# Waterpik® Clinical Research Summary







The evolution of the Waterpik® Water Flosser spans 6 decades beginning in the 1960s where research findings demonstrated safety and efficacy in improving oral health, to the 21st century demonstrating its superiority to other self-care aids.

This has been possible by the commitment of Waterpik® to adhere to the, "ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects".¹ These guidelines have their origin in the Declaration of Helsinki. This assures the public that the trial participants' rights, safety and well-being is protected and that the clinical trial data are credible.²

Clinical trials with the Waterpik® Water Flosser are conducted at independent universities and clinical research organizations (CRO) that follow these guidelines. We also strive to provide clinically meaningful results that address oral hygiene needs and products that are quick and easy to use.

Collectively, the 80+ research studies published in peer-reviewed journals have unequivocally demonstrated the Waterpik® Water Flosser is safe and effective for multiple patient needs.³ This information provides a solid base for making informed decisions regarding patient self-care recommendations that work and help increase compliance.

In 2017 the Waterpik® Water Flosser was the first in the powered interdental class to receive the American Dental Association (ADA) Seal of Acceptance. The research demonstrated its ability to remove plaque interdentally and along the gingival margin and reduce or prevent gingivitis.

It is well established that brushing is not enough. The addition of a Waterpik® Water Flosser to either a powered or manual toothbrush is an evidence-based and practical choice.

Sincerely,

Carol

Carol A. Jahn, RDH, MS | Director Professional Relations & Education

- 1. U.S. Department of Health and Human Services. Food and Drug Administration. Center for Drug Evaluation and Research. Center for Biologics Evaluation and Research. March 2018. [Accessed November 20, 2019] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e6r2-good-clinical-practice-integrated-addendum-ich-e6r1
- 2. World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects. [Accessed November 20, 2019] https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
- 3. Bibliography of Waterpik research, page 26 27

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## Waterpik® Sonic-Fusion®: Up to 2X as Effective as Regular Brushing & Flossing for improving Gingival Health

Comparison of sonic-flossing toothbrush to brushing and flossing on inflammation

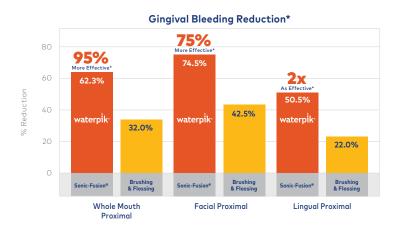
Lyle DM, Qaqish JG, Goyal CR, Schuller R. IADR/AADR/CADR General Session & Exhibition. Presented at IADR Virtual Oral Session, July 24, 2021. Submitted for publication.

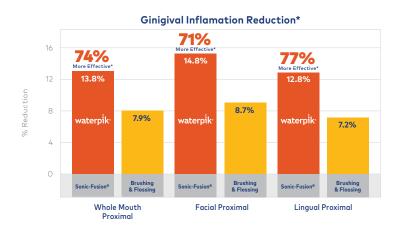
#### **Objective**

To determine the effectiveness of the Waterpik® Sonic-Fusion® in reducing plaque and clinical signs of inflammation as compared to manual brushing and flossing.

#### Methodology

One hundred and five subjects were randomized into three groups in this 4-week, parallel, single-blind, clinical trial. There were two experimental groups: Sonic-Fusion® with full (SFF) or compact (SFC) brush head. The control group use a manual brush and floss (MTF). Gingival health was measured using bleeding on probing (BOP) and the Modified Gingival Index (MGI) at baseline, 2-weeks, and 4-weeks. The Rustogi Modified Navy Plaque Index (RMNPI) scores were measured at baseline, 2-weeks, and 4-weeks. All subjects were provided written and verbal instructions.



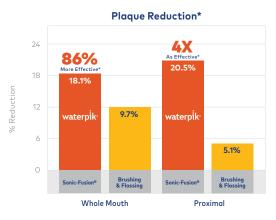


#### Results

All groups showed a significant reduction in BOP and MGI from baseline to 4-weeks (p<0.001). Both Sonic-Fusion® groups were significantly more effective than the MTF group for BOP, MGI, and RMNPI for whole mouth and interproximal areas.

#### Conclusion

This study demonstrates that the Waterpik® Sonic-Fusion® is up to twice as effective as traditional brushing and flossing for improving gingival health.



\*Statistically significant difference, p<0.001



## Waterpik<sup>®</sup> Sonic-Fusion<sup>®</sup>: Twice as Effective as Regular Brushing and Flossing for Removing Plaque and Improving Gingival Health.

Comparison of a Novel Sonic Toothbrush with a Traditional Sonic Toothbrush and Manual Brushing and Flossing on Plaque, Gingival Bleeding, and Inflammation: A Randomized Controlled Clinical Trial

Goyal CR, Qaqish, JG, Schuller R, Lyle D. Compend Contin Educ Dent. 2018;39(suppl 2):14-22.

#### Objective

To determine the effectiveness of Waterpik® Sonic-Fusion® in reducing plaque and the clinical signs of inflammation as compared to standard brushing and flossing.

#### Methodology

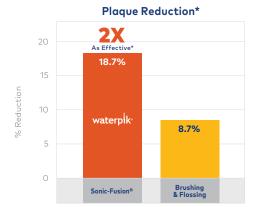
This is a randomized, controlled, parallel clinical trial. Thirty-five subjects were enrolled into each group. One group used Waterpik® Sonic-Fusion®, brushing for two minutes and flossing for one minute, and one group used an ADA standard toothbrush and dental floss. Gingival health was measured using bleeding on probing (BOP) and the Modified Gingival Index (MGI) at baseline, two weeks, and four weeks. The Rustogi Modified Navy Plaque Index (RMNPI) scores were measured at baseline, two weeks, and four weeks. All subjects were provided written and verbal instructions.

#### Results

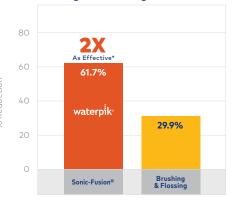
Both Sonic–Fusion® and standard brushing and flossing showed a significant reduction in plaque, BOP, and MGI from baseline to four weeks (p<0.001). The Waterpik® Sonic-Fusion® group was more than twice as effective than the standard brushing and flossing group for whole mouth measurements.

#### Conclusion

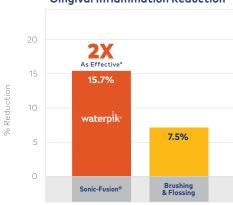
This study demonstrates that the Waterpik® Sonic-Fusion® is more than twice as effective as traditional brushing and flossing for improving oral health.



