

Evaluation of the Plaque Removal Efficacy of a Water Flosser Compared to String Floss in Adults After a Single Use

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Abstract

- **Objective:** To compare the plaque removal efficacy of a water flosser to string floss combined with a manual toothbrush after a single use.
- **Methods:** Seventy adult subjects participated in this randomized, single-use, single-blind, parallel clinical study. Subjects were assigned to one of two groups; Waterpik® Water Flosser plus a manual toothbrush (WF) or waxed string floss plus a manual toothbrush (SF). Each participant brushed for two minutes using the Bass technique. The WF group added 500 ml of warm water to the reservoir and followed the manufacturer's instructions, and the SF group used waxed string floss between each tooth, cleaning the mesial and distal surfaces as instructed. Subjects were observed to ensure they covered all areas and followed instructions. Scores were recorded for whole mouth, marginal, approximal, facial, and lingual regions for each subject using the Rustogi Modification of the Navy Plaque Index.
- **Results:** The WF group had a 74.4% reduction in whole mouth plaque and 81.6% for approximal plaque compared to 57.7% and 63.4% for the SF group, respectively ($p < 0.001$). The differences between the groups showed the water flosser was 29% more effective than string floss for overall plaque removal and approximal surfaces specifically ($p < 0.001$). The WF group was more effective in removing plaque from the marginal, lingual, and facial regions; 33%, 39%, and 24%, respectively ($p < 0.001$).
- **Conclusion:** The Waterpik Water Flosser and manual toothbrush is significantly more effective than a manual brush and string floss in removing plaque from tooth surfaces.

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Introduction

Plaque is a risk factor for periodontal disease and needs to be controlled or eliminated on a daily basis. Most people in the industrialized world brush their teeth at least once a day.^{1,2} However, the outcome is less than desirable as evidenced by epidemiological studies that show a significant prevalence in gingivitis and more advanced periodontal disease.³ Even the best brushers can only clean 60% of the tooth surface, leaving significant plaque in the interproximal area which is difficult to access with a toothbrush alone.⁴

Perhaps of greater importance is the need to remove plaque on the proximal surfaces of teeth. Periodontal infections generally start and are more pronounced in this area because it is an ideal place for biofilm to proliferate and it is difficult to remove.⁵ String floss has long been the standard of care for cleaning the proximal surface of the tooth. First introduced in the late 1800s, floss continues to be the recommendation of choice by most dental professionals. Recently, there have been systematic reviews

demonstrating that the recommendation of floss is based more on tradition than science. Hujoel and colleagues⁶ reported that daily flossing did not reduce the incidence of proximal caries. Surprisingly, the review reported a lack of studies on adults, and the studies with adolescents utilized professional flossing on school children. A systematic review by Berchier and colleagues⁷ compared brushing alone to brushing and flossing, and found no benefit in the reduction of inflammation or plaque. Likewise, Slot, *et al.*⁸ evaluated the efficacy of interdental brushes compared to brushing alone or brushing paired with string floss or wood stick. The review reported that five of eight studies showed a positive significant difference for plaque index in favor of the interdental brushes when compared to floss, and one of two when compared to wood sticks. There were no differences found for gingival bleeding or inflammation compared to either floss or wood sticks.

People do not like to floss, do not feel proficient with floss, and if given a choice will choose another interdental device.⁹⁻¹¹ There is a need for clinical studies that address the efficacy of interdental

devices. This study compared the plaque removal efficacy of a water flosser to string floss when paired with a manual toothbrush after a single use.

Materials and Methods

Subjects

Seventy-one (71) adult male and female subjects were recruited for the study (Table I). Subjects were enrolled if they met the following criteria:

1. Able to understand, read, and write in English and provide written informed consent prior to participation;
2. Not enrolled in another clinical study during the day of examination;
3. Non-smoker in good general health and not pregnant at the time of the study;
4. Reported not using antibiotics within six months of the study, require premedication for dental treatment, or have a systemic disease that influences the oral tissue (e.g., diabetes, autoimmune disease, medication);
5. Have a minimum of 20 scoreable teeth (not including 3rd molars), no probing depths greater than 5 mm, and a minimum pre-brushing plaque score of 0.6;
6. No hard or soft tissue lesions; and
7. Good dental health with no visible carious lesions, obvious advanced periodontal disease, orthodontic appliances, or removable partial dentures.

