Introduction

Periodontal infections are caused by bacteria and mediated by many factors, including host response, smoking, diabetes, oral hygiene regimens, and compliance.1-3 The traditional recommendation for daily oral hygiene is tooth brushing for supragingival plaque removal and flossing for interdental plaque removal. Research shows that individuals are not proficient in removing plaque with a toothbrush, with an average 43% and a range of 28–53% plaque removal from a single brushing.4 A systematic review comparing the addition of dental floss to manual tooth brushing showed there was no benefit for reducing gingivitis and plaque compared to brushing alone.5 Power toothbrushes have been shown to improve plaque removal and reduce accumulation over time compared to manual toothbrushes.6,7

Eighty to ninety percent of the populations of industrialized countries brush their teeth once or twice a day.8,9 The use of dental floss for interdental cleaning is minimal, with 77% of adults stating they do not use floss or any interdental aid.10 Epidemiological and clinical studies show that mechanical oral hygiene procedures, as performed by most subjects, are insufficient to control plaque formation and periodontal infections.4,9 The need for an oral hygiene regimen that is effective and will be used by individuals is clearly indicated.

A water flosser has been shown repeatedly to reduce the clinical signs of inflammation as measured by bleeding and gingivitis.

Abstract

• **Objective:** The primary objective of this study was to compare the effectiveness of a water flosser plus sonic toothbrush to a sonic toothbrush alone on the reduction of bleeding, gingivitis, and plaque. The secondary objective was to compare the effectiveness of different sonic toothbrushes on bleeding, gingivitis, and plaque.

• **Methods:** One-hundred and thirty-nine subjects completed this randomized, four-week, single-masked, parallel clinical study. Subjects were assigned to one of four groups: Waterpik® Complete Care, which is a combination of a water flosser plus power toothbrush (WFS); Sensonic® Professional Plus Toothbrush (SPP); Sonicare® FlexCare toothbrush (SF); or an Oral-B® Indicator manual toothbrush (MT). Subjects were provided written and verbal instructions for all power products at baseline, and instructions were reviewed at the two-week visit. Data were evaluated for whole mouth, facial, and lingual surfaces for bleeding on probing (BOP) and gingivitis (MGI). Plaque data were evaluated for whole mouth, lingual, facial, approximal, and marginal areas of the tooth using the Rustogi Modification of the Navy Plaque Index (RNMPI). Data were recorded at baseline (BL), two weeks (W2), and four weeks (W4).

• **Results:** All groups showed a significant reduction from BL in BOP, MGI, and RNMPI for all areas measured at the W2 and W4 visits (p < 0.001). The reduction of BOP was significantly higher for the WFS group than the other three groups at W2 and W4 for all areas measured (p < 0.001 for all, except p = 0.007 at W2 and p = 0.008 for W4 lingual comparison to SPP). The WFS group was 34% more effective than the SPP group, 70% more effective than the SF group, and 1.59 times more effective than the MT group for whole mouth bleeding scores (p < 0.001) at W4. The reduction of MGI was significantly higher for the WFS group; 23% more effective than SPP, 48% more effective than SF, and 1.35 times more effective than MT for whole mouth (p < 0.001) at W4. The reduction of MGI was significantly higher for WFS than the SF and MT for facial and lingual surfaces, and more effective than the SPP for facial surfaces (p < 0.001) at W4. The WFS group showed significantly better reductions for plaque than the SF and MT groups for whole mouth, facial, lingual, approximal, and marginal areas at W4 (p < 0.001; SF facial p = 0.025). For plaque reduction, the WFS was significantly better than the SPP for whole mouth (p = 0.003) and comparable for all other areas and surfaces at W4. The WFS was 52% more effective for whole mouth, 31% for facial, 77% for lingual, 1.22 times for approximal, and 1.67 times for marginal areas compared to the SF for reducing plaque scores at W4 (p < 0.001; SF facial p = 0.025). The SPP had significantly higher reductions than the SF for whole mouth and lingual BOP and MGI scores, and whole mouth, approximal, marginal, and lingual areas for plaque at W4.

