The Effect of Different Interdental Cleaning Devices on Gingival Bleeding

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Abstract

Objective: To compare the effectiveness of an oral irrigator (OI) with a prototype jet tip or a standard jet tip to floss as adjunct to daily toothbrushing on gingival bleeding. **Methods**: In this single masked, 3-group parallel, 4-week home use experiment, 108 subjects were randomly assigned to one of three groups: 1) OI with a prototype jet tip; 2) OI with a standard jet tip; 3) waxed dental floss. All groups used their assigned product once a day as adjunct to twice daily toothbrushing for two minutes with a standard ADA reference toothbrush. Professional instructions were given by a dental hygienist in OI use or floss use according to written instructions. All subjects also received a toothbrush instruction leaflet (Bass technique). Subjects were assessed for both bleeding and plaque at baseline and after two weeks and four weeks and were instructed to brush their teeth approximately 2 to 3 hours prior to their assessment. **Results**: With respect to mean bleeding scores the ANCOVA analysis with baseline as covariate and week 4 as dependent variable showed a significant difference between groups in favor of both the oral irrigator groups. For plaque, however, no significant difference among groups was observed. **Conclusion**: When combined with manual toothbrushing the daily use of an oral irrigator, either with prototype or standard jet tip, is significantly more effective in reducing gingival bleeding scores than is the use of dental floss, as determined within the limits of this 4-week study design.

Key words: Floss, dental water jet, oral irrigator, water flosser, gingivitis, bleeding, plaque, toothbrush

Introduction

Biofilms are 3-dimensional arrangements of bacteria that are loosely or more firmly adherent to teeth and tissue (Costerton *et al.*, 1994). Biofilms consist of microcolonies of bacteria embedded in slimy matrices and are self-sufficient, dynamic communities that can survive in hostile environments (Marsh and Bradshaw, 1995) The regular removal of dental plaque biofilm, which contains the bacteria responsible for caries formation and for the etiology of gingivitis and periodontitis, is the well-accepted *conditio sine qua non* of dental health (Gorur *et al.*, 2009). Mechanical removal is considered the most effective method to control the growth of the oral biofilm. The most common device used for mechanical plaque control is either a manual or power toothbrush. As toothbrush efficacy is limited to the surfaces of the teeth it can access (facial, lingual, and occlusal), another device is needed to clean the interdental area and the proximal surfaces of the teeth and surrounding gingivae. Other factors that affect the efficacy of mechanical plaque biofilm removal include brushing frequency, brushing time, toothbrush design, and brushing technique (Jepsen *et al.*, 1998; Van der Weijden *et al.*, 1993).

For most people, however, total plaque biofilm removal is not a realistic goal. It is difficult for patients to effectively remove or disrupt the biofilm from all surfaces of the teeth on a daily basis (Douglass *et al.*, 1993; Brown *et al.*, 1993). On average, people reduce their plaque scores by approximately 50% by brushing (Jepsen *et al.*, 1998). Therefore, compliance with instructions is a major consideration when recommending any self-care device. To be truly patient-centered, practitioners must shift to recommending available tools that, besides having demonstrated efficacy in reducing inflammation based on scientific evidence, are also preferred by patients (Slot *et al.*, 2008).

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A dental water jet or water flosser or oral irrigator (OI) is an electric device that delivers a pulsating fluid via controlled pressure which is aimed at the removal of interdental and subgingival plaque biofilm on tooth surfaces to reduce inflammation as a supplement to toothbrushing (Lobene, 1969; Drisko *et al.*, 1987; Cobb *et al.*, 1988; Flemmig *et al.*, 1990; Chaves *et al.*, 1994; Flemmig *et al.*,1995; Barnes *et al.*, 2005; Gorur *et al.*, 2009). The OI was introduced to the dental profession in 1962 and has been studied extensively for the past decades. Clinical studies demonstrate that an OI is safe and can significantly reduce bleeding and gingivitis in a variety of cohorts (Lobene *et al.*, 1969; Flemmig *et al.*, 1990; Brownstein *et al.*, 1990; Burch *et al.*, 1994; Newman *et al.*, 1994; Flemmig *et al.*, 1995; Felo *et al.*, 1997; Barnes *et al.*, 2005; Sharma *et al.*, 2008). However, erythrosine-based plaque indices have yielded equivocal data. Some studies have shown a reduction in plaque indices with the use of the OI compared to toothbrushing alone (Burch *et al.*, 1994; Felo *et al.*, 1997; Cutler *et al.*, 2000; Al Mubarak *et al.*, 2002; Sharma *et al.*, 2008), while other studies showed no significant differences (Ciancio *et al*, 1989; Brownstein *et al.*, 1990; Walsh *et al.*, 1992; Chaves *et al.*, 1994; Fine *et al.*, 1994).

