Efficacy of Two Interdental Cleaning Devices on Clinical Signs of Inflammation: A Four-Week Randomized Controlled Trial

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Abstract

- **Objective:** The purpose of this study was to compare the reduction of the clinical signs of inflammation by two power interdental cleaning devices combined with a manual toothbrush.
- **Methods:** Sixty-nine subjects completed this randomized, four-week, single-blind, two-group, parallel clinical study. Subjects were randomly assigned to one of two treatment groups: Waterpik® Water Flosser (WF) plus a manual toothbrush; or Sonicare® Air Floss Pro (AFP) plus a manual toothbrush. All subjects received both written and verbal instructions and demonstrated proficiency prior to starting the study. Instructions were reviewed at the two-week visit (W2). Data were evaluated for whole mouth, lingual, and facial areas for bleeding on probing (BOP) and Modified Gingival Index (MGI). Plaque data were recorded for whole mouth, lingual, facial, approximal, and marginal areas of the tooth using the Rustogi Modification of the Navy Plaque Index (RMNPI). BOP, MGI, and RMNPI were scored at baseline (BSL), two weeks, and four weeks (W4).
- **Results:** Both groups showed significant reductions in BOP and MGI from baseline for all regions and time points measured ($p < 0.001$). Both groups showed significant reductions from baseline for all areas at W4 for RMNPI ($p < 0.001$). The WF group was significantly more effective than the AFP group at reducing bleeding and gingivitis for all areas measured at all time points. At W4, the WF group was 54% more effective for bleeding and 32% for gingivitis ($p < 0.001$). Plaque accumulation was significantly less at W4 for the WF group compared to the AFP group (28%, $p = 0.017$).
- **Conclusions:** The Waterpik Water Flosser is significantly more effective than the Sonicare Air Floss Pro for reducing clinical signs of inflammation.

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Introduction

The toothbrush is designed to remove plaque from the facial, lingual, and occlusal tooth surfaces. It is widely used for daily oral hygiene, but the majority of individuals do not use it thoroughly or effectively to remove plaque.[1] The toothbrush is not designed to reach the proximal surfaces of teeth or the interdental area between the papilla and the tooth surface. Daily cleaning of the interdental area and proximal tooth surfaces requires a device that can penetrate between adjacent teeth. String floss is the most commonly recommended device, but research shows that adults and adolescents do not floss regularly and most people do so infrequently or not at all.[2,3] Evidence contradicts the regular recommendation of string floss as an effective device; lack of efficacy for plaque removal or reducing gingivitis when compared to brushing alone.[4,5] Individuals understand the importance of interdental cleaning but don't always feel confident using string floss and prefer devices that are easy to use. If given a choice, they will readily choose other devices over traditional floss.[6-8]

Dental professionals want to recommend devices that are easy, safe, and effective for individual needs and that foster compliance. The Water Flosser (WF) has been compared to traditional floss in clinical trials. Barnes, *et al.* found the WF plus manual brushing had a 50% greater reduction in gingivitis compared to manual brushing and flossing.[9] Rosema, *et al*. demonstrated twice the reduction in bleeding for the WF compared to flossing in two weeks. At four weeks, the flossing group showed no difference from baseline, but the WF group continued to show significant reduction in bleeding.[10]

The Water Flosser (Model WP-100) has also been compared to the Sonicare® Air Floss (Model HX-8181) in a single-use plaque removal study. The Water Flosser plus a manual toothbrush was significantly more effective than a manual toothbrush plus the Air Floss for supragingival plaque removal.[11] A follow-up study evaluated the reduction of gingivitis over four weeks and demonstrated that the Water Flosser plus manual toothbrush was 80% more effective at reducing gingivitis than a manual toothbrush plus Air Floss.[12]

A new Air Floss device was introduced recently with some modifications in the design. This study was designed to compare the Waterpik® Water Flosser (Model WP-100) plus manual toothbrush

to the Sonicare® Air Floss Pro (Model HX-8341) on reducing the clinical signs of inflammation.

