PHILIPS
sonicare

Clinical studies

Notes from Dr. Joerg Strate

Head of Global Clinical Affairs
Philips Consumer Lifestyle

It is with great pleasure and admittedly an element of pride that we present to you the updated edition of the Philips Sonicare Clinical Proof Bbrochure. Some will notice that the time intervals of these updates have become shorter—this is a reflection of the dynamic developments here at Philips. Not only has the very successful launch of AirFloss literally created a new segment in the oral care market, but our most recent innovations like PowerUp have broadened our portfolio and made the benefits of Philips Sonicare technology accessible to an even larger group of patients and consumers.

None of this has changed the fundamentals of how we approach innovation: rigorous processes ensure that every new product from Philips Sonicare will deliver on its promise to provide superior results that are independently clinically validated. In many of our new products. you will see even more clearly the unique signature of Philips, a technology leader, driven by research excellence and with a commitment to make innovation truly meaningful.

Dental professional expertise will continue to help us find new ways and better solutions to help patients achieve lasting oral health improvements more easily, more predictably and safely.

FlexCare Platinum represents the latest understanding of oral care needs, featuring our most advanced brush head technology for superior plaque removal in hard-to-reach areas and pressure sensor technology that helps patients always get the best results when using their FlexCare Platinum. And the clinical data? I think you'll find convincing evidence in this booklet.

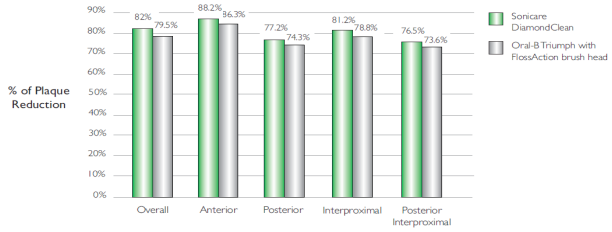
Philips – we continue our journey but we don't change the fundamentals.

Summary – Sonicare Superiority

Comparison of Plaque Removal by Philips Sonicare DiamondClean and Oral-B Triumph®

Argosino K, Jenkins W, Nelson M, Payne D, Rimmer T, Souza S.

Removes significantly more plaque than Oral-B Triumph overall and in hard to reach areas

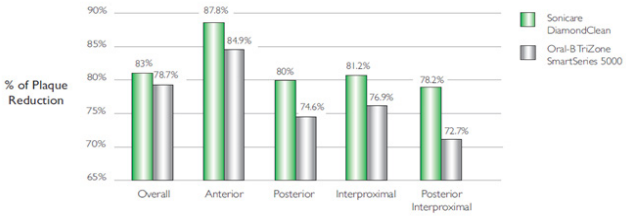


Comparison of plaque removal by Sonicare DiamondClean andOral-B TriZone SmartSeries 5000with SmartGuide

Maclure R, Moore F, Defenbaugh J, Souza S, Jenkins W, Ward M, Liu T, Nelson M.

Removes significantly more plaque than Oral-B Trizone [Deep Sweep] SmartSeries 5000 throughout the mouth

Removes significantly more plaque than Oral-B Trizone [Deep Sweep] SmartSeries 5000 in hard to reach areas



Comparison of Plaque Removal by Sonicare FlexCare Platinum and Oral-B Professional Care 5000 with Smart Guide

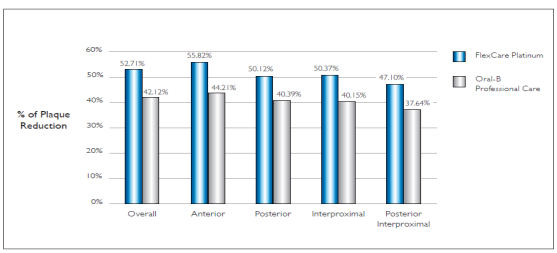
Defenbaugh J, Liu T, Souza S, Ward M, Jenkins W, Colgan P.

Removes significantly more plaque than Oral B ProfessionalCare 5000

Removes up to 25% more plaque than Oral B ProfessionalCare 5000

Delivers up to 3X more brush strokes than Oral-B Professional Care 5000 (for effective cleaning)

LS Means, Percent Plaque Removal



*Technical Memo Required

Plaque Removal

in vivo study

Comparison of plaque removal by Sonicare DiamondClean and Oral-B TriZone SmartSeries 5000 with SmartGuide

Maclure R, Moore F, Defenbaugh J, Souza S, Jenkins W, Ward M, Liu T, Nelson M.
Data on file, 2012.