Table I
Demographic Data

	WF (N = 34)	Waxed Floss (N = 36)	Overall (N = 70)
Age (years)			
Mean	45.2	44.6	44.9
SD	10.45	10.27	10.29
SEM	1.79	1.71	1.23
Range	25 – 63	25 – 64	25 – 64
Gender			
Male	6 (17.6%)	10 (27.8%)	16 (22.9%)
Female	28 (82.4%)	26 (72.2%)	54 (77.1%)

SD = Standard Deviation, SEM = Standard Error of the Mean
p-value for age ($p = 0.962$) from a Wilcoxon rank-sum test
p-value for gender ($p = 0.398$) from a Fisher's Exact test

The study forms and protocol were approved by the institutional review board (Institutional BRCL). Subjects completed a medical history and read and signed a consent form prior to inclusion in the study.

Study Devices

The Waterpik® Ultra Water Flosser (WF group, Model WP-100, Water Pik, Inc., Fort Collins, CO, USA) is a pulsating oral irrigator with a reservoir, pressure control, and handle for tip placement (Figure 1A). The tip is directed at the gingival margin and approximal areas of all teeth, following a pattern around the mouth cleaning the facial and lingual surfaces. The Classic Jet



Figure 1A. Water Flosser (Water Pik, Inc.). The Ultra unit used in the study includes five tip designs and pressure setting from low to high (1 – 10).



Figure 1B. Classic Jet Tip. Tip is held close at a 90-degree angle to the tooth at the gingival margin and follows a pattern around the mouth to clean all facial and lingual areas of the teeth.

Tip was used for this study (Figure 1B), delivering 500 ml of warm water using medium-high pressure.

Unflavored waxed dental floss (SF group; Johnson & Johnson, Morris Plains, NJ, USA) was precut to 18" and provided to the subjects. Subjects cleaned the proximal surfaces of all teeth following instructions for wrapping the floss around each tooth on the mesial and distal surfaces forming a "C," and moving up and down the surfaces several times.

Study Design

This independent, single-blind, single-use, parallel clinical trial compared the plaque removal efficacy of a manual toothbrush paired with either a WF or SF. Subjects were randomized into one of two groups prior to pre-cleaning plaque score recording. Group 1 received the WF and group 2 received the waxed string floss (SF). All subjects used a new American Dental Association standard manual toothbrush (Oral-B® Indicator 35, Procter & Gamble, Cincinnati, OH, USA) and

Crest® Cavity Protection Toothpaste, regular mint favor (Procter & Gamble, Cincinnati, OH, USA). The study endpoint was the single-use change scores of the Rustogi Modification of the Navy Plaque Index (RMNPI) for whole mouth, marginal, approximal, facial, and lingual areas.¹²

Subjects abstained from brushing and all other oral hygiene methods for 23–25 hours prior to their appointment. Oral soft and hard tissues were assessed at the pre- and post-cleaning evaluations. Subjects rinsed with an erythrosine (FD&C #3) disclosing solution (Gemiphene Corporation, Brantford, ON, Canada) for one minute and then expectorated. Data were collected by one experienced examiner proficient using the RMNPI, and who was blinded to the treatment assignments. There are nine sections to score with the RMNPI. Sections are combined to provide data for the marginal and approximal regions (Figure 2).

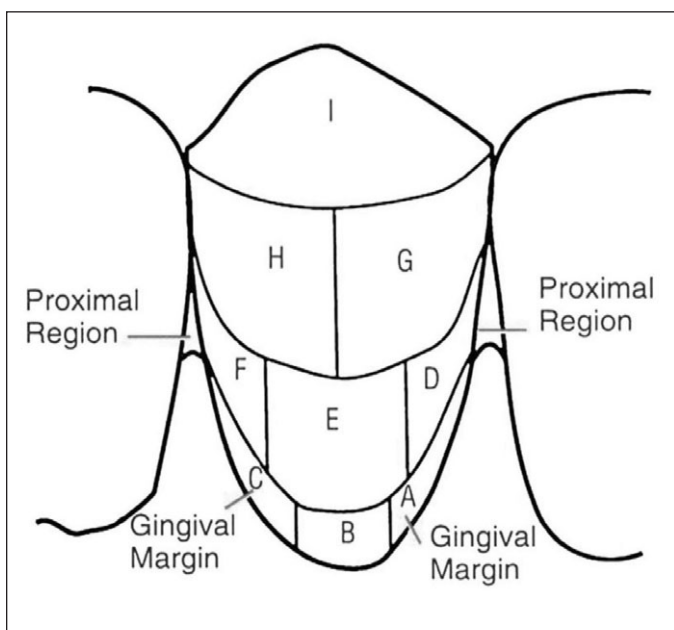


Figure 2. Rustogi Modification of the Navy Plaque Index. Plaque is assessed for each tooth area (A through I) and is scored using the following scale: 0 = absent, and 1 = present. Facial and lingual surfaces of all gradable teeth are scored and a mean plaque index (MPI) is calculated for each subject at each examination. Subjects' scores were calculated for the whole mouth (areas A through I), along the gingival margin (areas A through C), and proximal (approximal; areas D and F).

