# Comparison of Two Power Interdental Cleaning Devices on the Reduction of Gingivitis

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#### Abstract

- **Objective:** The objective of this study was to compare the reduction of gingivitis by two power interdental devices combined with a manual toothbrush.
- Methods: Eighty-two subjects completed this randomized, four-week, single-blind, two-group parallel clinical study. Subjects were randomly assigned to one of two groups: Waterpik<sup>®</sup> Water Flosser (WF) plus manual tooth brushing or Sonicare<sup>®</sup> Air Floss (AF) plus manual tooth brushing. Subjects were provided written and verbal instructions for all products at the baseline visit and instructions were reviewed at the two-week (W2) visit. Data were evaluated for whole mouth, lingual, and facial areas for gingivitis and bleeding on probing. Plaque data were evaluated for whole mouth, lingual, facial, approximal, and marginal areas of the tooth. Gingivitis, bleeding on probing, and plaque were scored at baseline (BSL), two weeks, and four weeks (W4).
- **Results:** Both groups showed significant reductions in gingivitis, bleeding on probing, and plaque from baseline for all regions and time points measured (p < 0.001). The WF group was significantly more effective than the AF group at reducing plaque and gingivitis at W2 and W4 for all areas measured (p < 0.001). At W4, the WF group was 80% more effective than AF for whole mouth gingivitis reduction, and twice as effective for the lingual region. In terms of plaque removal at W4, the WF group was 70% more effective for whole mouth (50.9% vs. 30%), 60% for approximal area (76.7% vs. 48%), and 47% for facial (52.8% vs. 35.9%) surfaces. The WF was twice as effective for lingual areas and more than three times as effective for marginal areas vs. the AF group (p < 0.001). Results for bleeding on probing showed the WF group was numerically better than the AF group for all areas and time points, with these improvements being statistically significance for whole mouth (p = 0.02) and facial area (p = 0.004) at W2, and for the facial area (p = 0.02) at W4.
- Conclusion: The Waterpik Water Flosser is significantly more effective than Sonicare Air Floss for reducing gingivitis and plaque.

#### (J Clin Dent 2012;23:22-26)

### Introduction

It is well established that periodontitis is an infectious disease caused by bacteria and mediated by the host response, habitual behavior, and/or systemic risk factors, *i.e.*, smoking and diabetes.<sup>1-3</sup> Daily removal or disruption of dental plaque, or biofilm, is important for improving gingival health.<sup>4</sup> Tooth brushing can remove supragingival plaque from tooth surfaces, but it has been shown that patients often leave areas of plaque behind.<sup>5</sup> A systematic review reported the mean reduction of plaque from a single brushing is 43%, with a range of 28–53%.<sup>6</sup>

Most individuals brush their teeth once or twice a day, and brushing more than twice a day has not shown incremental improvement in gingival health.<sup>7</sup> Studies report brushing results in insufficient plaque removal to prevent gingivitis and periodontitis.<sup>8</sup> Consequently, an additional device is needed to clean areas not accessible or missed by brushing, *i.e.*, proximal surfaces of teeth, interdental and subgingival areas, and supragingival areas where plaque has been left behind by brushing. There are several manual products on the market, such as dental floss, interdental brushes, and wood sticks, that are designed to clean one or more of these areas not cleaned by brushing. Recently, the focus has shifted to power products designed to supplement brushing. This study compared the effect of two power products designed to clean interdentally plus a manual toothbrush on improving gingivitis.