Objective

To compare the plaque removal efficacy of Sonicare DiamondClean and Oral-B TriZone SmartSeries 5000 power toothbrushes.

Methodology

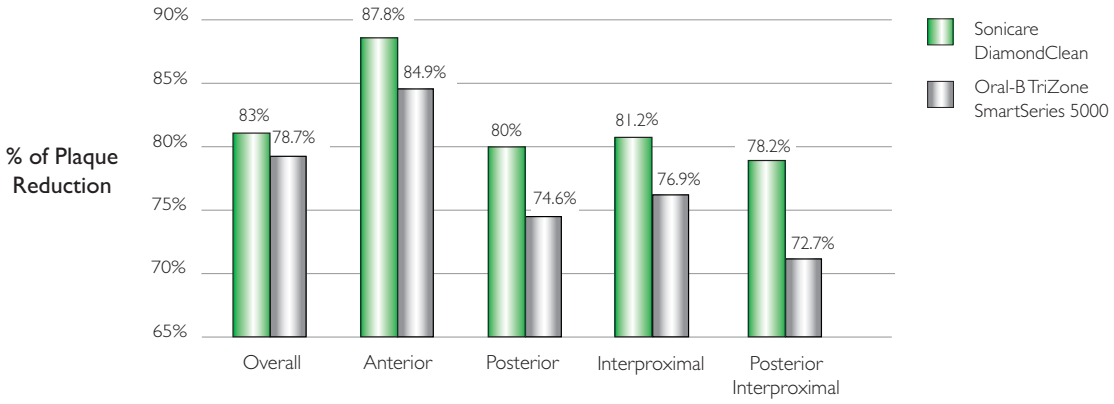
One-hundred nine healthy subjects aged 18 to 65 (mean age, 39.4 years) completed a randomized, cross-over single-blind clinical trial to assess the plaque removal efficacy and safety of Sonicare DiamondClean and Oral-B TriZone SmartSeries 5000 power toothbrushes. Study participants were non-smoking manual toothbrush users who presented with a Lobene and Soparker Modified Plaque Index score of ≥ 1.8 following 24 hours abstention from oral hygiene. Eligible subjects were enrolled in the study and randomly allocated to a sequence of power toothbrush product use for a three-day acclimation period followed by a three-day manual toothbrush washout. Subjects returned to the clinic for efficacy and safety assessment at Day 7 (+/- 1 day), having observed 24 (+/- 4) hours oral hygiene abstention. Subjects underwent a plaque evaluation by the blinded examiner and a safety assessment, followed by supervised product use for two minutes and a post-brushing plaque and safety examination. Thereafter, subjects were allocated the second power toothbrush per randomization and repeated the at-home acclimation and washout procedures. Subjects concluded the study at Day 14 (+/- 1 day) following plaque and safety examinations, as at Visit 3. Statistical analysis of the primary endpoint was performed utilizing a mixed-model F-test.

Results

Sonicare DiamondClean removed significantly more plaque overall (p-value=0.0008) than Oral-B TriZone SmartSeries 5000. Differences were more pronounced in hard-to-reach areas (posterior interproximal; p-value=0.0006). Both toothbrushes were safe for use.

Conclusion

Sonicare DiamondClean was found to remove significantly more plaque than Oral-B TriZone SmartSeries 5000 when assessed over the entire dentition as well as hard-to-reach areas.