• **Conclusion:** The Waterpik Complete Care is significantly more effective than the Sonicare FlexCare toothbrush for reducing gingival bleeding, gingivitis, and plaque. The Sensonic Professional Plus Toothbrush is significantly more effective than the Sonicare FlexCare for reducing gingival bleeding, gingivitis, and plaque.
indices. A study by Sharma, et al. showed the addition of a water flosser to manual brushing reduced gingivitis scores by 41.2% over four weeks. The pulsating action of a water flosser creates a compression and decompression phase of the gingival tissue, allowing for the water or other solution to reach the subgingival and interdental areas around the tooth, effectively removing plaque, bacteria, and debris. These areas are generally inaccessible by tooth brushing. The action of a sonic toothbrush creates sonic energy and fluid movement, but it is not equivalent to the hydrodynamic action of a water flosser. This study evaluates the regimen of power tooth brushing plus a water flosser to power tooth brushing alone on improving the oral health parameters of bleeding, gingivitis, and plaque.

**Materials and Methods**

**Subjects**

One-hundred and forty healthy, non-smoking male and female adults between the ages of 25 and 65 years (Table I) were enrolled in this study. Subjects had a minimum of 1.75 for their Modified Gingival Index (MGI), 50% bleeding on probing (BOP), and ≥ 0.60 for a Rustogi Modified Navy Plaque Index (RMNPI) score at baseline. Subjects had at least 20 scoreable teeth, not including third molars, and no hard or soft tissue lesions. Recruits were excluded from the study if they had visible signs of advanced periodontal disease, probing depth > 5 mm, any systemic disease such as diabetes or autoimmune disease, pregnant at the time of the study, medication use that could impact gingival health, or use of antibiotics within six months of the study. Subjects with orthodontic appliances, implants, crowns, bridges, veneers, or removable appliances were not included. The study protocol and case report forms (CRF) were approved by the institutional review board (Institutional BRCL). Subjects completed a medical history and read and signed an approved consent form.

**Study Devices**

The Waterpik® Complete Care (WFS; Model WP-900, Water Pik, Inc., Fort Collins, CO, USA) is a power-driven device that combines two products into one; the Waterpik® Water Flosser and the Waterpik® Sensonic® Professional Plus Toothbrush. The water flosser works through the combination of pressure and pulsation that provides a pulsating stream of water that can access the interdental, marginal, and subgingival areas around the tooth. The Waterpik Sensonic Professional Plus Toothbrush utilizes sonic technology to generate brushing strokes to clean the tooth surface with high and low bristle configuration to access line angles and crevices. The brush has a two-minute timer with sensory pause to indicate 30 seconds for quadrant brushing, three brush head designs, and two brushing modes. The handle is a slim, ergonomic design with rubber grips and contains a rechargeable battery. Subjects in Group 1 used the WFS product (Figure 1a).

The Waterpik Sensonic Professional Plus Toothbrush (SPP; Model SR-3000, Water Pik, Inc., Fort Collins, CO, USA) is a stand-alone device with the features mentioned above. Subjects in Group 2 used the SPP toothbrush (Figure 1b).

The Sonicare® FlexCare Toothbrush (SF; Philips Healthcare, Bothell, WA, USA) utilizes sonic technology to generate brushing strokes to clean the tooth surface. The brush comes with one brush head that is angled for posterior access, compact, and configured to clean hard-to-reach areas. It has interval pacing to indicate 30 seconds for quadrant brushing and a two-minute timer. There are three brushing modes and two brushing routines. The handle is ergonomic, slim, with a rubber grip, and contains a rechargeable battery. Subjects in Group 3 used the SF toothbrush (Figure 1c).

![Figure 1. (a) G1—Waterpik Complete Care Toothbrush; (b) G2—Waterpik Sensonic Professional Plus Toothbrush; (c) G3—Sonicare FlexCare Toothbrush.](image)

**Study Design**

This randomized, controlled, single-masked, four-week, parallel clinical trial evaluated improvements in gingivitis, bleeding, and plaque. Subjects were randomly assigned to one of four treatment groups: Group 1 (G1) used a combination device of a water flosser and sonic toothbrush (WFS); Group 2 (G2) used the sonic toothbrush SPP; Group 3 (G3) used the sonic toothbrush SF; and Group 4 (G4) used an ADA standard manual toothbrush (Oral-B® Indicator 35, Procter & Gamble, Cincinnati, OH, USA). All groups used Crest® Cavity Protection Toothpaste, regular mint flavor (Procter & Gamble, Cincinnati, OH, USA). Data were collected at baseline (BL), two weeks (W2), and four weeks (W4) for MGI, BOP, and RMNPI. Subjects were instructed not to use any other oral care device, rinses, or agents during the study.