## **Materials and Methods**

# Subjects

Eighty-two healthy, non-smoking male and female adults between the ages of 25 and 65 (Table I) were recruited for this

Table I   Demographic Data				
	Group I: WF n = 41	Group II: AF n = 41	p-value	
Age (years)			0.649	
Mean	45.7	44.8		
SD	9.79	9.05		
SEM	1.53	1.41		
Range	26-63	27-63		
Gender			0.602	
Male	8 (19.5%)	11 (26.8%)		
Female	33 (80.5%)	30 (73.2%)		
Smoking	0 (100%)	0 (100%)		

SD = Standard Deviation, SEM = Standard Error of the Mean. p-value for age from a t-test; p-value for gender from a Fisher's Exact test. study. Subjects enrolled met the inclusion criteria of a minimum of 1.75 for Modified Gingival Index (MGI), 50% bleeding on probing (BOP), and  $\geq$  0.60 for a Rustogi Modified Navy Plaque Index (RMNPI) score. All subjects had at least 20 scoreable teeth not including third molars, and no hard or soft tissue lesions. Exclusion criteria included advanced periodontal disease, probing depth greater than 5 mm, systemic disease such as diabetes or autoimmune disease, medication use that can influence gingival health, pregnant at the time of the study, or use of antibiotics within six months of this study. Subjects with orthodontic appliances, implants, crowns, bridges, or other appliances were not included. The study protocol and forms were approved by the institutional review board (Institutional BRCL). Subjects completed a medical history and read and signed a consent form.

#### Study Devices

The Waterpik<sup>®</sup> Water Flosser (WF; Water Pik, Inc., Fort Collins, CO, USA) is a power-driven device that has a reservoir, pressure control, and delivers a pulsating stream of water that is directed at the gingival margin and interproximal areas (Figure 1A). The reservoir holds enough water to clean the whole mouth from the facial and lingual surfaces. Subjects followed manufacturer's instructions, using a Classic Jet Tip directed at the gingival margin and following a pattern around the mouth, a medium-high pressure setting, and the reservoir filled with 500 ml of lukewarm water.

The Sonicare<sup>®</sup> Air Floss (AF; Philips Healthcare, Bothell, WA, USA) is a hand-held rechargeable device that utilizes air under pressure to deliver microdroplets of water and air to the interdental area (Figure 1B). The small reservoir holds two teaspoons of water. Subjects filled the reservoir to capacity with lukewarm water and followed manufacturer's instructions, placing the guiding tip between the teeth from the facial aspect and activating the device by pushing the activation button at each interproximal space.

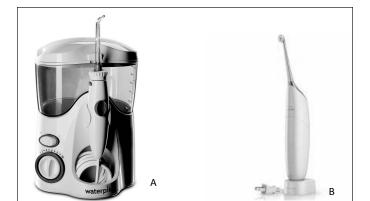


Figure 1. Products used in study. A. Water Flosser (Water Pik, Inc.). B. Air Floss (Philips Healthcare).

#### Study Design

This randomized, single-blind, four-week, two-group parallel clinical trial evaluated improvements in gingivitis with a toothbrush used with either a WF or an AF. Subjects were randomly assigned to one of two groups: Group I received an ADA standard manual toothbrush (Oral-B<sup>®</sup> Indicator 35, Procter & Gamble, Cincinnati, OH, USA) and a Waterpik Water Flosser model WP-100; Group II received the same manual toothbrush and a Sonicare Air Floss. Both groups used Crest<sup>®</sup> Cavity Protection Toothpaste, regular mint favor (Procter & Gamble, Cincinnati, OH, USA). Data were collected at baseline (BL), two weeks (W2), and four weeks (W4) for MGI, RMNPI, and BOP.

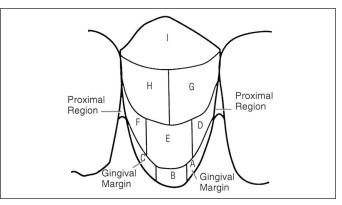
Subjects abstained from using their oral hygiene devices for 12–14 hours prior to their appointment. Oral soft and hard tissue assessments were done at BL, W2, and W4 time points. One examiner, who was blinded to the products assigned, scored all subjects at all time points. The MGI<sup>9</sup> was used to assess gingivitis around all natural teeth from the facial and lingual aspects, and scored using a 0–4 scale (Figure 2). Bleeding on probing was recorded on a binary scale as either positive (1) or negative (0).

#### Modified Gingival Index<sup>9</sup>

- 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 2. Criteria for the Modified Gingival Index.