The OI is likely to provide a particular benefit in terms of gingival health to a large part of the general public that does not clean the interproximal spaces on a regular basis (Research, Science and Therapy Committee, 2005). In 2001 the American Academy of Periodontology stated, "Among individuals who do not perform excellent oral hygiene, supragingival irrigation with or without medicaments is capable of reducing gingival inflammation beyond that normally achieved by toothbrushing alone. This effect is likely due to the flushing out of subgingival bacteria (Research, Science and Therapy Committee, 2001)." In a 2005 position paper, the American Academy of Periodontology stated that "supragingival lavage can assist individuals with gingivitis or poor oral hygiene. The greatest benefit is seen in patients who perform inadequate interproximal cleansing. Patients report that the OI facilitates the removal of food debris in posterior areas, especially in cases of fixed bridges or orthodontic appliances, when the proper use of interdental cleaning devices is difficult" (Research, Science and Therapy Committee, 2005). However, anecdotal discussions and commentary continue concerning the appropriate use and efficacy of this instrument. OI devices can be used with water but also with antimicrobial agents (Flemmig *et al.*, 1990, Brownstein *et al.*, 1990, Jolkovsky *et al.*, 1990; Newman *et al.*, 1994, Fine *et al.*, 1994; Chaves *et al.*, 1994; Flemmig *et al.*, 1995; Felo *et al.*, 1997).

The objective of the present study was to test the adjunctive effect to toothbrushing of an OI with either a prototype jet tip or a standard tip in the potential to improve gingival health over a 4-week period. This prototype tip, which is configured with filaments, may help the user guide the tip along the gingival margin and the interproximal area. Both OI tips were compared to the use of dental floss. These treatments were combined with the use of a regular flat trimmed manual toothbrush together with a standard dentifrice.

Materials and methods

Study population

One hundred seventy-two subjects (non-dental students) from different universities and colleges in and around Amsterdam responded to an e-mail advertisement and reported for a screening appointment. The volunteers were informed about the study, first in a recruitment letter and secondly at the screening. Participation was not limited by race or gender. Subjects received a written explanation of the background of the study, its objectives and their involvement. Before screening for their suitability they were all requested to give their written informed consent. Subjects were required to fulfill the following criteria: ≥18 years of age, a minimum of five evaluable teeth in each quadrant (with no partial dentures, orthodontic banding or wires); moderate gingivitis (50% bleeding on marginal probing, Galgut *et al.*, 1998), an absence of oral lesions and/or periodontal pockets > 5 mm and/or generalized recession, and the absence of pregnancy and systemic diseases such as AIDS, cirrhosis, diabetes, any adverse medical history or long-term medication, or any physical condition that limits manual dexterity. All subjects received oral and written information about the products and purpose of the study. One hundred eight subjects met the inclusion criteria and were enrolled into the study, which was conducted in accordance to the ethical principles that have their origin in the Declaration of Helsinki and was consistent with Good Clinical Practice guidelines. Medical Ethics Committee approval was obtained prior to the start of the study (MEC 09/198 #09.17.1322). All assessments took place at the Department of Periodontology at ACTA, Amsterdam, The Netherlands in September and October, 2009.

Study products

Three different interdental products were tested in this study, one product per group, with 36 subjects enrolled in each group. All subjects received a standard toothbrush (Oral-B Indicator 35, Procter & Gamble, Cincinnati, OH, USA, *Figure 1*) and standard fluoride dentifrice (Everclean, HEMA, Amsterdam, The Netherlands). In addition, subjects were randomized (see below for details) into one of three groups for assignment of an interdental cleaning device:

Group 1 (OIP): OI (DWJ-Waterpik® Ultra Water Flosser, Fort Collins, CO, USA) with a prototype jet tip (*Figure 2*, test group).

Group 2 (OIS): OI (DWJ-Waterpik® Ultra Water Flosser, Fort Collins, CO, USA) with a standard jet tip (*Figure 3*, benchmark control group, Husseini *et al.*, 2008).