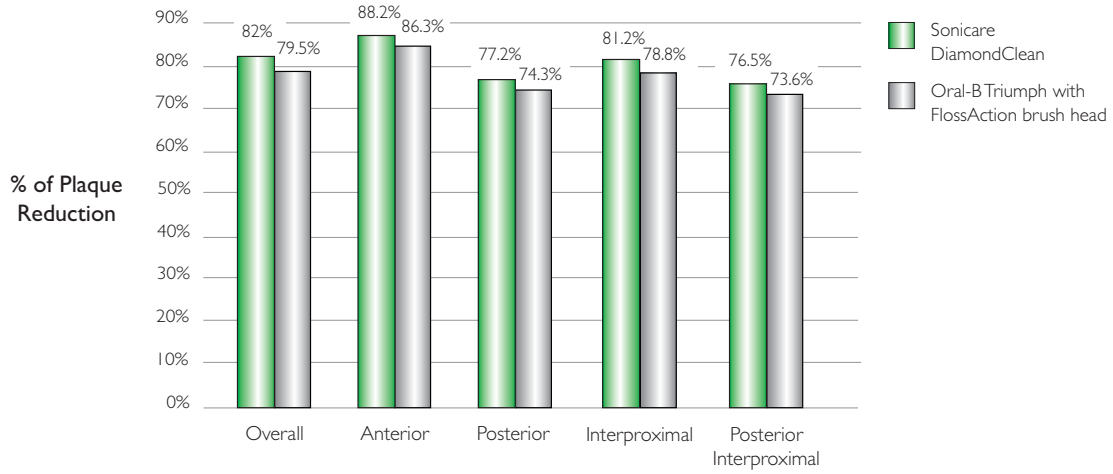
Plaque Removal

in vivo study

Comparison of Plaque Removal by Philips Sonicare DiamondClean and Oral-B Triumph®

Argosino K, Jenkins W, Nelson M, Payne D, Rimmer T, Souza S. Data on file, 2012

Objective	To compare the plaque removal efficacy and safety of two power toothbrushes; Philips Sonicare DiamondClean and Oral-B Triumph with FlossAction brush head.
Methodology	One-hundred four healthy adults, aged 18-65 were enrolled in a randomized, single-blind, cross-over design, ethics-approved clinical trial (67 females, 37 males; mean age 37 years). Eligible subjects were non-smokers who were routine manual toothbrush users with a minimum plaque score of 1.8 (Lobene and Soparker Modified Quigley and Hein) following 24hrs (+/-4) plaque accumulation. Enrolled subjects were randomized and dispensed appropriate products for a familiarization period of three days, followed by manual toothbrush use for a three-day wash-out. Subjects returned to clinic following 24hr (+/-4) plaque accumulation and received a pre-brushing plaque assessment by a blinded examiner, followed by supervised brushing with the assigned power toothbrush, and a post-brushing plaque examination. Subjects were then dispensed the alternate power toothbrush per randomization and followed the same home-use procedure of power toothbrush familiarization followed by manual toothbrush wash-out. Subjects presented to clinic for their final study visit with 24hr (+/-4) plaque accumulation and underwent 'pre' plaque exam followed by product use and 'post' plaque exam. Subjects were then dismissed from the study.
Results	Philips Sonicare DiamondClean was statistically significantly superior to Oral-B Triumph in reducing surface plaque overall, (p-value 0.0059), and in hard-to-reach posterior interproximal areas, (p-value 0.0048). Both products were safe for use.
Conclusion	Philips Sonicare DiamondClean removed significantly more plaque than Oral-B Triumph when assessed over the entire dentition, as well as in hard-to-reach areas.


% of Plaque Reduction
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
82%
79.5%
88.2%
86.3%
77.2%
74.3%
81.2%
78.8%
76.5%
73.6%
Overall
Anterior
Posterior
Interproximal
Posterior Interproximal
Sonicare DiamondClean
Oral-B Triumph with FlossAction brush head

Plaque Removal

in vivo study

Comparison of Plaque Removal by Sonicare FlexCare Platinum and Oral-B Professional Care 5000 with Smart Guide

