A direct comparison of two interdental cleaning devices on clinical signs of inflammation: a four-week randomised controlled trial

C Ram Goyal[1], J Qaqish[1], R Schuller[2], DM Lyle[3]

Key words: water flosser, air floss, inflammation, Waterpik, Sonicare, plaque, gingivitis

ABSTRACT

Objective: To compare the effectiveness of the water flosser to the air floss pro in reducing clinical signs of inflammation.

Method: Seventy subjects were randomised equally into two groups in this examiner-masked, parallel clinical trial: manual toothbrush and water flosser (WF) or manual toothbrush and air floss pro (AFP). Clinical signs of inflammation were measured by bleeding on probing (BOP) and the Modified Gingival Index (MGI) at baseline, 2-weeks and 4-weeks. Plaque was measured using the Rustogi Modified Navy Plaque Index (RMNPI) at baseline, 2-weeks and 4-weeks. A one-way analysis of variance was used for changes in mean scores between treatment groups.

Results: Seventy subjects completed the study. Both groups showed a significant reduction in BOP, MGI and RMNPI at 2- and 4-weeks ($p<0.001$). The WF group was 57% ($p<0.001$) more effective than the AFP group at reducing BOP, 60% ($p<0.001$) at reducing MGI, and 31% ($p=0.008$) for reducing plaque scores at 4-weeks.

Conclusion: This study demonstrates that the water flosser and manual toothbrush were significantly more effective than the air floss pro and manual toothbrush in the reduction of clinical signs of inflammation and plaque.

Introduction

Toothbrushes are primarily designed to remove plaque from the surfaces of the teeth visible in the oral cavity.[1] However, they are limited in their ability to reach interdentally and subgingivally where periodontal disease primarily starts.[2] Thus another device is needed to complement the toothbrush that is designed to clean the interdental area and proximal surface of the teeth.

For decades, brushing and flossing was the standard of care and recommended for all patients as the first line of defence in preventing gingivitis. Dental professionals have known for years that patients do not like to floss, do not feel comfortable with their abilities, or simply lie about their behaviour, even though it is obvious by the condition of their oral health.[3,4] If given a choice, patients will readily choose other devices over dental floss.[5]

Dental professionals want to recommend devices that are effective, easy to use, and foster adherence to oral care recommendations. Dental floss is no longer the standard of care for interdental cleaning based on clinical evidence. Systematic reviews have shown a lack of quality research on the effectiveness of dental floss and surveys have demonstrated that many people do not comply.[6,7,8] A 2008 systematic review found that the majority of the 11 studies included did not show a benefit for brushing and flossing on plaque and clinical parameters of gingivitis, compared to brushing alone.[6] This led the researchers to conclude there is a lack of evidence to support the routine recommendation of floss for interdental cleaning. Subsequently, a 2012 systematic review included 12 studies and reported there was some weak and unreliable evidence that adding tooth brushing to dental flossing, compared to brushing alone, reduced gingivitis and had better plaque reductions.[7]

A water flosser (WF) has been compared to dental floss in several clinical trials. Barnes *et al.* (2005) found a manual toothbrush and a WF had a 50% greater reduction in gingivitis compared to a manual brush and dental floss.[9] Rosema *et al.* (2011), reported twice the reduction in bleeding for the WF compared to dental floss in two weeks.[10] Notably, the WF continued to show improvements at four weeks but the dental floss reverted back to baseline scores. Magnuson *et al* (2013) demonstrated a 145% better reduction in bleeding around implants with a WF compared to dental floss and Sharma *et al* (2008) reported a 26% better reduction for adolescents in fixed orthodontic appliances.[11, 12]

An air floss device has also been compared to dental floss. As reported in a poster presentation in 2016, a 28-day study showed there were no differences between the air floss pro used with an antimicrobial (Listerine® or BreathRx®) and dental floss in plaque accumulation, gingival bleeding or gingivitis when paired with a manual toothbrush.[13] A single-use study poster presentation (2015) showed no differences in plaque removal between the air floss pro with water or Listerine® antiseptic, compared to dental floss when paired with a manual toothbrush.[14] To date, there are no studies published in peer-reviewed journals on the Sonicare® Air Floss or Air Floss Pro.