Group 3 (DF): standard waxed floss (Johnson & Johnson, New Brunswick, NJ, USA) (*Figure 4*, control group).

Clinical assessment

Clinical parameters were assessed at baseline (S1), week 2 (S2), and week 4 (S3). First gingivitis and then plaque was scored. All gingivitis assessments were carried out by the same trained examiner (NLH). All plaque assessments were carried out by a second trained examiner (CEB). All examinations were carried out under the same conditions. All teeth were examined for both indices at six sites per tooth (disto-buccal, mid-buccal, mesio-buccal, disto-lingual, mid-lingual, mesio-lingual) except for 3rd molars.

Criteria

Gingivitis was assessed as the primary outcome using the bleeding on marginal probing index (BOMP) as described by Van der Weijden *et al.* (1994a, 1994b) and Lie *et al.* (1998). In short, the gingival margin is probed at an angle of approximately 60° to the longitudinal axis of the tooth and the absence or presence of bleeding is scored within 30 seconds of probing on a scale 0 - 2 (0 = no bleeding, 1 = pinprick bleeding, 2 = excessive bleeding).

Plaque was assessed as a secondary outcome using the Turesky (1970) modification of the Quigley & Hein (1962) plaque index (TQHPI) as described in detail by

Figure 1. Toothbrush - Oral-B indicator 35

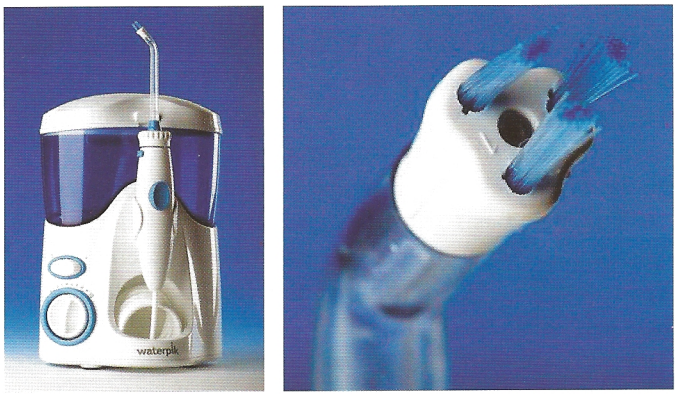

Figure 2. OIP - oral irrigator with prototype tip

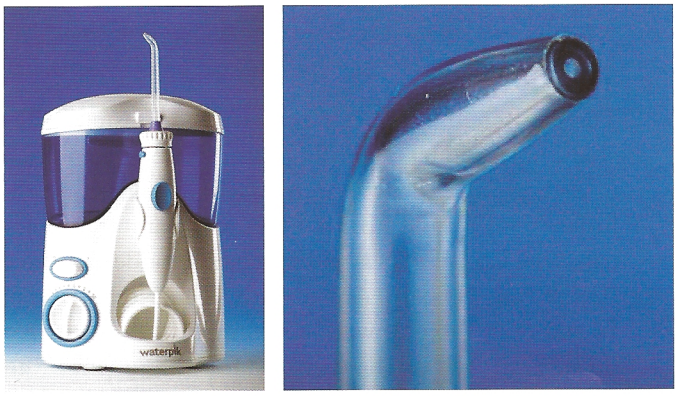

Figure 3. OIS - oral irrigator with standard tip

Figure 4. DF - standard waxed dental floss