Defenbaugh J, Liu T, Souza S, Ward M, Jenkins W, Colgan P. Data on file, 2013

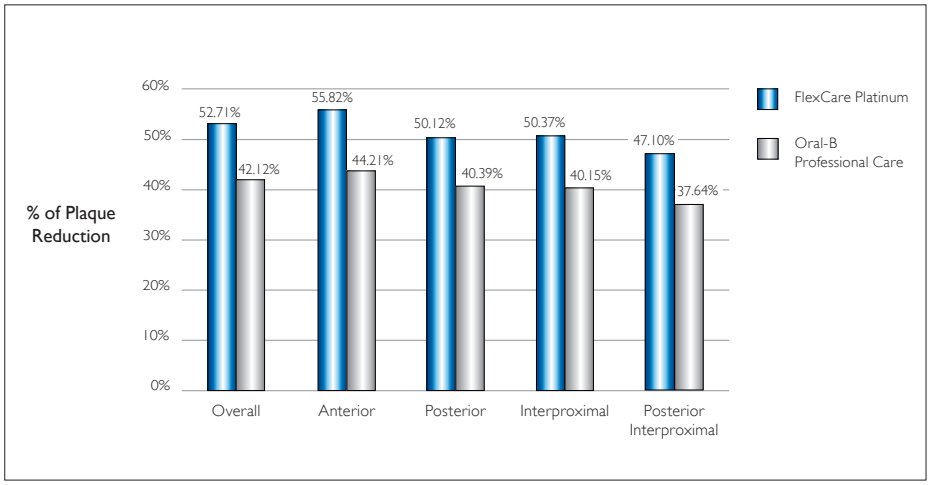
Objective	To compare the plaque removal efficacy and safety of two power toothbrushes; Sonicare FlexCare Platinum and Oral-B Professional Care 5000.
Methodology	One-hundred ten healthy adults (mean age 44.3 years, 94 female/16 male) were enrolled in this Ethics-committee approved crossover, Examiner-blinded clinical trial. Eligible subjects were non-smokers, aged 18-65 years who were routine manual toothbrush users. Enrolled participants had a minimum average plaque score of 1.8 (Lobene and Soparker Modified Quigley and Hein Plaque Index) following 24 (+/-4) hours plaque accumulation. All enrolled subjects were dispensed study products per randomization, either **Sonicare FlexCare Platinum and InterCare brush head or Oral-B Professional Care 5000 with FlossAction brush head and Smart Guide**, and instructed on product use technique. Study subjects commenced a 3-day power toothbrush use familiarization period followed by a manual toothbrush 3-day wash-out phase. Subjects then returned to clinic with 24 (+/-4) hours plaque accumulation and underwent an efficacy evaluation where plaque was assessed before and after supervised product use. Safety was assessed per subject report and intraoral examination. Subjects were then dispensed the alternate product per randomization and followed the same home-use procedure of power toothbrush familiarization followed by manual toothbrush wash-out. The final study visit was completed including the 24 (+/-4) hour plaque accumulation period and the in-clinic plaque and safety examinations before and after product use. Subjects were then dismissed from study.
Results	Philips Sonicare FlexCare Platinum was statistically significantly superior to Oral-B Professional Care 5000 in reducing surface plaque overall (p-value <0.0001) including in hard-to-reach posterior interproximal areas (p-value <0.0001). The reported safety events were mild in severity and were either unlikely or unrelated to test product use.

Conclusions

Philips Sonicare FlexCare Platinum was found to remove significantly more plaque than Oral-B Professional Care 5000 when assessed over the entire dentition and in all sub-regions of the mouth.

Both products were safe for use.

LS Means, Percent Plaque Removal



Plaque Removal

in vivo study

Comparison of plaque reduction by Sonicare FlexCare Platinum with InterCare brush head to Oral-B 6000 with CrossAction brush head

Maclure R, Moore F, Defenbaugh J, Mwatha A, Wei E, Ward M, Souza S, Jenkins W
Data on file, December 2014

Objectives

To compare the reduction in plaque of Philips Sonicare FlexCare Platinum with InterCare brush head and Oral-B 6000 with CrossAction brush head.

Methodology

One hundred and six healthy adults (84 females, 22 males) were enrolled and completed this Ethics-committee approved, cross-over, examiner-blinded clinical trial. Eligible subjects were non-smokers, aged 18–65 years who were routine manual toothbrush users. Enrolled subjects had a minimum average plaque score of ≥2.2 (Lobene and Soparker Modified Quigley and Hein Plaque Index) following 24 (+/-4 hrs) plaque accumulation. Subjects provided informed consent at Visit 1 and were screened for initial eligibility parameters. Within the following seven days, subjects returned to clinic for final efficacy assessments (plaque score) at Visit 2. Enrolled subjects were then randomized to either Sonicare FlexCare Platinum with InterCare brush head or Oral-B 6000 with CrossAction brush head. Both products were used in their respective "Deep Clean" modes. Subjects were provided instructions and were dispensed a compliance diary for home-use tracking. They were instructed to use the assigned power toothbrush for their next four brushings/two days to acclimate to usage; thereafter they were to utilize a manual toothbrush twice daily for a washout for the following five days. Subjects returned to clinic for Visit 3/Day 7 for safety and efficacy assessments where surface plaque was scored by the blinded Examiner before and after an in-clinic supervised brushing. Subjects were then provided the alternate power toothbrush and instructions, and followed the same home-use regime of power toothbrush use (two days) followed by manual toothbrush washout (five days). At the final visit (Visit 4/Day 14), efficacy and safety parameters were re-assessed following the same plaque assessment procedures and subjects were then dismissed from study.