This study was designed to compare the effectiveness of the Waterpik® Water Flosser to the Sonicare® Air Floss Pro on reducing clinical signs of inflammation.

Methods and materials

Subjects

Seventy healthy, non-smoking subjects were enrolled in this study who met the inclusion and exclusion criteria (Table 1). Both male and female subjects were enrolled with no consideration of race or ethnicity. Study demographics are shown in Table 2. The study and documents were approved by All Sum Institutional Review Board (ASIRB). All subjects read and signed a consent form and completed a medical history.

Study devices

This study compared two electric interdental cleaning devices that are currently on the market. The Waterpik® Water Flosser (WF; model WP-120, two pin plug; Waterpik International Inc., Reigate, Surrey, UK) is a power driven device that produces a pulsating stream of water under pressure. The tip is directed at the gingival margin and interdental areas and the pulsating water produces a compression and decompression phase at the gingival margin, which allows for expeditious removal of dental bacteria and debris interdentally and subgingivally (Figure 1). The water or other solution is placed in a reservoir calibrated with both millilitres (ml) and ounces. In this study the subjects in Group 1 used warm water and the Classic jet tip (Figure 2). The subjects used manufacturer's instruction following a pattern around the mouth with the pressure setting on medium-high (setting #8) and the reservoir filled with 500 ml of warm water.

Group 2 was provided the Sonicare® Air Floss Pro (AFP; model HX8340, two pin plug; Royal Philips, Amsterdam, NL). The AFP is a hand-held device that utilises air under pressure targeting the interproximal area (Figure 3). The device can be set on either 1, 2 or 3 puffs of air. There is a small reservoir that holds enough water or other agent for one or two uses and provides micro droplets with the puff(s) of air when the activation button is pressed. In this study, the subjects used warm water in the reservoir and set the handle on 3, providing three consecutive puffs of air with one activation. The subjects used manufacturer's instructions for usage of the device.

Inclusion
• Between 25 and 75 years of age
• Able to provide written informed consent prior to participation
• Agree to not participate in any other oral/dental products clinical study for the study duration
• In good general health
• Non-smoker
• Have 50% bleeding on probing sites
• Have no probing depths greater than 5 mm
• Have a minimum of 20 scoreable teeth (not including 3rd molars)
• No partial dentures, orthodontic brackets, wires or other appliances
• Agree to refrain from the use of any non-study dental device or oral care product for the study duration
• Agree to return for the scheduled visits and follow study protocol
• Agree to delay dental prophylaxis until study completion
• Have a minimum pre-brushing plaque score of 0.6
• Have a minimum of 1.75 gingivitis score
Exclusion
• Have probing depth greater than 5 mm
• Have a systemic or autoimmune disease (ex. Diabetes, Sjogren's syndrome)
• Have advanced periodontitis
• Taking medication that can influence gingival health (ex. Dialantin, calcium channel blockers, Cyclosporine, anticoagulants)
• Have orthodontic appliances or removable partial dentures
• Pregnant at time of study
• Use of antibiotics within 6 months of study

Table 1: Inclusion and Exclusion Criteria

	Group 1: WF (N=35)	Group 2: AFP (N=35)	Overall (N=70)	p-value**
Age (years)				0.4540
N	35	35	70	
Mean	46.9	50.0	48.4	
Standard Deviation	9.89	7.27	8.75	
Standard Error	1.67	1.23	1.05	
Minimum	25.0	33.0	25.0	
Maximum	64.0	64.0	64.0	
Gender				0.7280
Male	11 (31.4%)	8 (22.9%)	19 (27.1%)	
Female	24 (68.6%)	27 (77.1%)	51 (72.9%)	
Smoke				
No	35 (100.0%)	35 (100.0%)	70 (100.0%)	