Flowchart

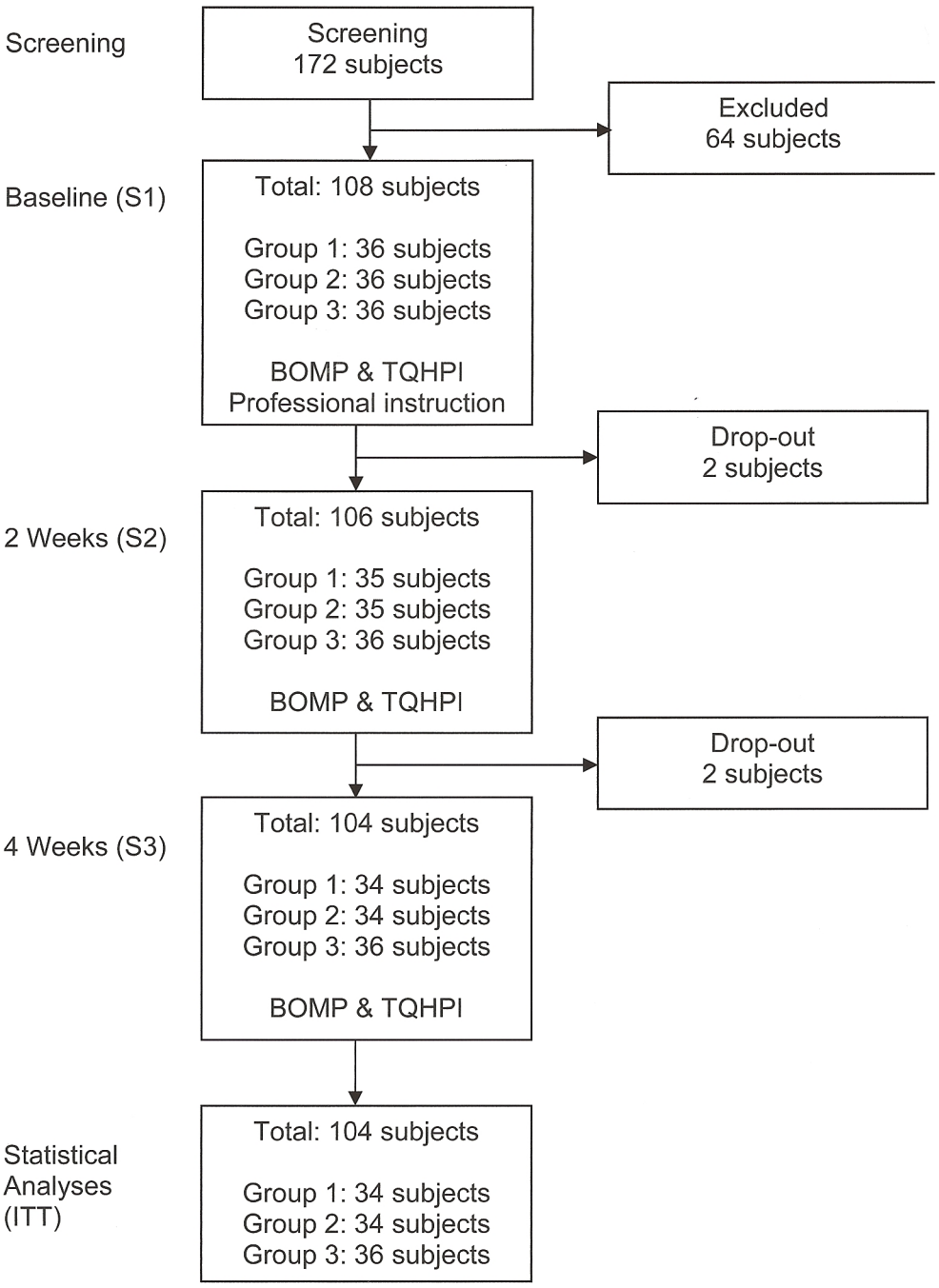

Figure 5. Flowchart

Paraskevas *et al.* (2007). Briefly, the teeth were dyed using a new cotton swab with fresh disclosing solution (Mira-2-Ton®; Hager & Werken GmbH & Co. KG. Duisburg, Germany) for each quadrant in order to disclose the plaque. Subsequently, the absence or presence of plaque was recorded on a 6-point scale (0-5, 0 = no plaque, 5 = plaque covering more than two-thirds of the tooth surface).

Study design

This study was designed as single masked, 3-group parallel, 4-week home use experiment. After meeting the inclusion criteria, completion of a medical questionnaire and informed consent, subjects returned to the clinic for their first (baseline) assessment (S1) for both clinical parameters (bleeding on marginal probing and plaque). At the start of the experiment all subjects received a unique trial number. Subjects were randomly assigned to one of three groups according to a randomization list (www.random.org). The allocation of products was carried out by the study coordinator, who was responsible for allocation concealment. All products were distributed in such a way that blindness of the examiners was assured. At the last visit (S3) the study coordinator assured blindness of the

examiners by collecting the study products in a separate room from where the clinical examinations took place. Subjects were also instructed not to mention anything to the examiners that could lead to allocation disclosure.