Materials and Methods

Subjects

Seventy healthy, non-smoking male and female adults between the ages of 25 and 70 years were recruited for this clinical trial (Table I). Subjects who met the inclusion criteria of a minimum score of

Table I
Subject Demographic Data

	Group 1: MTB + WF N=35	Group 2: MTB + AFP N=35	p-value
Age (Years)			0.351
Mean	45.7	48.6	
SD	9.12	9.51	
SEM	1.54	1.61	
Range	26-67	25-67	
Gender			0.606
Male	9 (25.7%)	13 (37.1%)	
Female	26 (74.3%)	22 (62.9%)	
Smoking	0 (100%)	0 (100%)	

1.75 for the Modified Gingival Index (MGI), 50% bleeding on probing sites (BOP), and a score of ≥ 0.60 for the Rustogi Modified Navy Plaque Index (RMNPI) were enrolled. Additionally, all subjects had at least 20 scoreable teeth excluding third molars, and no oral lesions on the hard or soft tissues. Subjects were excluded if they had advanced periodontal disease, visible caries, probing depths > 5 mm, autoimmune or systemic disease, such as Sjögren's syndrome or diabetes, or taking medications that may impact gingival health. Subjects who were pregnant, nursing, planning on getting pregnant, or had taken antibiotics within six months prior to recruitment were also excluded. None of the subjects had implants, orthodontic appliances, crowns or bridges, or partial dentures.

The study and documents were approved by the institutional review board (institutional ASIRB). All subjects completed a medical history and read and signed a consent form.

Study Devices

The Waterpik Water Flosser (WF; Model WP-100; Water Pik, Inc., Fort Collins, CO, USA) is a power driven device designed for interdental and subgingival cleaning. The device has a reservoir, pressure control, and delivers a pulsating stream of water that is directed at the gingival margin and interproximal areas (Figure 1). The reservoir is calibrated with both milliliters (ml) and ounces, and can be filled with water, mouth rinse, or antimicrobials. There are several tip designs for varying patient needs. In this study, the subjects used the Classic Jet Tip following manufacturer's instructions. This included directing the tip at the gingival margin and following a pattern around the mouth with the pressure setting on medium-high (8) and the reservoir filled with 500 ml of lukewarm water.

Figure 1. *Waterpik Water Flosser.*

The Sonicare Air Floss Pro (AFP; Model HX-8341) is a second generation interdental cleaning device from Philips Healthcare (Bothell, WA, USA). It is a hand-held, rechargeable device that utilizes air under pressure to deliver microdroplets of water and air to the interdental area (Figure 2). This device has a larger reservoir than its predecessor and can also deliver up to three bursts of air and microdroplets with one activation. Subjects followed manufacturer's instructions, including filling the reservoir to capacity with lukewarm water, placing the guiding tip between the teeth from the facial aspect, and activating the device by pushing the activation button at each interproximal space. In this study the device was set to 3, which delivered three bursts to each interproximal area with one push of the button.

Figure 2. *Sonicare Air Floss Pro.*

Study Design

This single-blind, parallel, four-week study included 70 subjects who were randomized into two groups. Group 1 received an ADA reference manual toothbrush (Oral-B® Indicator 35, Procter & Gamble, Cincinnati, OH, USA) and a Waterpik Water Flosser model WP-100. Group 2 received an ADA reference manual toothbrush and a Sonicare Air Floss Pro. All subjects used Crest® Cavity Protection Toothpaste, regular mint flavor (Procter & Gamble, Cincinnati, OH, USA). Data were collected at baseline (BSL), two weeks (W2), and four weeks (W4) for three clinical parameters: BOP, MGI, and RMNPI.