* P-values: Age = Wilcoxon rank-sum, Gender = Fisher's Exact Test

Table 2: Subject Demographic Data

Figure 1: Waterpik® Water Flosser (WP-120)

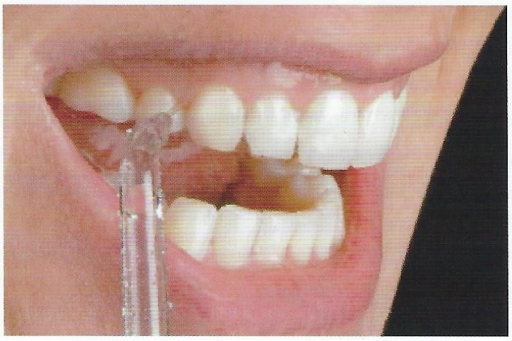

Figure 2: Classic Jet Tip placed at the interproximal space

Figure 3: Sonicare Air Floss Pro (HX8340)

Study design

This is a single centre, examiner masked, parallel, randomised controlled trial. A computer-generated randomisation schedule was prepared by the study statistician. Based on the randomisation schedule, patients were randomly assigned in a 1:1 ratio to one of the two treatment groups.

Subjects in both groups received a standard manual toothbrush (Oral-B® Indicator 35, Procter & Gamble, Cincinnati, OH, USA) and Crest® Cavity Protection Toothpaste, regular mint flavour (Procter & Gamble, Cincinnati, OH, USA). Data were recorded at baseline (BSL), two weeks (W2), and four weeks (W4) for the three clinical parameters: Bleeding on Probing (BOP), Modified Gingival Index (MGI)[15], and Rustogi Modification of the Navy Plaque Index (RMNPI).[16] Oral examination of hard and soft tissue was assessed at all visits and recorded.

Subjects abstained from all oral hygiene methods for 12 – 14 hours prior to all appointments scheduled. One examiner scored all data at all visits and was masked to group allocation. The primary objective was to determine the effectiveness of a WF in reducing clinical signs of inflammation as compared to the AFP at W4. The secondary objective was to determine the effectiveness of a WF in reducing plaque as compared to the AFP at W4.

Inflammation was assessed by BOP and MGI. Bleeding was scored at six sites per tooth on a binary scale as either positive (1) or negative (0). MGI was scored on all teeth on the facial and lingual sides of the tooth and scored using a 0 – 4 scale (Figure 4).

Modified Gingival Index

0 = Absence of inflammation

1 = Mild inflammation; slight change in colour, 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 unit

3 = Moderate inflammation; glasing, redness, oedema, and/or hypertrophy of the marginal or papillary gingival unit

4 = Severe inflammation; marked redness, oedema, and/or hypertrophy of the marginal or papillary gingival unit, spontaneous bleeding, congestion, or ulceration.

Figure 4

Subjects first swished with 2.5 ml erythrosine (FD&C #3) disclosing solution (Germiphene Corporation, Brantford, ON, Canada) for 15 seconds followed by rinsing with 10 ml water for 10 seconds, and then expectorated. Plaque was assessed using the RMNPI. The tooth surface (facial/lingual) was divided into 9 segments (Figure 5).

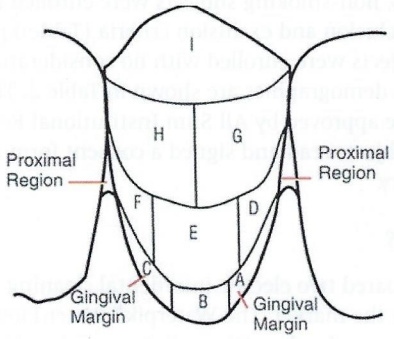

Figure 5: Rustogi Modification of the Navy Plaque Index. Plaque is assessed for each tooth area (A through I) and is scored using the following scale: 0 – absent, and 1 = present. Facial and lingual surfaces of all gradable teeth are scored and a mean plaque index (MPI) is calculated for each subject at each examination. Subjects' scores were calculated for whole mouth (areas A through I), along the gingival margin (areas A through C), and proximal (approximal) (areas D and F).