During the 4-week experimental phase OIS and OIP subjects used the OI once a day in the evening with lukewarm tap water and were instructed to finish one container of 500 ml at each occasion. Subjects in the control group (DF) used standard waxed dental floss once a day in the evening. At the baseline visit (S1), immediately following the baseline assessment, subjects used their allocated product for the first time. The study coordinator (NAMR) was present to provide detailed verbal instruction, a demonstration to ensure correct use, and aid with further personal instruction when necessary. Subjects in both OI groups were instructed to use the OI according to the instruction leaflet provided by the manufacturer. Subjects in the DF group were instructed to use their product according to the description of Van der Weijden *et al.* (2008). All subjects in each group were instructed to brush twice a day in their normal manner, once in the morning after breakfast and once in the evening. In the evening they subsequently used their assigned product (OI or DF). All participants were instructed to refrain from using any other oral hygiene product or device such as toothpicks, interdental brushes, mouthrinses, etc., during the study period. To check for compliance, subjects were asked to register the time of use of the products onto a calendar record chart.

After two weeks (S2), subjects returned to the clinic for the second clinical assessment for both gingivitis and plaque. After four weeks (S3), subjects visited the clinic for their final assessment for both parameters. Subjects were asked to return all products provided for this study as well as the calendar record chart. On each occasion subjects were instructed to brush between 2 and 3 hours prior to their appointments to avoid the risk of increased bleeding on probing as a result of toothbrushing (Abbas *et al.*, 1990). The day prior to each appointment all subjects received an SMS-message as a reminder with the following text: *"Remember that you have an appointment at ACTA! Note that you need to brush your teeth 2-3 hours prior to your visit. See you tomorrow! ACTA."* After the final assessment habitual oral hygiene procedures were resumed.

Data analyses

The unit of analysis was the subject and collected data were analyzed as intention to treat. The bleeding scores were used as the main response variable (Galgut *et al.*, 1998) and plaque scores as secondary response variable. *A priori* calculations with an alpha of 0.05, a difference of 0.0883 (between groups) of the bleeding index with 80% power, based on a pooled SD of 0.13 as derived from previous studies supported a sample size of 105. An analysis of covariance (ANCOVA) with S1 as covariate and S3 as dependent variable was performed to compare groups over time (Heynderickx *et al.*, 2005). Analyses comparing differences between the test and control groups at each time point were performed using non-parametric tests. Explorative analyses were performed to investigate the origin of the overall differences. *P* values of < 0.05 were accepted as statistically significant.

Results

Of 108 subjects who started the trial, four subjects did not complete the protocol. One chose not to continue the trial for personal reasons. Another left the country and moved abroad. Two did not attend the second visit because of scheduling conflicts. This resulted in a study population of 104 subjects providing evaluable data (*Figure 5*). The study population data on demographics and pre-study floss habits are presented in *Table 1*. No adverse events were reported by any of the subjects who participated in this study.

Results for bleeding on probing are presented in *Table 2*. The overall ANCOVA analysis showed a statistically significant difference between the three groups ($p = 0.007$). Mean overall reductions after four weeks of use (S1 to S3) were 0.15 for the OIP group, 0.17 for the OIS group, and 0.02 for the DF group. The mean bleeding scores of the three groups did not differ significantly at baseline. At session 2 the scores decreased for all three groups. Post testing showed that both the OI groups provided significantly lower bleeding scores as compared to the DF group. At session 3 a statistically significant difference could be detected among the three groups. Post testing showed that again both the OI groups had significantly lower bleeding scores as compared to the DF group. The 95% confidence interval of the difference compared to the DF group at S3 was -0.27 ± -0.04 for the OIP group and -0.28 ± -0.05 for the OIS group.

Results for plaque index are presented in *Table 3*. With regard to the plaque scores the overall ANCOVA analysis showed no statistically significant differences among the three groups ($p = 0.126$). Mean overall reductions after four weeks of use (S1 to S3) were -0.09 for the OIP group, 0.06 for the OIS group, and 0.01 for the DF group.

Discussion

Effective brushing remains the most obvious way of maintaining low levels of plaque and good gingival health. Gingivitis is known to be associated with the onset of periodontitis, and although the relationship between these two conditions may not be fully understood, the importance of maintaining good gingival health and

Table 1. Demographic data and pre-study flossing habits of the study population.