Subjects abstained from all oral hygiene methods for 12–14 hours prior to all appointments. One examiner scored all data at all visits and was blinded to group allocation. Oral exams were assessed at

all time points. Inflammation was assessed by BOP and MGI. Bleeding on probing was scored at six sites on a binary scale as either positive (1) or negative (0). MGI was scored on all teeth from the facial and lingual aspects and scored using a 0–4 scale (Figure 3).[13]

Modified Gingival Index

0 = Absence of inflammation
1 = Mild inflammation; slight change in color, little change in texture of any portion of but not the entire marginal or papillary gingival unit
2 = Mild inflammation; criteria as above but involving the entire marginal or papillary gingival unit
3 = Moderate inflammation; glazing, redness, edema, and/or hypertrophy of the marginal or papillary gingival unit
4 = Severe inflammation; marked redness, edema and/or hypertrophy of the marginal or papillary gingival unit, spontaneous bleeding, congestion, or ulceration

Figure 3. *Criteria for the Modified Gingival Index.*

Subjects rinsed with erythrosine (FD&C #3) disclosing solution (Germiphene Corporation, Brantford, ON, Canada) for one minute and then expectorated. Plaque accumulation was assessed using the RMNPI and divided the tooth into nine sections.[14] Emphasis is placed on the marginal and approximal regions (Figure 4). Whole mouth scores include all sections, marginal scores measure from the free gingival margin and include three areas, and approximal scores are measured on the mesial and distal line angles up to the contact point.

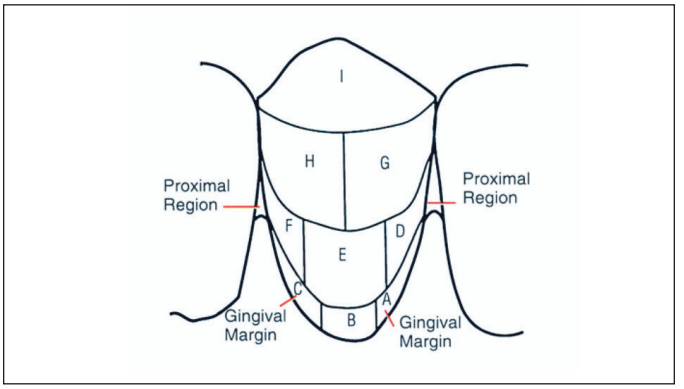

Figure 4. *Rustogi Modification of Navy Plaque Index. Plaque is assessed for each tooth area (A through I) and is scored using the following scale: 0 = absent and 1 = present. Facial and lingual surfaces of all gradable teeth are scored and a mean plaque index (MPI) is calculated for each subject at each examination. Subjects' scores were calculated for the whole mouth (areas A through I), along the gingival margin (areas A through C), and proximal (approximal) (areas D and F).*

At baseline, subjects received their toothbrush with instructions to brush as they normally do for two minutes in the morning and evening. A demonstration and verbal instructions were provided for their assigned device. Subjects were required to demonstrate proficiency with their assigned product during the baseline visit. They used the WF or AFP once a day in the evening only.

Data Analysis

The primary outcome was the reduction in the percentage of sites with bleeding after four weeks. The initial comparison was the mean change among the two groups, utilizing a one-way analysis of variance (ANOVA). The arcsine transformation was used to stabilize the variances of the percentage data (BOP).[15] The transformed data were used in the analysis; however, tables present the mean of observed subject-specific percentages for the groups.

Data were summarized using descriptive statistics (mean, minimum, maximum, and standard deviation) by treatment group and overall. Tables comparing treatment groups provide means, the standard deviation, and the p-value. Analysis for BOP at two weeks and MGI for two and four weeks followed the methods presented above for the four-week BOP analysis.

The secondary outcomes for the assessment of change in plaque accumulation utilized a one-way analysis of variance (ANOVA) separately for two and four weeks' change from baseline. Results for change in the RMNPI are provided for whole mouth, proximal, and marginal regions, as well as facial and lingual surfaces.

Demographic data were also summarized for all subjects enrolled and randomized. Between-treatment comparisons will be made using appropriate methods: t-test for continuous data and Fisher's Exact test for discrete data. Results of oral soft tissue evaluations are reported for baseline, at two weeks, and four weeks.