#### **Gingival Bleeding Reduction\***



#### **Gingival Inflammation Reduction\***



\*Statistically significant difference, p<0.001 twhole mouth results



## Waterpik<sup>®</sup> Sonic-Fusion<sup>®</sup>: Significantly More Effective than Sonicare<sup>®</sup> DiamondClean for Removing Plaque and Improving Gingival Health

Comparison of a Novel Sonic Toothbrush with a Traditional Sonic Toothbrush and Manual Brushing and Flossing on Plaque, Gingival Bleeding, and Inflammation: A Randomized Controlled Clinical Trial

Goyal CR, Qaqish, JG, Schuller R, Lyle D. Compend Contin Educ Dent. 2018;39(suppl 2):14-22.

#### Objective

To determine the effectiveness of Waterpik® Sonic-Fusion® in reducing plaque and the clinical signs of inflammation as compared to Sonicare® DiamondClean.

#### Methodology

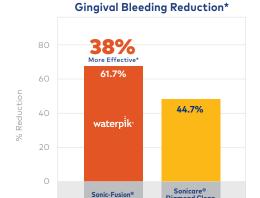
This is a randomized, controlled, parallel clinical trial. Thirty-five subjects who met the criteria were enrolled into each group. One group used Waterpik® Sonic-Fusion®, brushing for two minutes and flossing for one minute, and one group used Sonicare® DiamondClean electric toothbrush with DiamondClean Brush Head. Gum Health was measured using bleeding on probing (BOP) and the Modified Gingival Index (MGI) at baseline, two weeks, and four weeks. Plaque was evaluated by the Rustogi Modified Navy Plaque Index (RMNPI). Scores were measured at baseline, two weeks, and four weeks. All subjects were provided written and verbal instructions.

#### Results

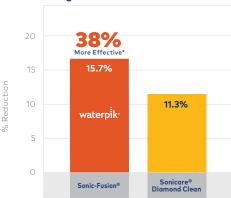
Both Sonic-Fusion® and Sonicare® DiamondClean showed a significant reduction in BOP and MGI from baseline to four weeks (p<0.001). The Waterpik® Sonic-Fusion® group was significantly more effective than Sonicare® DiamondClean for all clinical parameters, improving BPO by 38%, MGI by 38%, and RMNPI by 36%.

#### Conclusion

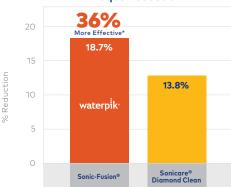
This study demonstrates that the Waterpik<sup>®</sup> Sonic-Fusion<sup>®</sup> is significantly more effective than Sonicare<sup>®</sup> DiamondClean for improving oral health.



#### Gingival Inflammation Reduction\*



#### Plaque Reduction\*



\*Statistically significant difference, p<0.001 twhole mouth results



#### Waterpik® Water Flosser Significantly Improves Oral Health Benefits over a High-End Oscillating Electric Toothbrush

Efficacy of the Use of a Water Flosser in Addition to an Electric Toothbrush on Clinical Signs of Inflammation: 4-Week Randomized Controlled Trial

Lyle, DM, Goyal CR, Qaqish JG, Schuller R. Compend Contin Ed Dent 2020; 41(3):170-177. Epub Jan 1, 2020.

#### Objective

To determine incremental efficacy of adding a Waterpik® Water Flosser to a high-end Oral-B® electric toothbrush, on the reduction of plaque and gingivitis, in comparison to brushing alone with the electric toothbrush.

#### Methodology

Seventy subjects completed this four week, randomized controlled trial. Subjects were assigned to one of two groups; Waterpik® Water Flosser plus Oral-B® Pro 2000 with Precision Clean brush head (WF); or Oral-B Pro 2000 with Precision Clean brush alone (OR). Gingivitis was evaluated by Bleeding on Probing (BOP) and Modified Gingival Index (MGI). Plaque was evaluated by Rustogi Modification of Navy Plaque Index (RMNPI). Data was collected at baseline, two weeks, and four weeks. Subjects were provided with manufacturer instructions on how to use.

#### Results

Both groups showed a significant reduction from baseline in BOP, MGI, and RMNPI at two weeks, and four weeks p<0.001. The WF group had significantly better results compared to the OR group for all clinical parameters, improving the reduction of BOP by 37%, MGI by 36%, and RMNPI by 33%, after four weeks.

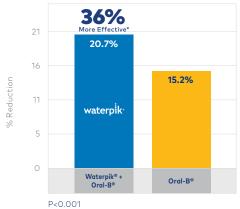
#### Conclusion

This study demonstrates that the addition of a Waterpik® Water Flosser to the use of a high quality oscillating electric toothbrush is significantly more effective versus using the electric toothbrush alone.

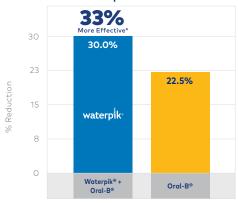
## Gingival Bleeding Reduction\* 37% More Effective\* 75.3% 55.1% Waterpik\* Oral-B\* Oral-B\*

P<0.001





#### Plaque Reduction\*



p=0.003
\*Statistically significant difference
†whole mouth results



#### Waterpik<sup>®</sup> Water Flosser: Adding a Waterpik<sup>®</sup> Water Flosser to a Manual Toothbrush is up to 3.1 Times as Effective as Brushing Alone

Effectiveness of Water Flosser Compared to Manual Toothbrush on Clinical Signs of Inflammation: A Randomized Controlled Trial

Goyal, CR, Lyle DM, Qaqish JG, Schuller R. Evaluation of the Addition of a Water Flosser to Manual Brushing on Gingival Health.

J Clin Dent 2018; 29(4):81-86. Study conducted at All Sum Research Center LTD, Mississauga, Ontario, Canada.

#### Objective

To determine the effectiveness of a Waterpik® Water Flosser in reducing clinical signs of inflammation as compared to brushing alone.

#### Methodology

Seventy-two subjects were randomized equally into two groups in this four week, parallel clinical trial: ADA standard manual toothbrush and Waterpik® Water Flosser (WF) or ADA standard manual toothbrush alone (MT). Inflammation was measured using bleeding on probing (BOP) and the Modified Gingival Index (MGI) at baseline, two weeks, and four weeks. The Rustogi Modified Navy Plaque Index (RMNPI) scores were measured at baseline, two weeks, and four weeks. Both groups brushed as they normally do and used the toothpaste provided.