	Total	OIP	OIS	DF
N	104	34	34	36
Female	74	24	27	23
Male	30	10	7	13
Age [range] (SD)	21.8 [18-36]	21.9 (3.2)	21.1 (2.3)	22.4 (3.1)
Daily floss users	6	2	1	3
Weekly floss users	16	7	4	5
Monthly floss users	20	9	7	4
Seldom/never floss users	62	16	22	24

OIP, oral irrigation device with prototype jet tip; OIS, oral irrigation device with standard jet tip; DF, dental floss

Table 2. Mean bleeding index (BOMP) and mean % bleeding scores for all groups at all sessions.

	N	Session 1	Session 2	Session 3	Relative Reduction S1 – S2	Relative Reduction S1 – S3
OIP - index	34	0.82 (0.25)	0.65 (0.24)	0.67 (0.26)†		
%		46 %	37 %	39 %	20 %	15 %
OIS index	34	0.83 (0.23)	0.61 (0.27)*	0.66 (0.26)*		
%		46 %	34 %	38 %	26 %	17 %
DF - index	36	0.86 (0.26)	0.74 (0.26)	0.84 (0.30)		
%		47 %	41 %	47 %	13 %	0 %
p - value (Kruskal Wallis)		0.579	0.084	0.016		

Standard deviation in parentheses. Univariate analyses of covariance with session 1 as covariate and session 3 as dependent variable. ($p = 0.007$). *Statistically significant difference compared to DF group, $p < 0.05$ (Mann-Whitney). †Statistically significant difference compared to DF group, $p = 0.020$ (Mann-Whitney). OIP, oral irrigation device with prototype jet tip; OIS, oral irrigation device with standard jet tip; DF, dental floss

Table 3. Mean Quigley & Hein plaque scores ± standard deviation for all groups at all sessions.

	N	Session 1	Session 2	Session 3
OIP	34	1.64 ± 0.43	1.61 ± 0.34	1.73 ± 0.37
OIS	34	1.79 ± 0.34	1.74 ± 0.29	1.73 ± 0.28
DF	36	1.60 ± 0.26	1.51 ± 0.27	1.59 ± 0.27

Univariate analyses of covariance with session 1 as covariate and session 3 as dependent variable. ($p = 0.126$). OIP, oral irrigation device with prototype jet tip; OIS, oral irrigation device with standard jet tip; DF, dental floss

preventing periodontitis is well recognised (Van Dyke *et al.*, 1999). As the interproximal area is known as where the onset of gingival inflammation is likely to occur, the reason for interproximal plaque control seems clear. Although it is universally recognized that interproximal cleansing is essential for controlling periodontal disease (Löe, 1979), many people have difficulty accomplishing this with traditional dental floss (Asadoorian, 2006). Thus, compliance with floss is low (Warren and Chater, 1996), and various adjuncts for interdental cleaning have been studied. Dental floss, toothpicks, woodsticks and interdental brushes have all been recommended for this purpose.

The present study focussed on the ability to reduce gingival inflammation in a population of young individuals with moderate gingivitis using an OI. The OI works through the direct application of a pulsed stream of water or other solution. A study duration of four weeks was chosen to monitor the changes in the bleeding index, which meets the ADA guidelines on OI's for studies assessing the effects of adjunctive therapies on reduction of gingivitis (ADA, 2008). Studies of longer duration will more clearly demonstrate the clinical benefit that subjects will obtain from this product.

The efficacy of use of floss on the bleeding index was considered inconclusive in a systematic review by Berchier *et al.* (2008). The results of the present study are

in support of this statement. In contrast, in the present study both OI groups did show statistically significant improvements after four weeks. At the end of the study both OI groups show a significant 15 - 17% reduction of the bleeding index as compared to baseline. For the DF group this difference was not observed. Comparisons among groups showed a significant difference at four weeks between the DF group and both OI groups. The absolute difference of 8% and 9% at four weeks for both OI groups as compared to the floss group reveals a relative effect of 17% (OIP) and 19% (OIS). In consideration of the ADA guidelines for oral irrigators, the results of the present study do not reach the lower limit of superiority of 20% as estimated proportionate reduction related to clinical relevance as compared to standard oral hygiene procedures (ADA, 2008). However, the ADA also has guidelines on adjunctive dental therapies (ADA, 1997). In those guidelines a lower limit of 15% is applied. The study outcomes of the present study do comply with this guideline, indicating a potential beneficial effect for the OI.