No statistical adjustments were made for multiple endpoints and multiple testing (multiplicity). The statistical analysis software used was SAS 9.4 for the PC Windows platform.

Data Management

Data were collected on Case Report Forms (CRFs) for each subject. Entries were recorded in black ball-point ink with any transcription or entry errors corrected by the following method; striking a single line through invalid data, initialing, and dating, followed by entry of correct data. CRFs were completed in their entirety and reviewed for completeness and accuracy of all data, then signed by the appropriate individual. The CRFs underwent key batch entry and verification. Data were tabulated according to clinical scoring appropriate for the assessment instrument used.

Results

Sixty-nine subjects completed the study. One subject was dropped from the WF group due to personal reasons. No adverse effects were reported. Baseline comparability was conducted for the evaluable subjects (n = 69). The two treatment regimens were comparable at baseline for bleeding index whole mouth ($p = 0.396$), but differed on facial and lingual scores ($p = 0.023$, $p = 0.004$, respectively). The group using the WF had slightly larger baseline values for facial and lingual bleeding scores. The treatment regimens were also comparable at baseline for MGI whole mouth, and facial scores ($p = 0.434$, $p = 0.354$, respectively). MGI baseline lingual scores were different ($p = 0.045$); again, the group using the WF had a slightly larger baseline value. Plaque biofilm did not differ at pre-treatment. Whole mouth, facial, and lingual pre-treatment plaque scores were not statistically different ($p = 0.338$, $p = 0.051$, and $p = 0.357$, respectively). The baseline plaque scores for the marginal region and proximal region were the same value (*i.e.*, 1) for each subject, indicating no differences at baseline.

Bleeding Index

Both treatment groups showed a significant improvement in BOP from baseline for W2 and W4 for all areas measured ($p < 0.001$). At W2, the WF group was significantly more effective than the AFP group for all areas measured (whole mouth and lingual $p < 0.001$, and facial $p = 0.007$). At W4, the differences increased to where the WF group was more effective than the AFP group by at least 50%

(whole mouth 54%; facial sites 58%; lingual sites 53%; $p < 0.001$, Tables II and III).

Gingival Index

Both treatment groups showed a significant improvement in MGI from baseline for W2 and W4 for all areas measured ($p < 0.001$). At W2, the WF group was significantly more effective than the AFP group for all areas measured (whole mouth $p = 0.003$, facial surfaces $p = 0.41$, lingual surfaces $p = 0.035$). At W4, the WF group was more effective than the AFP group for whole mouth (32%, $p < 0.001$), facial area (31%, $p = 0.004$), and lingual area (33%, $p = 0.012$; Tables II and IV).

Table II
Overall Means and Standard Deviations of Raw Scores for Inflammation Measures and Plaque Index

Group 1 (WF)	MGI Mean (SD)	BOP Mean (SD)	RMNPI Mean (SD)
Baseline (Whole Mouth)	2.2 (0.144)	0.52 (0.045)	0.63 (0.026)
2 weeks	1.9 (0.163)	0.32 (0.045)	0.55 (0.037)
4 weeks	1.8 (0.202)	0.13 (0.041)	0.48 (0.061)
Baseline (Facial)	2.1 (0.130)	0.48 (0.089)	0.62 (0.043)
2 weeks	1.8 (0.141)	0.27 (0.085)	0.53 (0.049)
4 weeks	1.7 (0.169)	0.07 (0.061)	0.45 (0.086)
Baseline (Lingual)	2.3 (0.209)	0.57 (0.104)	0.64 (0.040)
2 weeks	2.0 (0.260)	0.36 (0.104)	0.56 (0.046)
4 weeks	1.9 (0.285)	0.20 (0.066)	0.51 (0.078)
Baseline (Approximal)			1.00 (0.000)
2 weeks			0.82 (0.138)
4 weeks			0.62 (0.140)
Baseline (Marginal)			1.00 (0.000)
2 weeks			1.00 (0.005)
4 weeks			0.94 (0.059)
Group 2 (AFP)	**MGI Mean (SD)**	**BOP Mean (SD)**	**RMNPI Mean (SD)**
Baseline (Whole Mouth)	2.2 (0.136)	0.52 (0.023)	0.64 (0.036)
2 weeks	2.0 (0.134)	0.38 (0.035)	0.58 (0.054)
4 weeks	1.8 (0.148)	0.27 (0.023)	0.52 (0.060)
Baseline (Facial)	2.2 (0.174)	0.53 (0.076)	0.64 (0.054)
2 weeks	2.0 (0.140)	0.37 (0.082)	0.58 (0.065)
4 weeks	1.8 (0.166)	0.24 (0.065)	0.49 (0.069)
Baseline (Lingual)	2.2 (0.142)	0.51 (0.064)	0.63 (0.038)
2 weeks	2.0 (0.170)	0.38 (0.061)	0.58 (0.064)
4 weeks	1.9 (0.189)	0.29 (0.061)	0.54 (0.077)
Baseline (Approximal)			1.00 (0.000)
2 weeks			0.90 (0.111)
4 weeks			0.70 (0.146)
Baseline (Marginal)			1.00 (0.000)
2 weeks			1.00 (0.015)
4 weeks			0.98 (0.034)