Results

LS Mean (SE) Overall percent reduction for Philips Sonicare FlexCare Platinum with InterCare brush head was 74.10% (1.28), and for Oral-B 6000 with CrossAction brush head it was 65.41% (1.28).

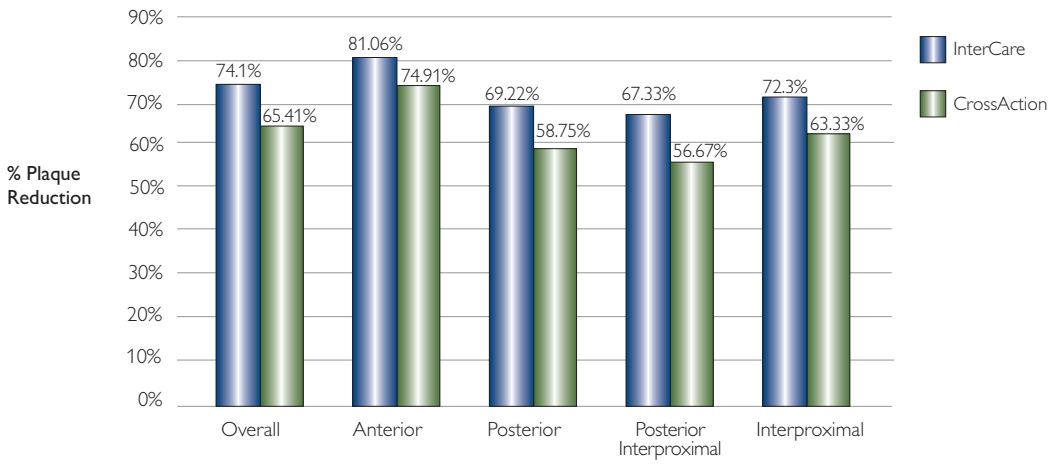
There were 23 adverse events reported, all of which were mild in severity. Eleven events were related or possibly related to the study.

Conclusions

Philips Sonicare FlexCare Platinum with InterCare brush head in Deep Clean mode was statistically significantly superior to Oral-B 6000 with CrossAction brush head in Deep Clean mode in removing surface plaque Overall (p-value <0.001), and in all sub-regions.

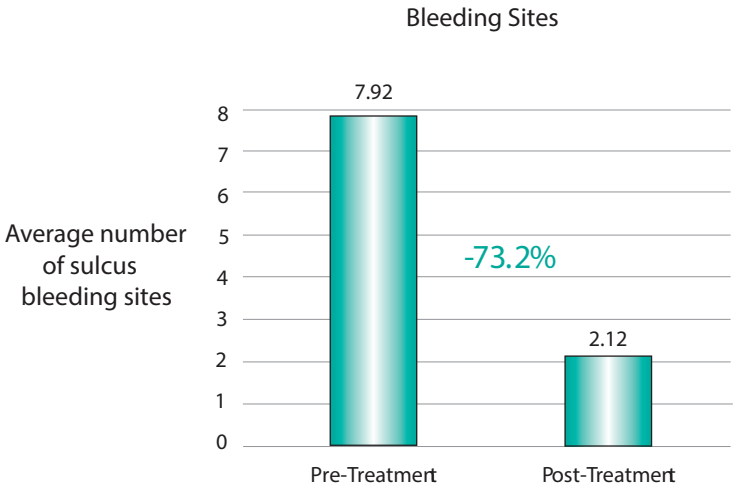
Both products were safe for use.

LS Means, Percent Plaque Reduction



Conclusion

Philips Sonicare AirFloss was reported by Registered Dental Hygienists (RDHs) to be a highly effective tool in improving interproximal cleaning and oral health among patients who have not successfully adopted interproximal care into their regular routine. Patients also reported better oral health and expressed a willingness to continue to use Philips Sonicare AirFloss after completion of the study. A large majority of RDHs in this study also indicated that they would recommend Philips Sonicare AirFloss to patients with mild to moderate gingivitis who currently do not floss.