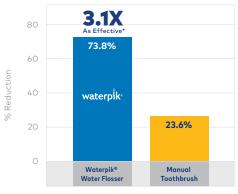
#### **Results**

Both groups showed a significant reduction in BOP, MGI, and RMNPI at four weeks (p<0.001, except marginal RMNPI for MT p=0.006). The WF group was significantly more effective for all clinical measures, up to 3.1x as effective for BOP, up to 2.7x as effective for MGI, and up to 2.4x as effective for plaque reduction.

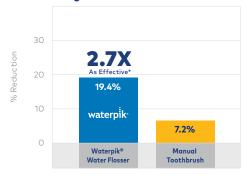
#### Conclusion

This study demonstrates that a Waterpik® Water Flosser and manual toothbrush are superior to brushing alone in the reduction of inflammation and dental plaque.

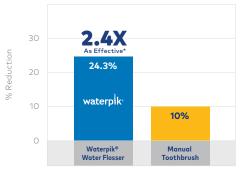
#### **Gingival Bleeding Reduction**



#### **Gingival Inflammation Reduction**



#### **Plaque Reduction**



p<0.001
\*Statistically significant difference
twhole mouth results



## Waterpik® Water Flosser Removes 99.9% of Plaque Biofilm After 3-Second Treatment

Biofilm Removal with a Dental Water Jet

Gorur A, Lyle DM, Schaudinn C, Costerton JW. Compend Contin Ed Dent 2009; 30 (Suppl 1):1-6. Study conducted at the University of Southern California School of Dentistry, USC Center for Biofilms, Los Angeles, California.

#### Objective

To evaluate the effect of the Waterpik® Water Flosser on plaque biofilm removal using scanning electron microscopy (SEM).

#### Methodology

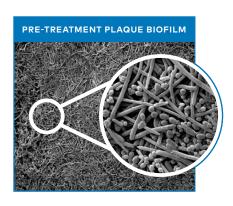
Eight periodontally involved teeth were extracted. Ten slices were cut from four teeth and were inoculated with saliva and left for four days to further grow plaque biofilm. Four slices were treated with the Classic Jet Tip, four slices were treated with the Orthodontic Tip, and two slices were used as controls. The remaining four teeth were treated with the Orthodontic Tip to evaluate the removal of calcified plaque biofilm. All teeth were treated using medium pressure for three seconds and evaluated by SEM.

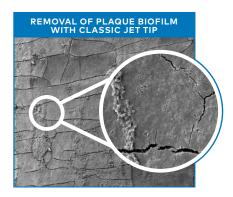
#### Results

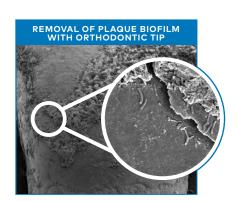
The Classic Jet Tip removed 99.9% and the Orthodontic Tip removed 99.8% of the plaque biofilm from the treated areas after a three-second exposure as viewed by SEM. The Orthodontic Tip significantly removed the calcified biofilm from the surface of the four teeth as viewed by the naked eye and SEM.

#### Conclusion

The Waterpik® Water Flosser significantly removes plaque biofilm.









## Waterpik® Water Flosser: Significantly More Effective than String Floss for Removing Plaque

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

Goyal CR, Lyle DM, Qaqish JG, Schuller R. J Clin Dent 2013; 24(2):37-42. Study conducted at BioSci Research Canada, Ltd., 3.

#### Objective

To compare the plaque removal efficacy of the Waterpik® Water Flosser to string floss combined with a manual toothbrush.

#### Methodology

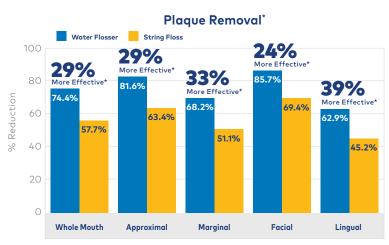
Seventy subjects participated in this randomized, single-use, single-blind, parallel clinical study. Subjects abstained from any oral hygiene for twenty-three to tweny-five hours prior to their appointment. Subjects were screened and assigned to one of two groups: Waterpik® Water Flosser plus a manual toothbrush, or waxed string floss plus a manual toothbrush. Instructions were provided for each product used. Each participant brushed for two-minutes using the Bass method. Group One used the Water Flosser with 500 ml of warm water and Group Two used waxed string floss cleaning all areas between the teeth. Subjects were observed to make sure 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 Navy Plaque Index.

#### Results

The Waterpik® Water Flosser was 29% more effective than string floss for overall plaque removal, 29% for approximal surfaces, and 33% for marginal surfaces.

#### Conclusion

The Waterpik® Water Flosser is significantly more effective than string floss in removing plaque for all tooth surfaces.



\*Statistically significant difference, p<0.001



## Waterpik® Water Flosser: Twice as Effective as String Floss for Reducing Gingival Bleeding

The Effect of Different Interdental Cleaning Devices on Gingival Bleeding

Rosema NAM, et al. J Int Acad Periodontol 2011; 13(1):2-10. Study conducted at the University of Amsterdam, Academic Center for Dentistry, Amsterdam.

#### Objective

To evaluate the efficacy of a manual toothbrush plus a Water Flosser versus a manual toothbrush plus traditional floss, to reduce gingival bleeding and plaque biofilm.

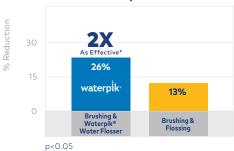
#### Methodology

One hundred and four subjects participated in this thirty-day, randomized, single-blind study. Group A used a Waterpik® Water Flosser with the Classic Jet Tip plus a manual toothbrush, Group B used a Waterpik® Water Flosser with the Plaque Seeker™ Tip plus a manual toothbrush, and Group C used waxed string floss plus a manual toothbrush. Subjects brushed twice daily and used either the Water Flosser or floss once daily in the evening. Gingival bleeding and plaque biofilm were evaluated at fourteen days and thirty days.

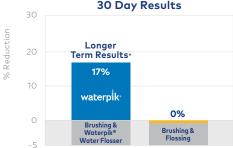
#### Results

After fourteen days, used in conjunction with manual toothbrushing, the Waterpik® Water Flosser with the Classic Jet Tip was twice as effective as traditional floss at reducing gingival bleeding.

#### Gingival Bleeding Reduction\* 14 Day Results



#### Gingival Bleeding Reduction\*



\*Statistically significant difference, p=0.007 \*Classic Jet Tip Data

At thirty days, the relative improvement in gingival bleeding for the Waterpik® Water Flosser groups was even more dramatic. There were no significant differences between the Waterpik® Water Flosser Classic Jet Tip and the Plaque Seeker™ Tip.