All subjects brushed their teeth as they normally do once in the morning and once in the evening. They used their interdental device once a day in the evening following tooth brushing. Verbal and written instructions for the WF or the AFP were provided to the subjects appropriate to their allocation.

Statistical analysis

The primary outcome was the reduction in the percentage of sites with bleeding on probing (BOP) after four weeks. The initial

Group 1 (WF)	BOP Mean	SD	MGI Mean	SD	RMNPI Mean	SD
Baseline (Whole Mouth)	0.55	0.043	2.15	0.114	0.64	0.036
2 weeks	0.31	0.075	1.86	0.177	0.53	0.062
4 weeks	0.13	0.064	1.68	0.196	0.47	0.081
Baseline (Proximal)	0.65	0.044	2.16	0.122	1.00	0.000
2 weeks	0.36	0.093	1.9	0.177	0.79	0.149
4 weeks	0.16	0.081	1.75	0.199	0.63	0.239
Baseline (Marginal)	0.34	0.078	2.13	0.104	1.00	0.000
2 weeks	0.2	0.07	1.77	0.185	0.97	0.028
4 weeks	0.08	0.042	1.53	0.205	0.95	0.039
Baseline (Proximal Facial)	0.59	0.094	2.07	0.103		
2 weeks	0.26	0.117	1.83	0.178		
4 weeks	0.07	0.097	1.66	0.211		
Baseline (Proximal Lingual)	0.71	0.115	2.25	0.163		
2 weeks	0.45	0.124	1.97	0.221		
4 weeks	0.24	0.103	1.85	0.216		
Baseline (Marginal Facial)	0.28	0.071	2.03	0.089		
2 weeks	0.12	0.071	1.67	0.199		
4 weeks	0.02	0.04	1.39	0.231		
Baseline (Marginal Lingual)	0.4	0.117	2.22	0.142		
2 weeks	0.28	0.119	1.87	0.229		
4 weeks	0.13	0.067	1.67	0.22		
Baseline (Facial)					0.64	0.060
2 weeks					0.51	0.075
4 weeks					0.45	0.093
Baseline (Lingual)					0.64	0.034
2 weeks					0.55	0.069
4 weeks					0.5	0.083

Group 2 (AFP)	BOP Mean	SD	MGI Mean	SD	RMNPI Mean	SD
Baseline (Whole Mouth)	0.55	0.041	2.13	0.098	0.63	0.023
2 weeks	0.4	0.06	1.96	0.143	0.56	0.060
4 weeks	0.28	0.049	1.84	0.155	0.51	0.058
Baseline (Proximal)	0.66	0.045	2.15	0.111	1.00	0.000
2 weeks	0.48	0.078	2.01	0.155	0.88	0.115
4 weeks	0.34	0.062	1.91	0.152	0.75	0.181
Baseline (Marginal)	0.32	0.08	2.09	0.089	1.00	0.000
2 weeks	0.25	0.063	1.86	0.137	0.99	0.016
4 weeks	0.16	0.041	1.70	0.173	0.96	0.081
Baseline (Proximal Facial)	0.65	0.1	2.08	0.107		
2 weeks	0.44	0.101	1.96	0.167		
4 weeks	0.28	0.08	1.86	0.154		
Baseline (Proximal Lingual)	0.67	0.086	2.21	0.159		
2 weeks	0.52	0.101	2.05	0.193		
4 weeks	0.40	0.108	1.95	0.186		
Baseline (Marginal Facial)	0.28	0.096	2.02	0.097		
2 weeks	0.21	0.074	1.8	0.162		
4 weeks	0.11	0.055	1.62	0.201		
Baseline (Marginal Lingual)	0.36	0.109	2.17	0.124		
2 weeks	0.29	0.087	1.93	0.174		
4 weeks	0.22	0.078	1.77	0.189		
Baseline (Facial)					0.63	0.044
2 weeks					0.54	0.079
4 weeks					0.48	0.076
Baseline (Lingual)					0.64	0.032
2 weeks					0.59	0.058
4 weeks					0.54	0.061