Table III
Bleeding on Probing Percent Reductions

	Whole Mouth Mean	Facial Mean	Lingual Mean
Group 1 (WF)			
2 weeks	39.4%	43.4%	36.0%
4 weeks	74.3%	84.8%	65.5%
Group 2 (AFP)			
2 weeks	27.2%	30.2%	24.2%
4 weeks	48.4%	53.7%	42.8%

Plaque Index

Both treatment groups showed a significant improvement in RMNPI from baseline for W2 and W4 for whole mouth, facial, lingual, and approximal areas ($p < 0.001$). Overall, the WF was significantly more effective than the AFP for most areas and surfaces measured. At W4, the WF was 28% more effective than the AFP for whole mouth ($p = 0.017$), 27% for approximal area ($p = 0.002$), 45% for lingual area ($p = 0.009$), and 150% for marginal area ($p = 0.022$; Tables II and V).

Discussion

Tooth brushing alone has been shown to be ineffective in complete plaque removal due to the inability to effectively clean the interproximal and subgingival areas.[16] There is also evidence that shows individuals tend to form habits that consistently miss areas of the teeth regardless of how often they brush.[17] The gold standard for interdental cleaning, primarily in the United States, is dental floss. However, that has been challenged recently by systematic reviews that demonstrated a lack of evidence that daily dental flossing is effective.[4,5] Specifically, a systematic review by Berchier, *et al.* found that the addition of flossing to brushing did not show a benefit in improving gingival health.[4]

Table IV
Gingival Index Percent Reductions

	Whole Mouth Mean	Facial Mean	Lingual Mean
Group 1 (WF)			
2 weeks	11.7%	12.6%	10.8%
4 weeks	18.9%	21.5%	16.6%
Group 2 (AFP)			
2 weeks	8.6%	9.3%	7.8%
4 weeks	14.4%	16.4%	12.5%

Table V
Plaque Index Percent Reductions

	Whole Mouth Mean	Facial Mean	Lingual Mean	Approximal Mean	Marginal Mean
Group 1 (WF)					
2 weeks	13.2%	14.9%	11.7%	18.4%	0.2%
4 weeks	24.0%	27.6%	20.4%	37.7%	6.0%
Group 2 (AFP)					
2 weeks	9.1%	10.2%	7.9%	10.5%	0.4%
4 weeks	18.8%	23.3%	14.1%	29.7%	2.4%

Another long-held assumption by the dental profession is that flossing can reduce interdental caries. A systematic review by Hujoel, *et al*. found no evidence that flossing reduces interdental caries when used by adolescents.[18] Surprisingly, there were no studies on adults related to flossing and caries.