#### Conclusion

The Waterpik® Water Flosser is a more effective alternative to traditional dental floss for reducing gingival bleeding and improving oral health.



### Waterpik® Water Flosser: Over 50% More Effective than String Floss for Reducing Gingivitis

Comparison of Irrigation to Floss as an Adjunct to Toothbrushing: Effect on Bleeding, Gingivitis and Supragingival Plaque

Barnes CM, Russell CM, Reinhardt RA et al. J Clin Dent, 2005; 16(3): 71-77. Study conducted at the University of Nebraska Medical Center, College of Dentistry, Lincoln, Nebraska.

#### **Objective**

To evaluate the ability of a Waterpik® Water Flosser paired with either a power or manual toothbrush, and a manual toothbrush and floss, to reduce gingivitis, bleeding, and supragingival plaque biofilm.

#### Methodology

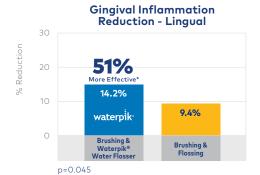
One hundred and five subjects participated in this four-week study. One group used a Waterpik® Water Flosser with a manual toothbrush and a second group used the Waterpik® Water Flosser with a power toothbrush. The control group used a manual toothbrush and floss. Subjects brushed twice daily and used either the Water Flosser or dental floss once daily. Plaque biofilm, bleeding, and gingivitis were evaluated at two and four weeks.

#### Results

At four weeks, the addition of a Waterpik® Water Flosser resulted in significantly better oral health, regardless of toothbrush type used, over manual brushing and flossing. Adding the Waterpik® Water Flosser was up to 93% better in reducing bleeding and up to 52% better at reducing gingivitis than traditional dental floss.

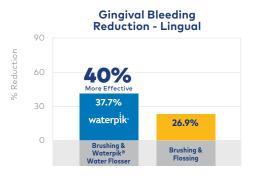
#### Conclusion

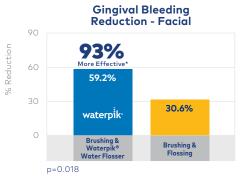
The Waterpik® Water Flosser is an effective alternative to traditional dental floss for reducing gingivitis.





p=0.035





\*Statistically significant difference



#### Waterpik® Water Flosser: Significantly More Effective than Interdental Brushes for Removing Plaque

Comparison of Water Flosser and Interdental Brush on Plaque Removal: A Single-Use Pilot Study.

Lyle DM, Goyal CR, Qaqish JG, Schuller R. J Clin Dent 2016; 27(1):23-26.

#### Objective

To determine the efficacy of a Waterpik® Water Flosser vs. interdental brushes for plaque removal.

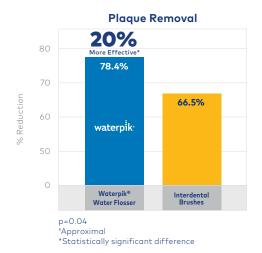
#### Methodology

Twenty-eight subjects completed this one-time use study. Subjects were randomly assigned to one of two groups: Waterpik® Water Flosser (WF) plus manual tooth brushing or interdental brushes (IDBs) plus manual tooth brushing. Plaque scores were obtained using the Rustogi Modification of the Navy Plaque Index (RMNPI). Subjects were instructed on the use of their interdental product. Post-cleaning scores were obtained after a supervised brushing and use of the interdental device. Scores were recorded for whole mouth, marginal, approximal, facial, and lingual regions for each subject.

#### Results

The Waterpik® Water Flosser group was significantly more effective than the IDB group for removing plaque from all areas measured. Specifically, the Waterpik® Water Flosser was 18% more effective for whole mouth and marginal areas, 20% for approximal areas, 11% for facial areas, and 29% for lingual areas.

# Plaque Removal 18% More Effective\* 70 71.5% 60 waterpik 60.6% Vaterpik Water Flosser p<0.001 \*Whole Mouth



#### Conclusion

The Waterpik® Water Flosser and manual toothbrush removes significantly more plaque from tooth surfaces than interdental brushes and a manual toothbrush after a single use.



## Waterpik<sup>®</sup> Water Flosser: Significantly More Effective than Interdental Brushes for Improving Gingival Health

Comparison of Water Flosser and Interdental Brush on Reduction of Gingival Bleeding and Plaque: A Randomized Controlled Pilot Study.

Goyal CR, Lyle DM, Qaqish JG, Schuller R. J Clin Dent 2016; 27: 61-65.

#### Objective

To determine the efficacy of a Waterpik® Water Flosser vs. interdental brushes for plaque and gingivitis reduction.

#### Methodology

Twenty-eight subjects completed this two week study. Subjects were assigned to one of two groups: the Waterpik® Water Flosser (WF) plus a manual toothbrush or interdental brushes (IDBs) plus a manual toothbrush. Gingival health was evaluated by measuring bleeding on probing (BOP) at six sites per tooth. Plaque removal was measured using the Rustogi Modification of the Navy Plaque Index (RMNPI).

#### Results

The Waterpik® Water Flosser was significantly more effective than the interdental brushes for reducing gingival bleeding. Notably, the Waterpik® Water Flosser was 56% more effective for reducing whole mouth bleeding, and 53% more effective for reducing whole mouth approximal bleeding.

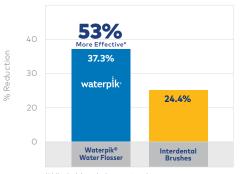
#### Conclusion

The Waterpik® Water Flosser is significantly more effective than interdental brushes for improving gingival health.

## Gingival Bleeding Reduction 40 56% More Effective\* 35.4% waterpik\*

†Whole Mouth

#### **Gingival Bleeding Reduction**



†Whole Mouth Approximal
\*Statistically significant difference, p<0.001



## Waterpik® Water Flosser: Significantly More Effective than Interdental Brush for Improving Gingival Health

Water flosser compared to interdental brush on bleeding scores and gingival abrasion

Slot DE, Lyle DM, Van der Sluijs E, Hennequin-Hoenderdos N, Van der Weijden F. J Dent Res 2018; 97(Special Iss. B): Abstract #0622 (www.iadr.org). Conducted at Academic Center for Dentistry Amsterdam (ACTA), Netherlands.

#### Objective

To compare the effectiveness of a Waterpik® Water Flosser (WF) and interdental brush (IDB) on bleeding indices and gingival abrasion.