The RMNPI<sup>10</sup> evaluates plaque reduction and divides the tooth into nine sections, emphasizing the marginal and approximal regions (Figure 3). Whole mouth scores include all nine sections, marginal scores follow the free gingival margin and include three areas, and approximal scores are based on the mesial and distal line angles up to the contact point. Subjects received their toothbrushes and were instructed to use the brush with the Bass technique for two minutes. Subjects then used their assigned interdental device prior to brushing as demonstrated following manufacturer's instructions.



**Figure 3.** Rustogi Modification of the 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 gradient 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).

#### Data Analysis

Data were collected on Case Report Forms (CRFs) for each subject. CRFs were completed in entirety, reviewed for completeness and accuracy, and signed by the appropriate individual. The CRFs underwent key batch entry and verification. Data were tabulated according to clinical scoring appropriate for MGI, BOP for whole mouth, facial, and lingual regions. The RMNPI was tabulated for whole mouth, marginal, approximal, facial, and lingual regions. Data were summarized using descriptive statistics (mean, minimum, maximum, standard error, and standard deviation) by treatment group. The baseline scores were evaluated separately for each treatment utilizing a paired t-test. Betweentreatment comparisons were evaluated using a two-independent groups t-test. All statistical tests were conducted using a significance level of  $\alpha = 0.05$ .

#### Results

All subjects completed the study and no adverse events were reported. Baseline comparability was assessed for MGI, BOP, and RMNPI, and did not differ for any of the measurements evaluated.

#### **Gingival Index**

Both groups showed a significant improvement in MGI from baseline at W2 and W4 for whole mouth, facial, and lingual scores. The WF was consistently significantly more effective at reducing gingivitis than the AF for all areas at both time points (p < 0.001). The WF reduced whole mouth scores at W4 by 41.2%, facial scores by 43.9%, and lingual scores by 39.4% compared to AF at 22.8%, 26.6%, and 19.1%, respectively. The WF was 80% more effective than AF for whole mouth, 65% more effective for facial surfaces, and two times as effective for lingual surfaces at W4 (Tables II and III, Figure 4).

#### **Bleeding Index**

Both treatment groups showed a significant reduction in bleeding on probing from baseline for whole mouth, facial, and lingual scores at W2 and W4 (p < 0.001). The WF was significantly better than the AF at W2 for whole mouth (p = 0.02) and facial surfaces (p = 0.004), and numerically higher for lingual surfaces. At W4, the WF had significantly better reductions than AF for facial surfaces (p = 0.02), and was numerically better for whole mouth and lingual surfaces (Tables II and IV).

#### **Plaque Index**

Both groups showed statistically significant changes from baseline to W2 and W4 for all areas measured (p < 0.001); whole mouth, approximal, marginal, facial, and lingual. The WF was consistently significantly more effective at removing plaque than the AF for all areas at both time points (p < 0.001). At W4, the WF removed 50.9% vs. 30% for AF of whole mouth plaque, 25% vs. 7.5% at the marginal area, 76.7% vs.48% at the approximal area, 52.8% vs. 35.9% on the facial surfaces, and 49% vs. 23.8% on the lingual surfaces. The WF differences ranged from one and a half times (facial) to more than three times (marginal) more effective than the AF for reducing plaque at W4 (Tables II and V, Figure 5).