Verbal instructions were given to each subject followed by a demonstration on a mouth model: Bass technique for the toothbrush; manufacturer's instructions for the water flosser; and standard flossing instructions for the waxed floss. Each subject brushed for a timed two-minutes and was supervised to make sure they were using the proper technique throughout the brushing process. They rinsed and immediately commenced with interdental cleaning using either the WF or SF. The WF group filled the reservoir with 500 ml of warm water and placed the pressure setting on medium-high. The subjects were done when they had cleaned each interproximal area and proximal surface with the floss or when the WF reservoir was empty.

Statistical Analysis

Data were collected for each subject and recorded on Case Report Forms (CRFs) in black ballpoint pen. The CRFs were completed and reviewed for accuracy of all data, and 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 RMNPI.

With 35 subjects per group, the study would have over 90% power to detect a clinically significant difference when the average plaque reduction for the Waterpik Water Flosser plus manual toothbrush is 75% when compared to the average reduction of 50% for waxed string floss plus manual toothbrush for whole mouth plaque.

The primary outcome was to determine the removal and reduction of plaque from tooth surfaces from pre-treatment baseline and between groups measured by the reduction in the RMNPI after a single use.

The primary comparison evaluated the mean change between the groups, utilizing a between independent groups one-way analysis of variance (ANOVA). Within groups pre-post comparisons were also evaluated using the pre-post change score. Data were summarized using descriptive statistics (mean, median, minimum, maximum, and standard deviation) by treatment group and overall. No statistical adjustments were made for multiple comparisons or multiple tests. All statistical tests were conducted using a significance level of $\alpha = 0.05$.

Results

Seventy subjects (70) completed the study. There were 34 subjects in the WF group and 36 subjects in SF group. One subject dropped out from the WF group due to personal reasons. There were no differences in demographics or baseline characteristics between the groups at baseline. The two treatments did not differ at pre-treatment for whole mouth and facial plaque scores and were the same for approximal and marginal regions, indicating no differences at baseline between the groups. The pre-treatment lingual scores were 0.64 for WF and 0.62 for SF which did differ statistically ($p = 0.04$), but was not considered clinically relevant (Table II).

Whole Mouth

The WF and SF groups showed statistically significant changes from pre-cleaning to post-cleaning score for whole mouth RMNPI; 74.4% and 57.7%, respectively ($p < 0.001$). The WF group was 29% more effective than the SF group for whole mouth plaque removal ($p < 0.001$; Table II, Figure 3).

Marginal Region

Both groups showed significant reduction between pre- and post-cleaning scores; 68.2% for WF group and 51.1% for SF group ($p < 0.001$). The difference between the groups was 33% ($p < 0.001$), demonstrating a significant difference in favor of the WF group (Table II, Figure 3).

Approximal Region

The WF and SF groups showed statistically significant

Table II
Pre-cleaning RMNPI and Post-cleaning Plaque Removal

		Pre-Cleaning Mean (SD)	Post-Cleaning Mean (SD)	Change Score Mean (SD)	% Change*
Whole Mouth	WF	0.65 (0.047)	0.17 (0.050)	0.48 (0.043)	74.4%
	SF	0.64 (0.039)	0.27 (0.069)	0.37 (0.053)	57.7%
Marginal	WF	1.00 (0.000)	0.32 (0.083)	0.68 (0.083)	68.2%
	SF	1.00 (0.000)	0.49 (0.114)	0.51 (0.114)	51.1%
Approximal	WF	1.00 (0.000)	0.18 (0.079)	0.82 (0.079)	81.6%
	SF	1.00 (0.000)	0.37 (0.101)	0.63 (0.101)	63.4%
Facial	WF	0.65 (0.069)	0.09 (0.062)	0.56 (0.070)	85.7%
	SF	0.66 (0.074)	0.20 (0.086)	0.46 (0.070)	69.4%
Lingual	WF	0.64 (0.041)	0.24 (0.078)	0.40 (0.060)	62.9%
	SF	0.62 (0.032)	0.34 (0.095)	0.28 (0.076)	45.2%