#### Methodology

Seventy-eight subjects completed this four week, randomized controlled trial. Subjects were assigned to one of two groups; Waterpik® Water Flosser (WF) plus a manual toothbrush or an interdental brush (IDB) plus a manual toothbrush. Gingival inflammation was evaluated by measuring Bleeding on Pocket Probing (BOPP) and Bleeding on Marginal Probing (BOMP). Data was collected on contra-lateral quadrants. The Gingival Abrasion Score (GAS) was used to compare the incidence of abrasion between the groups.

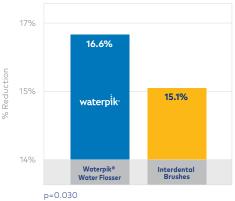
#### Results

Both groups demonstrated a significant reduction in BOPP and BOMP from baseline to four weeks for all sites and interdental sites separately. The WF group was significantly more effective than the IDB group for reducing BOPP for all sites at week four (p=0.030) and BOMP for all sites and interdental sites at week four (p=0.003, p=0.019 respectively). There were no differences in gingival abrasion scores between the groups.

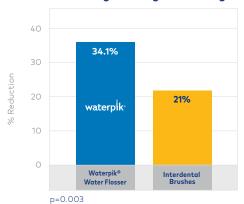
#### Conclusion

The Waterpik® Water Flosser is significantly more effective than the interdental brush for improving gingival health in this clinical study.

#### **Bleeding on Pocket Probing**



#### **Bleeding on Marginal Probing**



\*Statistically significant difference



### Waterpik<sup>®</sup> Water Flosser: Unequivocally Proven Safe in Clinical Studies Over 6 Decades

Safety of a Water Flosser: A Literature Review

Jolkovsky DL, Lyle DM. Compendium of Continuing Education in Dentistry 2015; 36(2):2-5.

#### Objective

Since the introduction of the first Waterpik® Water Flosser in 1962, over sixty clinical trials have been published. Collectively, the studies demonstrate significant plaque removal, reduction of gingival bleeding, and reversal of inflammation (gingivitis). The majority of the studies are randomized controlled trials and published in peer-reviewed journals providing the reader with the best evidence to make informed clinical decisions. This literature review was designed specifically to address the safety of a Water Flosser.

#### Methodology

This review was divided into four sections: histological findings, subgingival pathogens, probing pocket depth and clinical attachment levels, and bacteremia.

#### Results

- Histological findings: Studies showed a significant reduction in inflammation on the cellular level compared to non-treated sites which showed varying levels of inflammation. This confirms that a Waterpik® Water Flosser is safe for the periodontal pocket tissue.
- Subgingival pathogens: Studies show significant removal of subgingival pathogens, even in deep pockets, with the use of a Waterpik® Water Flosser. This was not generally seen in non-Water Flossed sites. This addresses the concern that bacteria might be driven deeper into pockets.
- Pocket depths and clinical attachment levels: Studies show a significant improvement in probing pocket depth and clinical attachment levels or no change. These studies address the concern that a Waterpik® Water Flosser might break the epithelial attachment.
- Bacteremia: Research shows the incidence of bacteremia is the same for tooth brushing, flossing, wood sticks, water flossing, and mastication.

#### Conclusion

The Waterpik® Water Flosser has been proven safe.

#### Findings from Clinical Studies on the Safety of the Waterpik® Water Flosser

- Histological reduction in inflammation
- Reduction or stability of probing pocket depth
- Improvement or stability of clinical attachment levels
- Removal of subgingival pathogenic bacteria
- Improvements in morphological subgingival flora
- No adverse effects reported
- Clinical changes demonstrating a reduction in gingivitis, inflammation, and plaque



#### Waterpik® Water Flosser: Safe and Effective up to 100 psi

**Evaluation of Water Flosser Saftey at High Pressure Settings** 

Goyal CR, Lyle DM, Qaqish JG, Schuller R. Evaluation of the safety of a water flosser on gingival and epithelial tissue at different pressure settings. Compend Contin Ed Dent 2018; 39(Suppl. 2):8-13.

#### **Objective**

To evaluate Waterpik® Water Flosser safety on gingival and epithelial tissue at high pressure settings.

#### Methodology

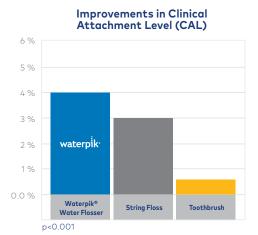
One hundred and five subjects were randomly assigned to one of three treatment groups in this six week, parallel clinical trial: Waterpik® Water Flosser plus manual toothbrush (WF), string floss plus manual toothbrush (SF), manual toothbrush only (MT). Data was collected on six designated teeth at baseline, two weeks, four weeks, and six weeks for clinical attachment level (CAL), probing pocket depth (PPD) and oral soft tissue (OST). For CAL and PPD data was recorded at six sites per tooth. Subjects were instructed to brush twice a day with the toothbrush and tooth paste provided. Written and verbal instructions were given for the WF and SF groups. The WF group changed pressure settings as instructed: #4 – 8 for two weeks, #9 for two weeks, and #10 for two weeks.

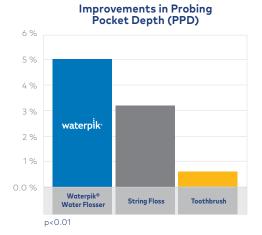
#### Results

No adverse effects were reported. The Waterpik® Water Flosser exhibited stability in clinical attachment level and probing pocket depths. The results compared favorably to string floss or manual brushing alone, demonstrating it is comparable, and in some sites, better than the SF and MT groups. No negative impact to Oral Soft Tissue occurred.

#### Conclusion

This study removes any concerns that the Waterpik® Water Flosser, regardless of pressure, is associated with a negative impact on the gingival tissue or epithelial attachment as measured by CAL and PPD. In fact, CAL and PPD improvements were observed for the Water Flossing group.







#### Waterpik<sup>®</sup> Water Flosser: An Effective Alternative to Subgingival Antibiotic Treatment for Periodontal Maintenance Patients

Periodontal Maintenance Following Scaling and Root Planing, Comparing Minocycline Treatment to Daily Oral Irrigation with Water

Genovesi AM, Lorenzi C, Lyle DM et al. Minerva Stomatol 2013; 62(Suppl. 1 to NO. 12):1-9. Study conducted at the Tuscan Stomatologic Institute, Department of Dentistry, Versilia General Hospital, Lido di Camaiore (LU), Italy.

#### Objective

Assess the efficacy of daily Water Flossing in comparison to subgingival minocycline treatment for subjects with moderate to severe periodontitis.