Gum Health and Plaque Removal

in vivo study

A study to assess the effects of Philips Sonicare AirFloss Pro, when used with antimicrobial rinse, on gum health and plaque removal

Amini P, Gallob J, Olson M, Defenbaugh J, Souza S, Mwatha T, Jenkins W, Ward M.
Data on file, 2014

Objectives

To compare the effects of four home use oral hygiene regimens on gum health and plaque reduction

Methodology

Two-hundred eighty seven healthy adults (mean age 35.7 years, 184 female/103 male) were enrolled in this ethics-committee approved parallel, examiner-blinded clinical trial. Eligible subjects were non-smokers, aged 18–65 years, who were routine manual toothbrush users and self-reported as irregular, at most, in performing interdental cleaning. Enrolled participants had a minimum average plaque score of 0.5 per Rustogi Modified Navy Plaque Index following 2–6 hours plaque accumulation, and a minimum of 10 sites ≥1 per Gingival Bleeding Index. All enrolled subjects were dispensed study products per randomization, either an ADA reference manual toothbrush alone twice daily, or an ADA reference manual toothbrush in addition to once daily use of string floss or Sonicare AirFloss Pro with rinse (either Philips BreathRx or Listerine Cool Mint) dispensed to the interproximal space via the device. Subjects were instructed on product use technique and were to utilize the prescribed regimen for the following 28 days. Subjects returned to clinic at an interim time point of 14 days, and finally at 28 days for efficacy and safety evaluations following the 2–6 hour plaque accumulation period. Efficacy measures included gingival inflammation (MGI), gingival bleeding (GBI) and surface plaque (MPI). Safety was assessed per subject report and intraoral examination. Study products were collected from study participants at Day 28 and they were dismissed from study.

Results

For Gingival Inflammation (MGI) at Day 28, the overall percent reduction for the manual toothbrush treatment group was 1.09%. For string floss, it was 11.41% and for AirFloss Pro plus mouth rinse it was 9.03%.

For Gingival Bleeding (GBI) at Day 28, the overall percent reduction for the manual toothbrush treatment group was 4.02%. For string floss it was 43.31%, and for AirFloss Pro plus mouth rinse it was 38.63%

For plaque reduction (MPI) at Day 28, the overall percent reduction for the manual toothbrush treatment group was 5.71%. For string floss it was 26.47%, and for AirFloss Pro plus mouth rinse it was 23.18%.

There were four reported safety events that were deemed mild in severity and resolved.

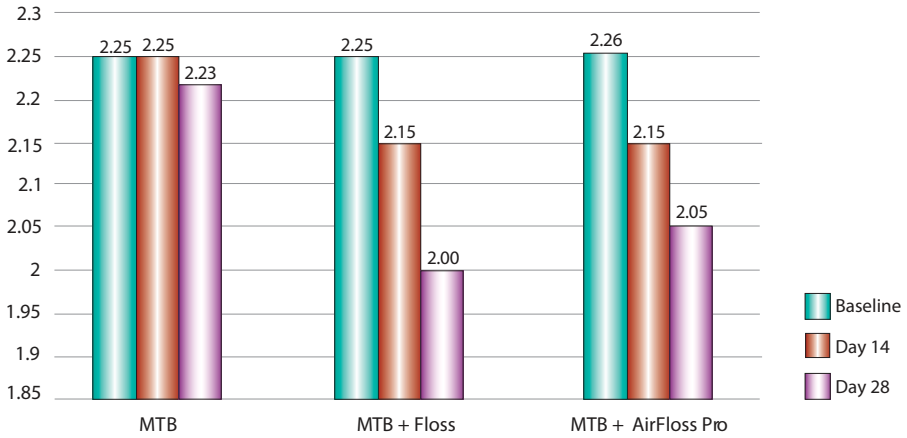
Conclusions

The use of an interproximal cleaning regimen as an adjunct to manual toothbrushing improves gum health and reduces plaque significantly better than manual toothbrushing alone.