Subjects abstained from using their oral hygiene devices for 12–14 hours prior to their scheduled appointments for data collection. Oral soft and hard tissues were examined at all visits and any adverse events were recorded. Data collection was completed by one examiner who was blinded to the group assignment.
and product used for all indices and time points. Subjects were instructed not to discuss their product with the examiner. The MGI, as described by Lobene, et al., was used to assess gingivitis around all natural teeth from the facial and lingual surfaces, and was scored using a 0–4 scale (Figure 2).22

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
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<tbody>
<tr>
<td>0</td>
<td>Absence of inflammation</td>
</tr>
<tr>
<td>1</td>
<td>Mild inflammation; slight change in color, little change in texture of any portion of but not the entire marginal or papillary gingival unit</td>
</tr>
<tr>
<td>2</td>
<td>Moderate inflammation; criteria as above but involving the entire marginal or papillary gingival unit</td>
</tr>
<tr>
<td>3</td>
<td>Severe inflammation; marked redness, edema and/or hypertrophy of the marginal or papillary gingival unit, spontaneous bleeding, congestion or ulceration</td>
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</table>

Figure 2. Criteria for the Modified Gingival Index.

Bleeding on probing was scored using a binary scale as either positive (1) or negative (0). Plaque was scored using the RMNPI, which divides the tooth into nine sections, emphasizing the marginal and approximal areas. Whole mouth scores include all nine sections, marginal scores follow the free gingival margin and include three sections, approximal scores include mesial and distal line angles up to the contact point (Figure 3).23

Figure 3. 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).

Subjects in G1, G2, and G3 received written and verbal instructions as demonstrated following the manufacturer’s instruction booklets. Brushing time and sequence were based on the instruction booklet, changing location based on the 30-second indicator, and brushing for two minutes as measured by the built-in timer. Subjects were instructed to brush twice a day in the morning and evening. G2 used the toothbrush on the high setting and G3 used the toothbrush on the clean mode. After brushing, G1 used the water flosser once a day in the evening. The reservoir was filled with 500 ml of warm water; the pressure dial was set on medium high (~70 psi) and subjects used the Classic Jet Tip to clean all teeth from the facial and lingual aspects. This takes, on average, one minute. G4 brushed as they normally do twice a day using the new manual toothbrush provided.

Data Analysis

Data were collected on Case Report Forms (CRFs) for each subject. Entries were recorded using a black ballpoint pen. 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. 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. Between-treatment comparisons were made using a one-way analysis of variance (ANOVA), and the p-values for the treatment regimen comparisons were calculated. The arcsine transformation was used to stabilize the variances of the BOP change from baseline. P-values from the analysis using the transformed data for BOP are reported. The treatment percent differences are the ratio of the differences for the respective treatments. All means and standard errors reported are from untransformed data. No statistical adjustments were made for multiple endpoints and multiple testing (multiplicity). The randomization was conducted using nQuery Advisor 7.0, and the statistical analysis software used was SAS 9.1 for the PC platform.

Results

One-hundred and thirty-nine subjects completed the study. One subject in G4 dropped out due to a death in the family. There were no adverse events during the study and none of the subjects reported any problems. The four treatment groups were comparable at baseline for MGI, BOP, and RMNPI.

Bleeding Index

All treatment groups showed statistically significant reductions from BL at W2 and W4 for whole mouth, facial, and lingual BOP scores (p < 0.001). The reduction of BOP was significantly higher for the WFS group than the other three groups at W2 and W4 for all areas measured (p < 0.001, p = 0.007, p = 0.008; Table II). The WFS group was 34% more effective than the SPP group, 70% more effective than the SF group, and 1.59 times more effective than the MT group for whole mouth bleeding scores at W4 (p < 0.001; Table III). Bleeding on probing reductions were significantly higher for SPP and SF compared to MT at W2 and W4 for whole mouth, facial, and lingual surfaces. At W4, the SPP was 26% more effective at reducing whole mouth bleeding (p < 0.001) and 31% more effective at reducing bleeding on the lingual surfaces (p = 0.011) than the SF group (Table II).

Gingival Index

All treatment groups showed statistically significant reductions from BL at W2 and W4 for whole mouth, facial, and lingual MGI scores (p < 0.001; Table II). The reduction of MGI was significantly higher for the WFS group, 23% more effective than SPP, 48% more effective than SF, and 1.35 times more effective than
### Changes from BL were significant for all group at all endpoints (p < 0.001).  