SD = Standard Deviation

*Change from pre-cleaning $p < 0.001$

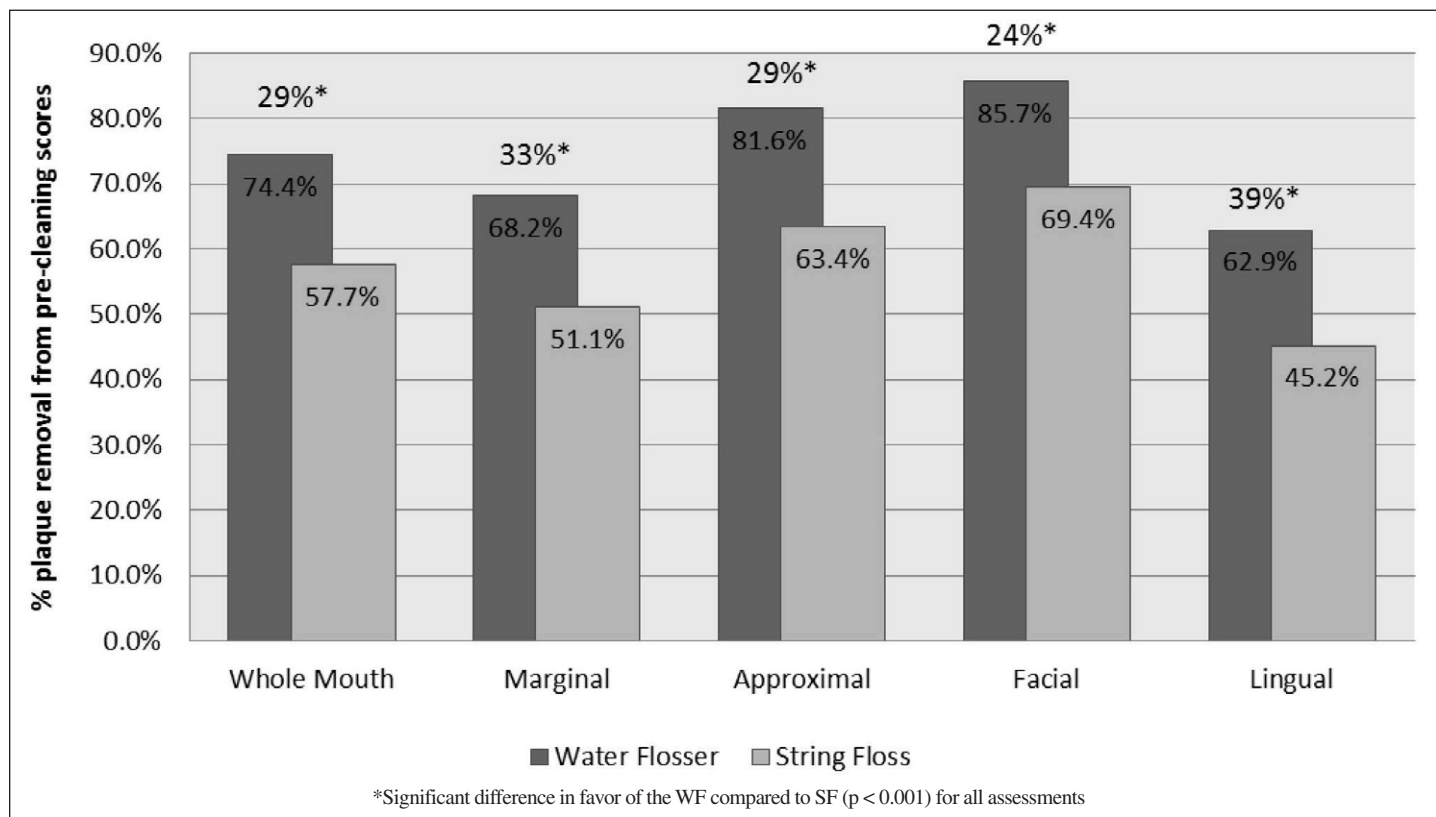


Figure 3. Mean % reduction in Plaque (RMNPI)

changes from pre- and post-cleaning scores for the approximal region; 81.6% and 63.4%, respectively. The WF group showed superior plaque removal compared to the SF group (29%, $p < 0.001$; Table II, Figure 3).