#### Methodology

In this single-center, parallel, single-blind, randomized clinical study, thirty subjects with moderate to severe periodontitis were placed into a minocycline-treated group or a Water Flossing group. Scaling and root planing was carried out, and both groups received instruction on proper home-based oral hygiene. One group was administered minocycline inside their deepest periodontal pockets at the initial hygiene visit. The second group was instructed to use a Waterpik® Water Flosser once a day. Clinical and microbiological parameters were measured at baseline and repeated after thirty days.

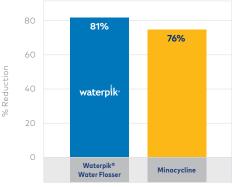
#### Results

Both the Waterpik® Water Flosser and minocycline treatment groups experienced a significant reduction in all clinical parameters tested at thirty days. The Water Flosser group reduced bleeding 81% v. 76% for the minocycline group. Moreover, both procedures effectively reduced the typical parameters of periodontitis (bleeding on probing, pocket depth, and clinical attachment levels). Differences between the two therapies were not statistically significant for clinical parameters or bacterial suppression.

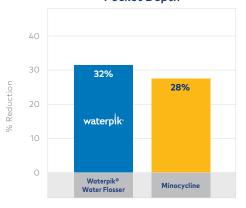
#### Conclusion

The Waterpik® Water Flosser is an effective alternative to subgingival antibiotics for periodontal maintenance patients over a thirty day period.

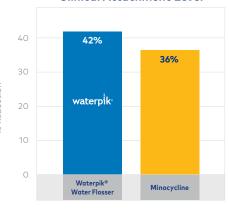
#### Bleeding on Probing



#### Percent Improvement of Pocket Depth



#### Percent Improvement of Clinical Attachment Level





#### Waterpik® Water Flosser: Using the Water Flosser to Deliver a Dilute of CHX Improves Periodontal Pocket Depth and Clinical Attachment Levels better than rinsing with CHX.

Evaluation of the efficacy of subgingival irrigation in patients with moderate-to-severe chronic periodontitis otherwise indicated for periodontal flap surgeries.

Jain R, Chaturvedi R, Pandit N, Grover V, Lyle DM, Jain A. J Indian Soc Periodontol 2020; 24(4):348-353. Study conducted at Institute of Dental Services, Panjab University, Chandigarh, India.

#### Objective

To evaluate the efficacy of a water flosser and toothbrush using 0.06% chlorhexidine (CHX) with Pik Pocket<sup>®</sup> tip compared to 0.12% rinse and toothbrush in moderate-to-severe chronic periodontitis patients who postponed or declined surgical intervention.

#### Methods

Forty subjects (40) were enrolled in this 3-month, randomized controlled clinical trial. Subjects were assigned to one of two groups: Group A was instructed to irrigate with 0.06% CHX twice a day after brushing and Group B was instructed to rinse with 15 ml of 0.12% CHX twice a day after brushing. All subjects received Phase I therapy consisting of scaling, root planing and oral hygiene instructions specific to their device and a standard manual toothbrush and toothpaste. Gingival index (GI), oral hygiene index simplified (OHIS) and bleeding on probing (BOP) scores were recorded at baseline, 2 weeks, 4 weeks, and 12 weeks post Phase I therapy. Pocket depth (PD) and clinical attachment level (CAL) were recorded on 6 sites per tooth. The modification of Lobene stain index was used to assess intensity and area for each subject to monitor the staining by CHX.

#### Results

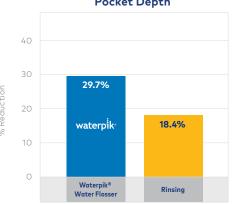
Thirty-six (36) subjects completed the study. Both groups showed a significant difference from baseline to 12 weeks for GI, OHIS, and BOP. There were no differences between the groups. Group A, irrigation with 0.06% CHX, was more effective than Group B, rinsing with 0.12% CHX, for reducing PD and CAL.

Group A had significantly less staining on the lingual surface than Group B (p=0.014).

#### Conclusion

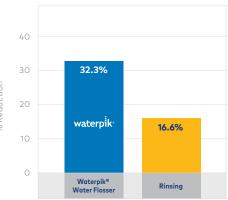
Waterpik® Water Flossing with 0.06% CHX and Pik Pocket® tip twice a day can significantly improve periodontal health status.

#### Percent Improvement of Pocket Depth\*



\*Statistically significant difference, p=0.004

#### Percent Improvement of Clinical Attachment Level\*



\*Statistically significant difference, p=0.002



## Delivering CHX with the Waterpik® Pik Pocket™ Tip is More Effective than Rinsing with CHX for Implant Maintenance

Effects of Subgingival Chlorhexidine Irrigation on Peri-Implant Maintenance

Felo A, Shibly O, Ciancio S, Lauciello F, Ho A. Am J Dent 1997; 10:107-110.

#### **Objective**

To evaluate the effect of the Waterpik® dental water with the Pik Pocket™ tip using half strength (0.06%) chlorhexidine (CHX) compared to rinsing with full strength (0.12%) CHX.

#### Methodology

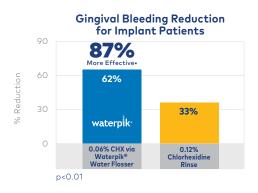
This randomized, three-month study involved twenty-four patients with a minimum of two implants. Once daily, half the subjects used the Waterpik® dental water jet with the Pik Pocket™ tip with 0.06% CHX and the other half rinsed with 0.12% CHX. Plaque, gingivitis, bleeding, stain, and calculus were evaluated.

#### Results

Patients who used the Waterpik® dental water jet and the Pik Pocket™ tip had significantly greater reductions in plaque, gingivitis, and stain than those who only rinsed with CHX. For bleeding, the Waterpik® dental water jet was 87% more effective at reducing gingival bleeding.

#### Conclusion

Patients who used the Waterpik® dental water jet and the Pik Pocket™ tip had significantly greater reductions in plaque, gingivitis, and stain than those who only rinsed with CHX.





p<0.005 \*Statistically significant difference



## Waterpik® Water Flosser: 2 Times as Effective as String Floss for Implant Patients

Comparison of the Effect of Two Interdental Cleaning Devices Around Implants on the Reduction of Bleeding: A 30-day Randomized Clinical Trial

Magnuson B, Harsono M, Stark PC, et al. Compend Contin Ed Dent 2013; 34(Special Issue 8):2-7. Study conducted at Tufts University, School of Dental Medicine, Boston, Massachusetts.

#### Objective

To compare the efficacy of a Waterpik® Water Flosser to string floss for implant patients.