Table 3: Overall Means and Standard Deviations of Raw Scores for BOP, MGI, and RMNPI

comparison was the mean change among the two groups, utilising one-way analysis of variance (ANOVA). The arcsine transformation was used to stabilise the variances of the percentage data.[17] The transformed data was used in the analysis; however, tables present the mean of subject-specific percentages for the groups. Data were summarised using descriptive statistics by treatment group and overall. Tables comparing treatment groups provide differences in the least squares mean, the standard deviation of the differences, and the p-value.

The secondary outcomes were to determine the effectiveness of a WF in reducing gingival inflammation and plaque as compared to AFP. Gingival inflammation was measured using the Modified Gingival Index (MGI). Plaque reduction was measured using the Rustogi Modified Navy Plaque Index (RMNPI) at baseline and after two and four weeks.

There were no changes from the planned analysis. 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 and coded to maintain confidentiality. 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 principle investigator. The CRFs underwent key batch entry and verification. Data were tabulated according to the clinical scoring appropriate for the index used.

Results

All seventy subjects completed the study. No adverse events were reported by any subjects nor were there any intraoral findings reported on the CRFs by the examiner. Baseline comparability was conducted for all indices. The two treatment groups were comparable at BSL for BOP, MGI, and RMNPI at all endpoints measured (Table 3).

4 Weeks	Whole Mouth	Proximal	Facial Proximal	Lingual Proximal	Marginal	Facial Marginal	Lingual Marginal
WF	76.2%	75.8%	87.9%	65.6%	77.7%	91.2%	68.2%
AFP	48.5%	48.4%	57.2%	39.9%	48.8%	60.6%	39.8%
Difference between groups	57%	57%	54%	64%	59%	50%	72%
p-value	p<0.001	p<0.001	p<0.001	p<0.001	p<0.001	p<0.001	p<0.001

2 weeks	Whole Mouth	Proximal	Facial Proximal	Lingual Proximal	Marginal	Facial Marginal	Lingual Marginal
WF	44.0%	45.0%	56.0%	35.8%	40.3%	56.0%	29.1%
AF	26.1%	26.8%	31.5%	22.3%	23.2%	25.6%	21.4%
Difference between groups	69%	68%	78%	60%	73%	118%	36%
p-value	p<0.001	p<0.001	p<0.001	p<0.001	p<0.001	p<0.001	p=0.028

Table 4: Bleeding on Probing Percent Improvements

4 Weeks	Whole Mouth	Proximal	Facial Proximal	Lingual Proximal	Marginal	Facial Marginal	Lingual Marginal
WF	21.9%	18.8%	19.8%	17.8%	28.2%	31.9%	24.8%
AF	13.7%	11.1%	10.7%	11.6%	19.0%	19.7%	18.3%
Difference between groups	60%	68%	86%	54%	48%	62%	36%
p-value	p<0.001	p<0.001	p<0.001	p<0.001	p<0.001	p<0.001	p<0.001

2 Weeks	Whole Mouth	Proximal	Facial Proximal	Lingual Proximal	Marginal	Facial Marginal	Lingual Marginal
WF	13.5%	11.9%	11.5%	12.3%	16.8%	18.0%	15.8%
AF	8.0%	6.5%	5.8%	7.1%	11.1%	11.1%	11.1%
Differences between groups	54%	65%	98%	38%	40%	62%	19%
p-value	p<0.001	p<0.001	p<0.001	p=0.001	p<0.001	p<0.001	p=0.002

Table 5: Modified Gingival Index Percent Improvements

Bleeding on probing

Both groups showed changes from BSL to W2 and W4 for all BOP endpoints ($p<0.001$). The WF group (group 1) was at least 50% more effective than the AFP group (group 2) for reducing BOP at W4 for all endpoints ($p<0.001$) (Table 4).