Facial and Lingual

Both groups demonstrated significant differences from pre-cleaning scores to post-cleaning scores for the facial and lingual surfaces ($p < 0.001$). The WF group was significantly more effective than the SF group for plaque removal on the facial surfaces, 85.7% versus 69.4% ($p < 0.001$). Likewise, the

WF group was more effective for plaque removal on the lingual surface, 62.9% compared to 45.2% ($p < 0.001$). The WF was 24% more effective on the facial and 39% on the lingual surfaces compared to the string floss group (Table II, Figure 3).

Discussion

Tooth brushing is the most common and practical way to remove supragingival plaque from the tooth surface to help prevent gingival inflammation. People tend to form brushing habits that are repeated, leading to consistent areas that are not

cleaned regardless of how many times they brush or for how long.¹³ Brushing time and technique are variables that impact outcomes, with an average brushing time of 50 seconds and techniques that do not clean the angles and margins effectively.¹³ Plaque left on tooth surfaces, especially at the marginal area, can impact the initiation and proliferation of subgingival bacteria, increasing the risk for gingivitis and periodontal infections.^{14,15}

Twice-daily brushing for two minutes is based on empirical rather than scientific evidence, since asking people to brush more frequently or longer can be futile. This needs to be coupled with interdental cleaning once daily to control biofilm formation where infection and gingivitis are likely to occur.⁵ The use of dental floss as the standard of care is questionable and other devices should be investigated.

The purpose of this study was to evaluate the efficacy of a water flosser interdental cleaning device and compare it to string floss on plaque removal after a single use. The RMNPI allowed for evaluation of different areas and surfaces of the tooth, and provided a clearer picture of the plaque removal efficacy of each product. It is interesting to note that string floss has been around for well over a century, but there is little data available to support its standing as a primary interdental cleaner.⁷ The water flosser, originally known as an oral irrigator, was first introduced to the dental profession in 1962. Currently, there are over 50 clinical studies on one design (Waterpik Water Flosser) that has a pulsation and pressure combination and has shown significant reductions in inflammation and plaque. The water flosser has been tested on many different cohorts such as implants,¹⁶ fixed orthodontics,¹⁷ individuals living with diabetes,¹⁸ gingivitis,^{19,21} and those with mild to moderate periodontal disease,^{22,23} demonstrating significant improvements in oral health in favor of the water flosser group compared to traditional or normal oral hygiene regimens, including string floss.

In this study, the WF group was more effective in removing plaque from all areas and surfaces compared to the SF group. The 29% better reduction in approximal scores is important, especially since the flossing group was instructed and supervised in the proper technique of wrapping the floss around the tooth so that this area would be cleaned; thereby expecting the best results from the subjects in this situation. The WF was also more effective on the lingual (39%) and marginal (33%) areas compared to floss. These areas should be cleaned easily with a toothbrush, but as noted, people do not brush effectively. A water flosser has the added benefit of cleaning these areas along with the toothbrush without adding another device or rinse. Additionally, research has shown that the water flosser cleans significantly deeper than a manual toothbrush,²⁴ which may reach one mm using the Bass technique.²⁵ The water flosser has been shown to reach on average 50% of the pocket with 75% penetration in the majority of pockets > 7 mm.²⁴

This water flosser study looked at pre and post measures for plaque removal compared to string floss. Longer studies have shown a reduction in plaque with a water flosser compared to baseline or floss over time.^{17,19} In one study the plaque removal was equivalent to the floss group, but the improvements in gingival inflammation were significantly more effective for the water flosser.²¹ It has also been reported that improvements in

oral health with a water flosser were not related only to improvements in plaque, but related to a down regulation of pro-inflammatory mediators.²⁶ This study was designed to look at plaque removal specifically.

All products were found to be safe to use and there were no reported adverse events from the single brushing and interdental cleaning with either the WF or SF. Subjects did not have any problems using either product. These results are in line with other studies that showed a significant reduction in plaque from baseline in favor of the water flosser compared to the control group. The question of whether a water flosser can remove plaque has been answered in the affirmative. More importantly, the outcomes showing a reduction in inflammation,^{19,23,26} pocket depth,²⁶ subgingival bacteria,²⁷⁻²⁹ and gingival bleeding¹⁹⁻²³ in studies of four weeks and greater can support the regular recommendation of the water flosser as a key device in maintaining optimal oral health.

Conclusions

From an analysis of this clinical trial we observed the following:

1. The Waterpik Water Flosser paired with a manual toothbrush is significantly more effective than string floss for removing plaque. Specifically, the group utilizing the WF had 29%–39% better plaque removal.
2. The WF is significantly more effective than string floss in reducing plaque, including in hard-to-reach areas of the mouth often missed by brushing.
3. Both the WF and SF are safe to use.

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