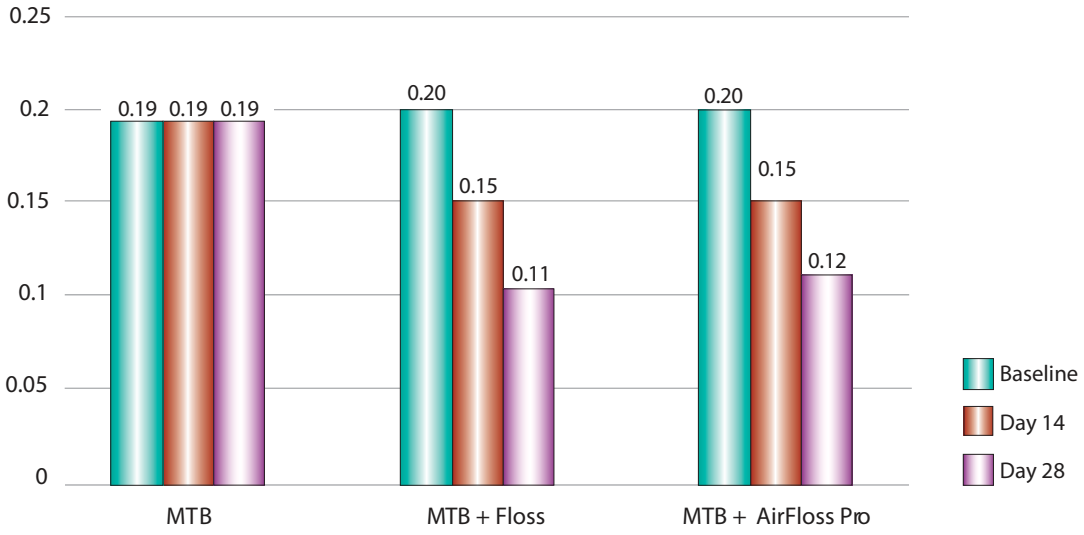
Among the adjunct interproximal cleaning regimens, Sonicare AirFloss Pro used with mouth rinse (either Philips Sonicare BreathRx or Listerine Cool Mint) dispensed to the interproximal space was shown to be as effective as string floss in improving gum health and removing interdental plaque for all efficacy measures (MGI, GBI, MPI).

All study products were safe for use.

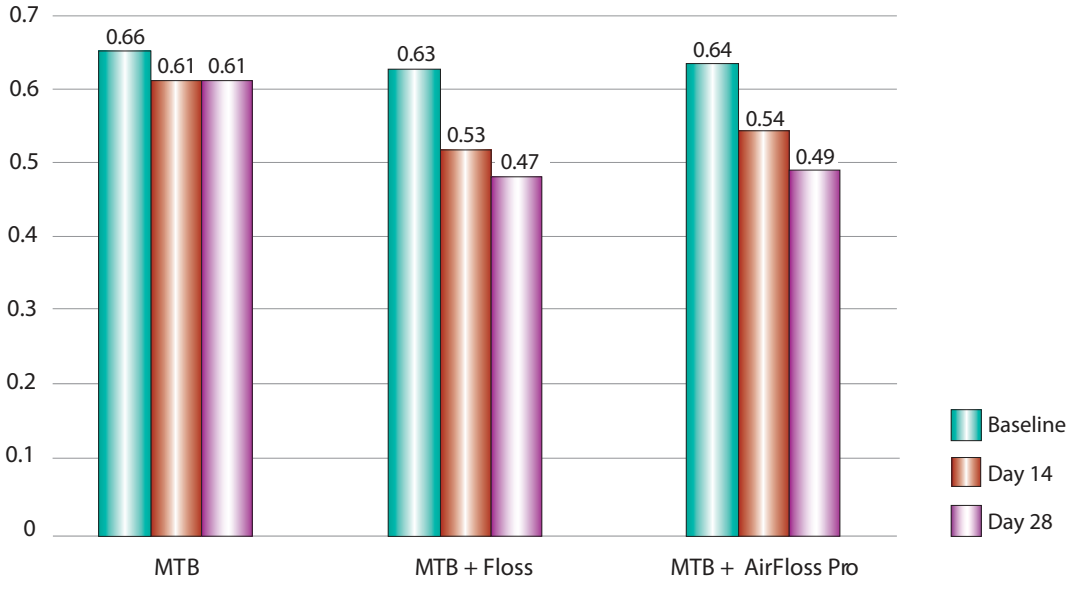
LS Means, Modified Gingival Index, Overall, Baseline, Day 14 and Day 28



LS Means, Gingival Bleeding Index Overall, Baseline, Day 14 and Day 28



LS Means, Modified Plaque Index Overall, Baseline, Day 14 and Day 28



Preference

Multicenter, practice-based, clinical observation of Philips Sonicare AirFloss

In a survey of 340 US dental hygienists and 670 US patients with mild to moderate gingivitis instructed to use Philips Sonicare AirFloss with mouthwash in a 60-day, in-vivo study. Data on file, 2013.