#### **Methods**

Subjects were randomized into two groups; Group One used a manual toothbrush and a Waterpik® Water Flosser with the Plaque Seeker™ Tip (WF) and Group Two used a manual toothbrush and string floss (SF). There were twenty-two implants in each group, and the primary outcome was the reduction in the incidence of bleeding on probing. Subjects brushed twice a day and used either the WF or SF once a day.

#### Results

There were no differences between the groups at baseline. At thirty days, eighteen of the twenty-two (81.8%) implants in the WF group showed a significant reduction in BOP compared to six of the eighteen (33.3%) from the floss group. The WF group experienced 145% better reduction in gingival bleeding around implants vs. the string floss group (p=0.0018).

#### Conclusion

The Waterpik® Water Flosser is significantly more effective than string floss for improving gingival health around implants and is safe to use.

#### Gingival Bleeding Reduction 14 Day Results



#### Gingival Bleeding Reduction 30 Day Results



\*Statistically significant difference, p=0.0018



## Waterpik® Water Flosser: Significantly more effective at reducing the severity of mucositis.

The effect of adjunctive oral irrigation on self-administered oral care in the management of peri-implant mucositis. A randomized controlled clinical trial.

Bunk D, Eisenburger M, Hackl S, Eberhard J, Stiesch M, Grischke J. Clin Oral Implant Res 2020; 00:1-13. doi:10.1111/clr.13638. https://onlinelibrary.wiley.com/doi/full/10.1111/clr.13638?af=R. Study conducted at the Hannover Medical School, Hannover, Germany.

#### Objective

To evaluate the effect of adjunctive oral irrigation in addition to self-administered oral care on prevalence and severity of peri-implant mucositis.

#### Methods

Sixty (60) subjects completed this 12 weeks, randomized controlled, parallel clinical trial. Subjects were assigned to one of three treatment groups:

- Group 1 performed a standardized routine oral hygiene (ROH) consisting of brushing twice with and without toothpaste, interdental cleaning with device of choice.
- Group 2 performed ROH + water flossing with 50 ml water 1 x a day following tooth brushing and interdental cleaning in the evening.
- Group 3 performed ROH + water flossing with 50 ml 0.06% chlorohexidine (CHX) solution 1x a day following tooth brushing and interdental cleaning in the evening.

Clinical assessment was performed at baseline, 4, 8 and 12 weeks and included bleeding on probing (BOP), modified plaque-index (mPI) and mucositis-severity-score (MSS).

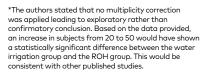
#### Results

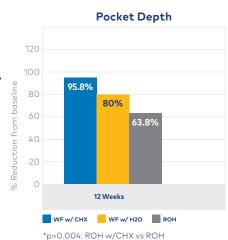
Waterpik® Water Flosser with 0.06% provided the highest reductions and was significantly more effective than the ROH group for BOP and MSS. Both Waterpik® groups reduced the mucositis-severity-score from moderate to mild.

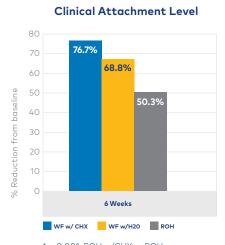
There were no differences between the CHX irrigation and the water irrigation groups for any measurement.\* The water irrigation was significantly more effective than the ROH group for adjusted mucositis-severity-scores at 12 weeks.

#### Conclusion

The Waterpik® Water Flosser with water was safe and more effective at reducing the severity of mucositis compared to ROH (brushing and interdental cleaning). The addition of 0.06% CHX showed a greater improvement.









#### Waterpik<sup>®</sup> Water Flosser: Removes > 90% Of Biofilm On Titanium Implant Surface Disc; Better Than CHX, Titanium Brushes And Nylon Brushes.

Effect of implant cleaning on surface alterations and titanium dissolution

Kotsakis G, Black R, Kum J et al. J Periodotol 2020; 1-12. DOI: 10.1002/JPER.20-0186. https://doi.org/10.1002/JPER.20-0186. Conducted at University of Washington, Seattle, USA.

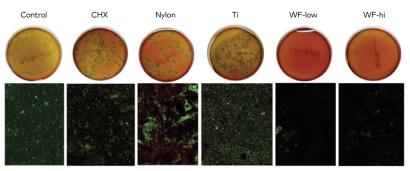
#### Objective

To determine the effects that mechanical peri-implantitis treatments have on titanium implant surfaces, and whether surface changes are associated with increases in titanium dissolution and loss of cytocompatibility.

#### Methodology

This study utilized two hundred acid etched micro-rough Titanium (Ti) discs as the substrate and multi species of human dental biofilm. A biofilm sample was obtain from a 56-year-old non-smoker male diagnosed with severe peri-implantitis. The biofilm sample was grown anaerobically on the 10 mm diameter Ti discs for 48 hrs. Sterile saline was used as negative control and 0.12% Chlorhexidine (CHX) was used as

#### Biofilm Removal after 30 second treatment.



Antimicrobial effect assays. Green stain is live bacteria, red stain is dead bacteria still on the disc and black area shows were the bacteria was removed. Image courtesy of Georgios A. Kotsakis, DDS, MS.

positive control. The mechanical treatments were a nylon brush (NB) and titanium brush (TB) with a surgical implant motor function at 300 rpms or a Waterpik® Water Flosser (WF) on low setting or high setting for 30s.

The discs were assessed for biofilm removal using colony forming units (CFU), surface alterations using scanning electron microscopy (SEM), atomic force microscopy (AFM) and stereomicroscopic imaging, and corrosion resistance and titanium dissolution rates using electrochemical cell model (over 30 days). Cell viability relationship to Ti surface changes was assess using a re-osseointegration model to evaluate the ability of osteoblasts to attach and proliferate following the different interventions.

#### Results

**Biofilm removal:** The WF groups showed >90% biofilm removal compared to saline solution (p<0.01). The CHX group was the least effective. The TB and NB showed partial biofilm removal.

**Surface alterations:** The WF and NB groups were similar to control demonstrating little to no change of the Ti surface. The Ti brush showed the most variation with larger peaks and valleys consistent with surface abrasion.

**Corrosion resistance and dissolution rates:** WF groups were the most stable resisting corrosion and dissolution of the Ti.

**Cytocompatibility:** WF groups and nylon brush group did not differ from control in number of live cell counts for increased compatibility. Ti brush and CHX had the least live cells.

#### Conclusion

The Waterpik® Water Flosser was more effective in removing biofilm compared to CHX, nylon brush, and Ti brush.