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

Group I (WE)	Gingival Index Mean (SD)	Bleeding Index Mean (SD)	Plaque Index Mean (SD)
Group I (WF)	. ,		
Baseline (whole mouth)	2.01 (0.057)	66.3 (8.59)	0.62 (0.019)
14 Days	1.46 (0.175)*	12.8 (5.23) ‡	0.48 (0.085)*
28 Days	1.18 (0.182)*	4.4 (1.53)	0.30 (0.113)*
Baseline (facial)	2.02 (0.091)	68.7 (9.14)	0.63 (0.039)
14 Days	1.35 (0.222)*	10.9 (6.11)†	0.47 (0.103)*
28 Days	1.13 (0.201)*	3.8 (2.12) <sup>‡</sup>	0.30 (0.130)*
Baseline (lingual)	1.99 (0.051)	63.9 (11.55)	0.60 (0.028)
14 Days	1.56 (0.170)*	14.8 (5.36)	0.48 (0.085)*
28 Days	1.23 (0.197)*	5.0 (2.00)	0.31 (0.120)*
Baseline (approximal)			1.00 (0.000)
14 Days			0.62 (0.268)*
28 Days			0.23 (0.228)*
Baseline (marginal)			1.00 (0.000)
14 Days			0.97 (0.052)*
28 Days			0.75 (0.197)*
Group 2 (AF)			
Baseline (whole mouth)	2.00 (0.063)	65.7 (9.23)	0.62 (0.021)
14 Days	1.69 (0.196)*	18.2 (8.94) <sup>‡</sup>	0.54 (0.053)*
28 Days	1.54 (0.220)*	6.8 (2.07)	0.43 (0.088)*
Baseline (facial)	2.02 (0.088)	66.3 (11.47)	0.63 (0.041)
14 Days	1.63 (0.232)*	17.0 (8.97) <sup>†</sup>	0.54 (0.074)*
28 Days	1.48 (0.231)*	6.8 (2.47)‡	0.41 (0.132)*
Baseline (lingual)	1.99 (0.058)	65.0 (10.28)	0.61 (0.027)
14 Day	1.61 (0.230)*	19.5 (9.98)	0.54 (0.061)*
28 Days	1.76 (0.190)*	6.7 (2.62)	0.46 (0.079)*
Baseline (approximal)			1.00 (0.000)
14 Days			0.84 (0.165)*
28 Days			0.52 (0.231)*
Baseline (marginal)			1.00 (0.000)
14 Days			1.00 (0.008)*

Change from baseline p < 0.001 for both groups for all endpoints.

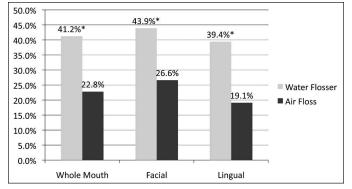
\*WF was statistically significantly better than AF (p < 0.001).

<sup> $\dagger$ </sup> WF was statistically significantly better than AF (p = 0.004).

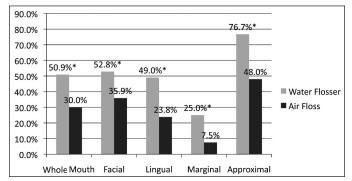
<sup> $\ddagger$ </sup> WF was statistically significantly better than AF (p = 0.02).

Table III	
Gingival Index Percent Reductions	

	Whole Mouth Mean	Facial Mean	Lingual Mean
Group I (WF)			
Day 14	27.4	32.9	21.9
Day 28	41.2	43.9	39.4
Group II (AF)			
14 Day	15.3	19.0	11.5
28 Day	22.8	26.6	19.1



**Figure 4.** Mean percent reduction in MGI at 4 weeks.\*Significant difference (p < 0.001).



**Figure 5.** Mean percent reduction in Plaque Index (RMNPI) at 4 weeks. \*Significant difference (p < 0.001).

Table IV

	Whole Mouth Mean	Facial Mean	Lingual Mean
Group I (WF)			
Day 14	80.6	84.1	76.9
Day 28	93.4	94.5	92.2
Group II (AF)			
14 Day	72.2	74.4	70.0
28 Day	89.7	89.7	89.6

Table V					
Dlagua	Inday	Doroont	Deductions		

Plaque Index Percent Reductions					
	Whole Mouth Mean	Facial Mean	Lingual Mean	Approximal Mean	Marginal Mean
Group I ( Day 14 Day 28	WF) 23.2 50.9	25.7 52.8	20.7 49.0	38.2 76.7	2.9 25.0
Group II ( 14 Day 28 Day	(AF) 12.2 30.0	14.2 35.9	10.2 23.8	16.5 48.0	0.2 7.5