### MT for whole mouth at W4 (p < 0.001). At W4, the reduction of MGI scores was significantly higher for WFS than SF and MT for facial and lingual surfaces, and more effective than the SPP for facial surfaces at W4 (p = 0.001; Table IV).  

### SPP and SF were significantly higher than MT for reducing MGI scores at W2 and W4 for all areas measured (p < 0.001). The SPP was 20% more effective for whole mouth and 33% more effective for lingual surface compared to SF for reducing gingivitis scores at W4 (p = 0.001 and p = 0.005, respectively).  

### Plaque Index  
All groups showed statistically significant reductions in RMNPI scores from BL to W2 and W4 for all areas and surfaces measured (p < 0.001; Table II). The WFS group showed significantly better reductions for plaque than the SF and MT groups for whole mouth, facial, lingual, approximal, and marginal areas at W4 (p < 0.001; SF facial p = 0.025). The WFS was significantly better than the SPP for whole mouth plaque (p = 0.003).
and comparable for all other areas and surfaces at W4. For plaque reduction, the WFS group was 52% more effective for whole mouth, 31% for facial, 77% for lingual, 1.22 times for approximal, and 1.67 times for marginal areas compared to the SF at W4 (p < 0.001, facial p = 0.025; Table V).

### Table V

<table>
<thead>
<tr>
<th>Day 14</th>
<th>Whole Mouth</th>
<th>Approximal</th>
<th>Marginal</th>
<th>Facial</th>
<th>Lingual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1 (WFS)</td>
<td>12.6%</td>
<td>12.7%</td>
<td>3.6%</td>
<td>14.5%</td>
<td>10.6%</td>
</tr>
<tr>
<td>Group 2 (SPP)</td>
<td>10.5%</td>
<td>13.0%</td>
<td>3.1%</td>
<td>12.1%</td>
<td>9.0%</td>
</tr>
<tr>
<td>Group 3 (SF)</td>
<td>9.0%</td>
<td>8.2%</td>
<td>2.1%</td>
<td>12.1%</td>
<td>5.9%</td>
</tr>
<tr>
<td>Group 4 (MT)</td>
<td>6.3%</td>
<td>5.3%</td>
<td>1.3%</td>
<td>8.9%</td>
<td>3.7%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>WFS Comparison to:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole Mouth</td>
</tr>
<tr>
<td>Group 2 (SPP)</td>
</tr>
<tr>
<td>p = 0.200</td>
</tr>
<tr>
<td>Group 3 (SF)</td>
</tr>
<tr>
<td>p = 0.035</td>
</tr>
<tr>
<td>Group 4 (MT)</td>
</tr>
<tr>
<td>p = 0.020</td>
</tr>
</tbody>
</table>

*SPP was statistically significantly better than MT (p < 0.001).

### Table VI

<table>
<thead>
<tr>
<th>Ratios of Percentage Reduction Between Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power Toothbrush</td>
</tr>
<tr>
<td>BOP</td>
</tr>
<tr>
<td>Week 2</td>
</tr>
<tr>
<td>Group 3 (SF) 1.23* 1.21 1.27 1.26* 1.23 1.31†</td>
</tr>
<tr>
<td>p = 0.163 p = 0.080 p = 0.089</td>
</tr>
<tr>
<td>SPP Comparison to:</td>
</tr>
<tr>
<td>Week 4</td>
</tr>
<tr>
<td>Group 3 (SF) 1.25† 1.17 1.32† 1.20* 1.06 1.33†</td>
</tr>
<tr>
<td>p = 0.223 p = 0.671</td>
</tr>
</tbody>
</table>

*SPP was statistically significantly better than SF and MT (p < 0.001).†SPP was statistically significantly better than MT (p = 0.004).‡SPP was statistically significantly better than SF (p = 0.024).

The SPP had significantly higher reductions than the SF for whole mouth plaque at W4 (29%, p < 0.001), lingual (50%, p = 0.234), marginal (1.33 times, p < 0.001), and approximal (1.13 times, p < 0.001) areas. There was no difference in plaque scores between SF and MT for approximal and marginal areas. SPP showed significantly higher reductions for RMNPI compared to MT for all time points and areas measured (Table VI).

A summary of comparative ratios of percentage reductions between toothbrush groups is shown in Table VI.