## Waterpik® Water Flosser: 3 Times as Effective as String Floss for Orthodontic Patients

The Effect of a Dental Water Jet with Orthodontic Tip on Plaque and Bleeding in Adolescent Orthodontic Patients with Fixed Orthodontic Appliances

Sharma NC, Lyle DM, Qaqish JG et al. Am J Orthod Dentofacial Orthop 2008; 133(4): 565-571. Study conducted at BioSci Research Canada, Ltd., Mississauga, Ontario, Canada.

#### Objective

To compare the use of a manual toothbrush and the Waterpik® Water Flosser with the Orthodontic Tip to manual toothbrushing and flossing with a floss threader on bleeding and plaque biofilm reductions in adolescents with fixed orthodontic appliances. A control group consisted of brushing only.

#### Methodology

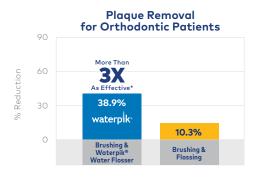
One hundred and five adolescents with fixed orthodontics participated in this single-center, randomized study. Bleeding and plaque biofilm scores were collected at baseline, day fourteen, and day twenty-eight.

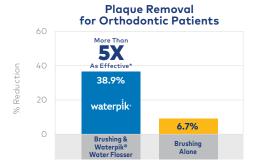
#### Results

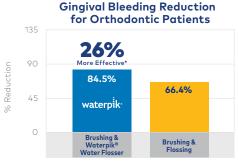
The Waterpik® Water Flosser was over three times as effective than flossing and over five times as effective than brushing alone for the reduction of plaque biofilm. For bleeding, the Waterpik® Water Flosser was 26% better than flossing and 53% better than brushing alone.

#### Conclusion

Adding a Waterpik® Water Flosser with the Orthodontic Tip to manual toothbrushing is significantly more effective at improving oral health in adolescent orthodontic patients than adding manual floss or brushing alone.







\*Statistically significant difference, p<0.001
†Whole Mouth



## Waterpik<sup>®</sup> Water Flosser: Significant Reduction in Plaque Biofilm, Gingivitis, and Bleeding for Patients with Diabetes

Comparative Evaluation of Adjunctive Oral Irrigation in Diabetics

Al-Mubarak S, Ciancio S, Aljada A, et al. J Clin Periodontol 2002; 29:295-300. Study conducted at the University of Buffalo, School of Dental Medicine.

#### Objective

To compare the addition of the Waterpik® Water Flosser with the Pik Pocket™ subgingival irrigation tip to routine oral hygiene on the periodontal health of people with diabetes.

#### Methodology

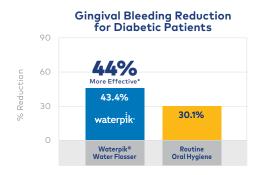
Fifty-two subjects with periodontal disease and either type 1 or type 2 diabetes participated in this three month randomized clinical trial. All subjects had scaling and root planing at baseline then were assigned to either add a Waterpik® Water Flosser with the Pik Pocket™ Tip twice daily to their oral hygiene routine or to continue practicing their regular oral hygiene routine. Periodontal health was measured via clinical and metabolic parameters.

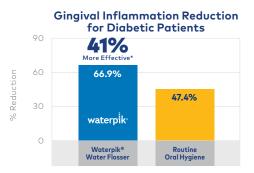
#### Results

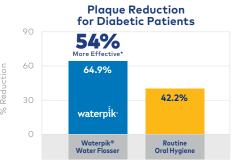
Adding the Waterpik® Water Flosser was superior to normal oral hygiene in reducing the traditional measures of periodontal disease: plaque biofilm, gingivitis, and bleeding on probing. The Waterpik® Water Flosser also reduced the serum levels of pro-inflammatory cytokines IL-1ß and PGE<sub>2</sub>, as well as the level of reactive oxygen species, a bacteria and host-mediated pathway for tissue destruction implicated in the pathogenesis of over one hundred conditions.

#### Conclusion

The Waterpik® Water Flosser provides significant periodontal health benefits, both clinically and biologically for people with diabetes.







\* Statistically significant difference, p≤0.03
†Whole Mouth



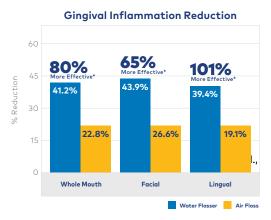
#### Waterpik® Water Flosser vs. Sonicare Air Floss

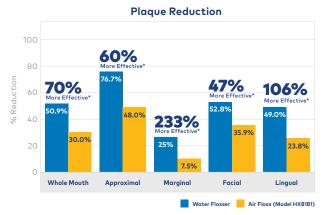
#### Waterpik<sup>®</sup> Water Flosser: 80% More Effective than Sonicare<sup>®</sup> Air Floss for Reducing Gingivitis

Comparison of two power interdental cleaning devices on the reduction of gingivitis

Sharma NC, Lyle DM, Qaqish JG, Schuller R. J Clin Dent 2012; 23(1): 22-26. Study conducted at BioSci Research Canada, Mississaugu, Ontario, Canada.

#### Go to Waterpik.com to read the full abstract.



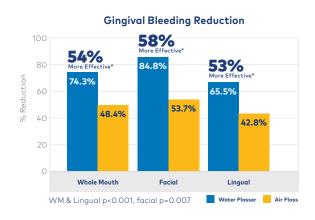


#### Waterpik® Water Flosser: Significantly More Effective than Sonicare® Air Floss Pro for Improving Gingival Health

Efficacy of Two Interdental Cleaning Devices on Clinical Signs of Inflammation: A Four-Week Randomized Controlled Trial.

Goyal CR, Lyle DM, Qaqish JG, Schuller R. J Clin Dent 2015; 26:55 – 60. Study conducted at All Sum Research Center, Mississauga, Ontario, Canada.

#### Go to Waterpik.com to read the full abstract.





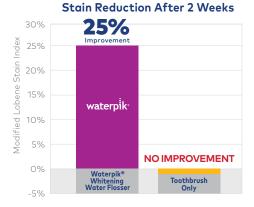
#### Whitening

### Waterpik<sup>®</sup> Whitening Water Flosser: Improved Stain Removal Over Tooth Brushing Alone

Evaluation of Tooth Whitening using a Liquid Dentifrice Delivered by the Whitening Water Flosser

Milliman JL, Milleman KR, Battershell K, Lyle DM. Study conducted at Salus Research, Fort Wayne, IN. 2014.

Go to Waterpik.com to read the full abstract.





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