 ± 0.23	26	0.42 ± 0.22	0.0103	0.0624
Anterior/Lingual	26	0.32 ± 0.13	26	0.23 ± 0.19	0.0061	0.0650
Posterior/Lingual	26	0.39 ± 0.17	26	0.25 ± 0.18	0.0103	0.0095
Posterior/Interproximal	26	0.53 ± 0.21	26	0.38 ± 0.18	0.0008	0.0232

¹p-value from post-ANCOVA t-test.

²p-value from test for sequence effect, employing the subject within sequence MSE as the error term.

reduction on whole mouth assessment favoring the test product ($p = 0.0029$). As part of that analysis, an assessment of sequence effects, based upon the order of presentation of products to the subjects was performed, and also showed a near significance sequence effect in the data from the crossover ($p = 0.0553$). This finding would indicate that the statistically significant difference between treatments might have been affected, in part, by the order in which subjects were given the products.

As a result, a further assessment of the mean plaque reductions for each of the phases of the crossover in this study was performed. As can be seen in Table VI, both products appeared to perform comparably in plaque removal during the first phase of the crossover. However, during the second phase of the crossover (Table VII), the plaque removal results for the two products were largely different, with the test product (Floss Pick) exhibiting significantly greater plaque removal than standard floss.

The percent plaque removal scores from Phase 1 of the study for the various sites in the oral cavity are shown in Table VIII. Both products exhibited comparable interproximal plaque removal, as well as at selected sites in both the anterior and posterior areas.

Table VI
Results for Phase 1 of Crossover
Whole Mouth Plaque

	Floss Pick	Standard Floss
Pre-treatment Plaque Score	2.36 + 0.11	2.30 + 0.27
Post-treatment Plaque Score	1.90 + 0.21	1.84 + 0.33
Percent Plaque Reductions	19.5%	19.8%
Sig. Level	p < 0.0001	p < 0.0001

Table VIII
Percent Plaque Removal
Oral Site Comparison
Phase 1 Crossover

	Floss Pick	Standard Floss
Whole Mouth	19.5%	19.8%
Interproximal	21.4%	21.1%
Anterior	22.1%	22.3%
Posterior	17.7%	17.9%
Posterior/Lingual	15.3%	15.2%
Posterior/Interproximal	19.5%	19.4%

Table IX
Percent Plaque Removal
Oral Site Comparison
Phase 2 Crossover

	Floss Pick	Standard Floss
Whole Mouth	19.5%	9.5%
Interproximal	22.2%	10.9%
Anterior	18.5%	9.9%
Posterior	20.4%	9.1%
Posterior/Lingual	19.3%	7.3%
Posterior/Interproximal	23.0%	10.4%

The percent plaque removal scores from Phase 2 of the study for the various sites in the oral cavity are shown in Table IX. A statistically significant sequence effect was revealed.

Discussion

This study evaluated the plaque removal efficacy of two commercially available dental floss formats. The products were used

according to directions that accompany the products. Twenty-six people participated in this study and used both products in a randomly assigned, crossover manner. The overall results, when both phases of the crossover data were combined, demonstrated that the Mint Floss Pick removed 19.4% of the plaque, while the standard floss removed 15% of the plaque. Both products removed statistically significant amounts of plaque versus pre-treatment levels. The study also found a statistically significant sequence effect in that the plaque removal was somewhat dependent upon whether the subject used standard floss first, or the Mint Floss Pick first.

The order of product use may have played a significant role in the appearance of the reported sequence effect seen in the statistical analysis of the study. Clearly, persons who used the standard floss first and the flosser/pik device second did not exhibit a large difference in their plaque removal performance for either product. However, persons using the flosser/pik first and the standard floss second demonstrated largely diminished plaque removal upon use of the standard floss. Perhaps the motivation for proficient cleaning performance normally exhibited by clinical panelists was somewhat reduced based upon their familiarity with a standard floss product. Conversely, those persons given the flosser/pik second were still enticed enough by the unique nature of the flosser/pik that they continued to use the device proficiently to remove plaque to a level comparable to those that had used the flosser/pik product first. This effect is somewhat similar to the reported Hawthorne Effect of study novelty seen in some clinical trials.⁴⁴⁻⁴⁶ Future research in this area should assess consumer product preferences, which might help to provide an understanding of the motivation provided by the use of this unique cleaning agent. Alternatively, it could be equally true that a product which combines the action of floss along with the pointed mechanical cleaning of a dental pick might also be capable of producing significantly greater plaque removal.

It should be noted that the pre-treatment level of plaque remained consistent for both groups during both phases of the trial. Additionally, the test product (flosser/pik) provided consistent reductions in plaque based upon use (19.5%) during both phases of the trial. However, during the second phase of the crossover, the subjects using the standard floss had a much lower level of plaque removal than that seen for subjects using the standard floss during the first phase of the crossover. Without an understanding of the source of the sequence effects seen in this crossover study, it is difficult to declare superior performance for the test product versus the standard floss control. However, based upon the data, an assessment of non-inferiority was performed to compare the results of the test product versus the standard floss, and the test product was considered "at least as good as" the standard floss for its performance in plaque removal.

Conclusion

The results of this trial demonstrated that both products provide significant reductions in dental plaque when used according to the products' marketed use instructions. Statistical comparisons of the two products confirmed that the test product (Floss Pick) was at least as good as the standard rolled floss control product in cleaning capability when evaluated through assessment of the removal of dental plaque.

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