This was followed up by a 2012 review by Sambunjk and colleagues at the Cochrane Group who reported there was some evidence from twelve studies that flossing, in addition to tooth brushing, resulted in less gingival bleeding compared to tooth brushing alone, but no evidence of a benefit on the reduction of plaque.[5] They noted the studies were of poor quality and conclusions must be viewed as unreliable. The team also reported there were no studies that demonstrated a benefit on preventing interproximal caries, confirming the review by Hujoel, *et al.*[18] A

systematic review by Slot, *et al*. evaluated the efficacy of interdental brushes and found improved biofilm removal and gingival health compared to brushing alone or using dental floss.[19] The studies used in this review were on subjects with sufficient space for interdental brushes to penetrate without trauma to the soft tissue. A 2015 review by Chapple, *et al*. reported that interdental devices are effective where there is enough space to pass through the interproximal area without trauma. Otherwise, another interdental device is needed.[20]

The purpose of this study was to compare two interdental cleaning devices, a Water Flosser to a redesigned Air Floss, in reducing the clinical signs of inflammation. A Water Flosser works by the direct application of a pulsated stream of water under pressure, and penetrates the interdental and subgingival areas. Numerous studies published in peer-reviewed journals have demonstrated the efficacy of a Water Flosser in removing plaque, reducing gingivitis, and gingival bleeding compared to routine oral hygiene, including brushing and flossing.[9,10,21-26] The WF has been tested in more than 60 studies and has repeatedly demonstrated it is safe and improves oral health. A literature review on the safety of a Water Flosser reported there is no evidence of adverse events.[27] Findings have shown histological reductions in inflammation, reduction or stability of probing pocket depth, improvement or stability of clinical attachment levels, removal of subgingival bacteria, and improvements in morphological subgingival flora. Clinical trials have been conducted on various patient populations, including those with orthodontic appliances, crowns, bridges, veneers, implants, gingivitis, and individuals living with diabetes or in a periodontal maintenance program demonstrating significant improvements in oral health compared to traditional regimens.[21-28] The Water Flosser has also been compared to string floss in several studies.[9-11,23,26] These studies showed significant reduction in plaque, bleeding, or gingivitis for subjects in fixed orthodontic appliances, with implants and moderate gingivitis compared to brushing and flossing.

A 28-day study reported there were no differences between the Air Floss Pro used with an antimicrobial rinse (Listerine® or BreathRx®) and string floss in plaque accumulation, gingival bleeding, or gingivitis.[29] The poster presentation included four adverse events (gingival irritation) possibly related to study products: one in the manual toothbrush and string floss group and three in the manual toothbrush and AFP groups. A single-use study on plaque removal also found no differences when the Air Floss Pro with water or Listerine antiseptic rinse were compared to string floss.[30] Both of these studies were presented as abstracts during the 2015 IADR Annual Sessions. To date, there are no studies published in peer-reviewed journals on the Sonicare Air Floss or Air Floss Pro.

The Waterpik Water Flosser has demonstrated superior results in reducing clinical signs of inflammation and supragingival plaque removal compared to the Sonicare Air Floss and Air Floss Pro (Table VI).

Table VI
Ratios of Percentage Reduction Between Groups

	Whole Mouth	Facial	Lingual	Approximal	Marginal
Two Weeks					
MGI	1.36	1.35	1.38		
BOP	1.45	1.44	1.49		
RMNPI	1.46	1.45	1.47	1.75	0.52
Four Weeks					
MGI	1.32	1.31	1.33		
BOP	1.54	1.58	1.53		
RMNPI	1.28	1.18	1.45	1.27	2.50

Conclusions

1. The Waterpik Water Flosser is significantly more effective than the Sonicare Air Floss Pro in improving gingival health. Notably, the group utilizing the WF had 31%–33% better reductions in MGI and 53%–58% better reductions in BOP.
2. The WF is significantly more effective than the AFP in reducing plaque, including in hard-to-reach areas of the tooth often missed by brushing. Notably, the WF group was 28% more effective for whole mouth, 27% for the approximal area, 45% for lingual surfaces, and 150% for the marginal area.
3. There were no adverse events reported for either product.

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