### Discussion

Oral hygiene regimens need to provide effective benefits for improving oral health. The traditional brushing and flossing recommendation does not work based on epidemiological research and systematic reviews. Even though people claim to brush regularly they do not clean interdently, leading to the high incidence of gingival infections affecting 50% of the population in the USA, with similar findings globally. Today, patients are savvy dental consumers with access to a plethora of information about oral disease and self-care devices, and ask educated questions of their dentist and dental hygienist. Even so, they still do not floss or use other interdental aids, and if they do they tend to not use them correctly. Finding the right regimen for patients can be challenging. Perhaps more important is finding the regimen that is not only effective but is fast and easy to use. The purpose of this study was to compare the regimen of using a power toothbrush plus a water flosser daily for four weeks to two different power toothbrushes and a manual toothbrush (control) on the reduction of plaque and gingival inflammation as measured by bleeding and gingivitis indices.

This study showed that the use of a power toothbrush twice a day plus a water flosser once daily was consistently more effective than using a power toothbrush alone twice a day. The water flosser, also known as a dental water jet or oral irrigator, is a powered device that provides a pulsating stream of water or other
agent under pressure. This provides two areas of hydrokinetic activity; the impact zone where the solution hits the tooth surface and mechanically removes plaque, and the flushing zone where the solution is deflected and penetrates the interdental and sub-gingival areas.\textsuperscript{15-21} The combination of a power or manual toothbrush plus a water flosser has been shown to be more effective than manual brushing and flossing for reducing bleeding, gingivitis, and plaque, providing an alternative to string floss.\textsuperscript{16-18}

The WFS group showed significantly more effective results for all parameters; importantly, the differences were substantial compared to the SF group, especially for bleeding and gingivitis. The differences in favor of the WFS ranged from 66–73% for BOP and 45–50% for MGI at W4 compared to SF. The differences between the WFS and the SPP groups were also significant, but the differences were lower compared to the SF differences. The brushes used in the WFS and the SPP groups were the same and the SF is from a different manufacturer. It is important to note that each brush had a two-minute timer and 30-second interval indicators which help patients brush for the recommended time. The water flosser group spent about one minute more each day. Studies have shown that subjects like using the water flosser, find it easy to use, and have continued to use it after the study was completed, with 74% still using it one year later.\textsuperscript{26-29}

The ADA clinical research guidelines for toothbrushes require a 15% reduction in gingivitis from baseline.\textsuperscript{30} The guidelines for home irrigating devices require a 20% difference compared to traditional products for superiority.\textsuperscript{31} In this study, the WFS group was at least 20% better than the other three groups, with an 18.2% reduction from baseline for gingivitis scores. The large reduction in bleeding for all four groups is most likely related to the high percentage of bleeding at baseline. These reductions would be clinically visible to the clinician.

The secondary objective was to compare the different power toothbrushes on the reduction of bleeding, gingivitis, and plaque. The SPP demonstrated significantly better whole mouth reductions compared to the SF; 26% for BOP, 20% for MGI and 29% for RMNPI. The SPP was also more effective than the SF for lingual surfaces (31% for BOP, 33% for MGI, and 50% for RMNPI) at W4.

This study provides a suggested regimen that was found consistently superior to the use of a power toothbrush only. The clinical signs of inflammation were reduced by the WFS group from 67–71.3% for gingival bleeding and 17–19.4% for gingivitis at W4. The combination of a water flosser plus power toothbrush added one minute a day to daily brushing recommendations. Additional studies comparing other regimens may be needed.

Conclusions

The results of this study revealed the following:

1. The Waterpik Complete Care was significantly better than the Waterpik Sensonic Professional Plus Toothbrush, Sonicare FlexCare, and the Oral-B Indicator toothbrush in improving gingival health. Notably at W4, the Waterpik Complete Care group was 66–73% more effective for BOP and 45–50% more effective for MGI compared to Sonicare FlexCare.

2. The Waterpik Complete Care was significantly better than the Sonicare FlexCare (52%) and the Oral-B Indicator toothbrush (1.34 times) for reducing plaque at W4.

3. The Waterpik Sensonic Professional Plus was significantly better than the Sonicare FlexCare at improving gingival health. Notably, the Sensonic Professional Plus Toothbrush group was superior for all whole mouth and lingual measures (26% and 31% for BOP, respectively; 20% and 33% for MGI, respectively).

4. The Waterpik Sensonic Professional Plus was significantly better than the Sonicare FlexCare at reducing plaque; specifically 29% for whole mouth, 50% for lingual, 1.13 times for approximal, and 1.33 for marginal areas.

5. All products were safe to use.

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

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References