Gingival index

Both groups showed significant changes from BSL to W2 and W4 for all MGI endpoints ($p<0.001$). The WF group was 60% more effective than the AFP group for reducing whole mouth MGI. Notably, the WF was 86% more effective for facial proximal area and 54% for lingual proximal area ($p<0.001$) (Table 5).

Plaque index

Both groups showed significant changes from BSL to W2 and W4 for all RMNPI endpoints ($p<0.001$). At W4 the WF group was significantly more effective than the AFP group for whole mouth (31%, $p=0.008$), proximal (51%, $p=0.017$) and lingual (46%, $p=0.004$) endpoints (Table 6).

Discussion

Self-performed oral hygiene of brushing and string flossing is no longer the standard of care for daily oral hygiene. The consensus report of the 11th European workshop on periodontology systematically reviewed the literature on effective prevention of periodontal and peri-implant diseases. Tonetti and colleagues (2015) reported oral health providers need to routinely recommend an effective patient-centred oral hygiene programme including incorporating behaviour change techniques.[18] The oral hygiene programme should be based on careful selection of devices, such as toothbrushes and interdental aids, tailored to the needs and preferences of the patient.

There is a need for information on the clinical effectiveness of different interdental aids on managing gingivitis and how they compare to tooth brushing alone, or to each other. The WF and AFP have both been compared to dental floss. The WF consistently demonstrated superior benefits for reducing clinical signs of gingival inflammation[9-12] and the AFP demonstrated similar outcomes to dental floss.[12,13] The WF has also demonstrated it is more effective

2 weeks	Whole Mouth	Proximal	Marginal	Facial	Lingual
WF	17.3%	3.0%	21.4%	20.2%	14.7%
AF	10.9%	1.1%	12.2%	14.2%	7.7%
Differences between groups	59%	168%	76%	42%	88%
p-value	p=0.001	p=0.005	p<0.001	p=0.013	p=0.002

4 Weeks	Whole Mouth	Proximal	Marginal	Facial	Lingual
WF	25.9%	36.9%	5.3%	29.8%	22.1%
AF	19.8%	24.5%	3.6%	24.6%	15.1%
Differences between groups	31%	51%	46%	21%	46%
p-value	p=0.008	p=0.017	p=0.052	p=0.0648	p=0.004

Table 6: Plaque Index Percent Improvements

than the AFP for plaque removal and reduction of clinical signs of inflammation in randomised controlled trials.[19-21]

This study compared the effectiveness of the WF to the AFP on reducing the clinical signs of inflammation over four weeks using devices sold in the United Kingdom (two-pin models). At all-time points and endpoints, the WF was significantly more effective than the AFP for reducing clinical signs of inflammation. This data is consistent with previous studies that showed the WF was more effective than the AF and AFP for reducing plaque, gingival bleeding and gingival inflammation.

Conclusion

The Waterpik® Water Flosser is significantly more effective than the Sonicare® Air Floss Pro for improving gingival health. Most notable, the WF was 57% more effective for whole mouth and proximal bleeding on probing and 60% and 68% more effective for whole mouth and proximal MGI scores, respectively.

The WF is significantly more effective than the AFP for reducing plaque for whole mouth (31%), proximal area (51%) and lingual area (46%).

There were no adverse events reported for any of the products used in this study.

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AUTHOR AFFILIATIONS:

1. All Sum Research Center Ltd., Mississauga, Ontario, Canada
2. Reinhard Schuller Consulting, Toronto, Ontario, Canada
3. Water Pik, Inc., Fort Collins, Colorado, USA

CORRESPONDENCE TO:
Email: dlyle@waterpik.com