With respect to plaque, the DF group started with a markedly lower score as compared to both OI groups. All subjects were instructed to brush 2-3 hours prior to examination, to reduce the risk of greater bleeding tendency (Abbas *et al.*, 1990). As the difference in PI scores was consistent throughout the study and was not reflected in bleeding index scores, it seems that subjects who were randomly allocated to the floss group coincidently performed better instant plaque removal by brushing at visit days. In a study carried out by Galgut *et al.* (2000) the effect of unevenly distributed baseline data is discussed and it was concluded that this might not influence the results and the conclusions drawn. Historically, plaque reductions are considered a prerequisite for an oral hygiene device to be considered effective (Löe *et al.*, 1965). A recent systematic review (Husseini *et al.*, 2008) reported no statistically significant reduction in plaque when the OI was used as an adjunct to toothbrushing when compared to toothbrushing only. Despite a lack of effect on plaque index, the studies that were included in this review did find a significant effect on bleeding and gingival indices. The mechanisms of actions underlying these clinical changes for the bleeding index in the absence of a clear effect on plaque are not understood, although different hypotheses have been put forward (Husseini *et al.*, 2008). One of the hypotheses is that supragingival irrigation alters the population of key pathogens, reducing gingival inflammation (Flemming *et al.*, 1995). Another hypothesis is that the water-pulsation may alter the specific host-microbial interaction in the subgingival environment (Chaves *et al.*, 1994). There is also the possibility that the beneficial action of an OI is at least partly because of the removal of loosely adherent soft deposits interfering with plaque maturation and stimulation of the immune response (Frascella *et al.*, 2000). Other explanations could be a mechanical stimulation of the gingiva or a combination of the above-mentioned factors (Frascella *et al.*, 2000; Flemmig *et al.*, 1990). Furthermore, irrigation may reduce the thickness of the plaque, which may not be easily detectable using 2-dimensional scoring systems (Jolkovsky *et al.*, 1990).

The absence of an effect for DF at four weeks may also seem surprising. A transient effect of 6% BI reduction was observed at two weeks. However, a recent systematic review supports this finding that dental floss has no significant effect on plaque or bleeding indices (Berchier *et al.*, 2008). The small effect observed at two weeks is most likely the result of a novelty or Hawthorne effect. The Hawthorne effect is a reaction of subjects to the realization they are in a study and are being observed (Adair *et al.*, 1984). The novelty effect and Hawthorne effect can be considered as certain placebo effects. The impact of a placebo effect should not be underestimated (Finniss *et al.*, 2010). In a study by Feil *et al.* (2002), the Hawthorne effect was intentionally used and shown to improve oral health. The novelty effect is something that could have influenced all groups within this model. Subjects were pre-selected on having "no experience" with an OI, whereas only six out of the 104 were regular flossers (*Table 1*). The rebound that is observed from the 2-week to the 4-week follow-up is, however, most evident in the floss users. With respect to the Hawthorne effect, this is probably not only present in the DF group but also in both OI groups, as subjects were selected on having a bleeding index of > 50%. However at session 1 the bleeding index was already reduced to 46-47% for all three groups. This indicates that subjects already acted as if they were entered into the protocol before the first assessment of the primary response variable.

The results of the present study add to the existing data and clearly show a reduction in inflammation from using an OI. Interestingly, the reduction in bleeding could not be linked to plaque removal. This is similar to data presented by Flemmig *et al.* (1990) showing no change in plaque scores for either the brushing group or the brushing and irrigation group from baseline to 6 months, but a significant difference in bleeding on probing and gingival index scores in favor of the irrigation group. Likewise, Flemmig *et al.* (1995) reported that the water irrigation group was significantly better at reducing bleeding on probing and gingival index scores compared to the regular oral hygiene group at six months. Also in this study there were no statistically significant differences detected in plaque scores among the groups. Chaves *et al.* (1994) found similar reductions in plaque scores for water irrigation compared to toothbrushing alone, and a significant difference for bleeding on probing in favor of the irrigation group at six months.

These studies support the present data in finding no correlation between reduction of plaque biofilm and inflammation in 3-6 months.

Conclusion

There is a long-standing, well-documented body of evidence supporting the use of an oral irrigator. An oral irrigator is at least as effective as dental floss for reducing gingival bleeding and gingivitis. When combined with manual toothbrushing the use of an oral irrigator, either with a prototype or standard jet tip, is significantly more effective in reducing gingival bleeding scores as compared to the use of dental floss, as determined within the limits of this 4-week study design.

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D.M. Lyle is the director of professional and clinical affairs for Water Pik, Inc. The authors employed by ACTA declare that they have no conflict of interest.

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