Table VI
Ratios of Percentage Reduction Between Groups

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14 Days	Whole Mouth	Facial	Lingual	Approximal	Marginal
MGI	1.80	1.73	1.91		
BOP	1.12	1.13	1.10		
RMNPI	1.90	2.02	1.81	2.32	11.89
28 Days					
MGI	1.80	1.65	2.01		
BOP	1.04	1.05	1.03		
RMNPI	1.70	1.47	2.06	1.60	3.33

#### Discussion

Tooth brushing needs to be supplemented by a device that can clean the interdental and subgingival areas. Traditionally, dental floss has been the most recommended device for this purpose, but recent systematic reviews have challenged the assumptions held by the dental profession for decades; namely, that floss can reduce interdental caries and is better at removing plaque and reducing gingivitis than brushing alone. Specifically, a review by Berchier, et al. found that the addition of flossing to brushing did not show a benefit in improving gingival health, while Hujoel, et al. found no evidence that flossing reduces interdental caries when used by adolescents.<sup>11,12</sup> The authors reported they did not find any study with adults on interproximal caries reduction and flossing. A systematic review with interdental brushes had a different result with improved biofilm removal and gingival health when compared to brushing alone or other interdental devices.<sup>13</sup> Wood sticks did not show an additional benefit when added to brushing for improved gingival health.<sup>14</sup>

The removal of plaque from the teeth and surrounding areas is important in preventing the initiation and proliferation of subgingival pathogenic bacteria and gingivitis.<sup>15,16</sup> The purpose of this study was to compare a water flosser to an air flosser in reducing gingivitis. The WF, also known as an oral irrigator or dental water jet, works through the direct application of a pulsated stream of water or other solution under pressure, and penetrates the interdental and subgingival area. It has been shown to significantly reduce gingivitis compared to routine oral hygiene, including brushing and flossing. The WF has been tested in more than 50 studies and has repeatedly demonstrated it is safe and improves oral health. It was recently evaluated in a systematic review that found it improved gingival health better than brushing alone.<sup>17-32</sup> Clinical trials with orthodontic appliances, crowns, bridges, implants, and cohorts of individuals living with diabetes or in periodontal maintenance showed superior benefits compared to traditional oral hygiene.18,20-22,24-26,28,29,31 Most recently, a WF has shown superior results for the reduction of gingivitis, bleeding, and plaque compared to tooth brushing and string flossing in three separate trials.<sup>19,31,32</sup>

The AF is new to the market and designed to deliver microdroplets of water and air under pressure directly to the interdental area via a hand-held rechargeable device. To date, there are no full studies published in peer-reviewed journals on the efficacy of the AF in reducing clinical parameters or how it performs in comparison to dental floss or other interdental aids. An abstract was published recently that reported the results of a study that compared an AF plus manual brushing to brushing alone on the removal of interdental plaque as measured by the reduction of proteins, MGI, and Gingival Bleeding Index.<sup>33</sup> It reported that the addition of an AF to manual brushing was more effective for all measurements, but did not include any numerical data. Publication in a peer-reviewed journal will provide information that is missing from the abstract.

This study compared the WF to the AF for reduction in gingivitis, and also reported bleeding on probing and plaque data. The WF reduced gingivitis significantly better than the AF for all areas and regions measured, ranging from 65–100% better reductions (Table VI). It was also significantly better at reducing plaque accumulation in two weeks and four weeks, and removing plaque as reported in a previous single-use study.<sup>34</sup> The WF was also better at reducing significantly more plaque from areas often missed during tooth brushing, *i.e.*, marginal, lingual, and approximal regions.

#### Conclusions

- 1. The Waterpik Water Flosser paired with a manual toothbrush is significantly better than the Sonicare Air Floss in improving gingival health. Notably, the group utilizing the WF had 65–100% better reductions in gingivitis scores.
- The WF is significantly better than the AF in reducing plaque, including in hard-to-reach areas of the tooth often missed by brushing.
- 3. Both the WF and AF are safe to use.

Acknowledgment: The authors would like to thank the entire staff at BioSci Research Canada, Ltd. for their support, input, expertise, and professionalism on this study. This study was supported by a research grant from Water Pik, Inc., Fort Collins, Colorado.

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