Introduction

A practice-based study was conducted to assess the influence of the Philips Sonicare AirFloss device on oral hygiene in an inconsistently flossing patient population with mild to moderate gingivitis. The study was executed and administrated by participating Registered Dental Hygienists (RDHs) who assigned the product to selected patients for a 60-day study period.

Objective

- To evaluate the oral health results of patients with mild to moderate gingivitis performing a daily interproximal cleaning regimen using Philips Sonicare AirFloss, which included tracking clinical markers of gingivitis, bleeding sites and overall oral health among participants.
- Assess Registered Dental Hygienist (RDH) and patient perceptions of the Philips Sonicare AirFloss device.

Methodology

The study group consisted of 670 patients, 323 adult male and 347 adult female dental patients between the ages of 25 and 64. They were evaluated by 340 Registered Dental Hygienists (RDH). The study was conducted in 47 states among patients who met the study criteria of mild to moderate gingivitis and reluctance to adopt a regular interproximal cleaning regimen. Each participant was provided with Philips Sonicare AirFloss and asked to fill the device with BreathRx mouthwash for routine use at home per the manufacturer's instructions for a 60-day period.

The RDHs were asked to provide pre and post-treatment assessment of the patients' oral health condition and measurements of clinical markers such as levels of gingival inflammation and number of bleeding sites.

Both the patients and the RDHs completed surveys after the trial period to assess their perceptions of the Philips Sonicare AirFloss device and the results it provided.

Results

Final analysis of data from 670 patient participants and 340 Registered Dental Hygienists (RDHs) showed that both groups were highly satisfied with Philips Sonicare AirFloss as an effective tool for increasing daily interproximal cleaning and improving oral health. Almost all (95%) of RDHs expressed a willingness to recommend Philips Sonicare AirFloss to patients who currently do not floss.

In addition:

RDHs (Patient Improvement Observations):

- RDHs reported improved gum health in 95% of their patients including reduction of gingival inflammation and bleeding
- RDHs reported an average of a 73% reduction in bleeding sites
- RDHs reported that 96% of patients showed improved oral hygiene
- RDHs reported that 95% of patients showed a reduction in gingival bleeding
- RDHs reported that 95% of patients showed a reduction in gingival inflammation
- 92% of RDHs observed a reduction in gingival inflammation in patients
- 91% of RDHs observed a reduction in gingival bleeding in patients
- 92% of RDHs noted an improvement in the patient's gum health

RDHs (General Observations):

- 95% of RDHs would recommend Philips Sonicare AirFloss to patients who do not currently floss
- 93% of RDHs would recommend Philips Sonicare AirFloss to patients who have gingivitis
- 91% of RDHs would recommend Philips Sonicare AirFloss to a friend or family member
- 90% of RDHs reported that Philips Sonicare AirFloss would make it easier for their patients to incorporate interdental cleaning into their daily oral care routine

Patients:

- 82% of patients said that they loved Philips Sonicare AirFloss and wouldn't want to give it up
- 91% of patients said it would be an easy addition to their current oral routine
- 91% of patients indicated feeling better about their oral health after using the Philips Sonicare AirFloss
- 90% of patients said they would now include Philips Sonicare AirFloss in their daily oral care routine
- 89% of patients would recommend Philips Sonicare AirFloss to a friend or family member
- 85% of patients who tried Philips Sonicare AirFloss said they wouldn't want to give it up
- 81% of patients said their mouth never felt cleaner and fresher than with using Philips Sonicare AirFloss with mouth rinse

Gum Health and Plaque Removal

in vivo study

A study to assess the effects of Philips Sonicare AirFloss Pro, when used with antimicrobial rinse, on gum health and plaque removal

Amini P, Gallob J, Olson M, Defenbaugh J, Souza S, Mwatha T, Jenkins W, Ward M.
Data on file, 2014

Objectives

To compare the effects of four home use oral hygiene regimens on gum health and plaque reduction

Methodology

Two-hundred eighty seven healthy adults (mean age 35.7 years, 184 female/103 male) were enrolled in this ethics-committee approved parallel, examiner-blinded clinical trial. Eligible subjects were non-smokers, aged 18–65 years, who were routine manual toothbrush users and self-reported as irregular, at most, in performing interdental cleaning. Enrolled participants had a minimum average plaque score of 0.5 per Rustogi Modified Navy Plaque Index following 2–6 hours plaque accumulation, and a minimum of 10 sites ≥1 per Gingival Bleeding Index. All enrolled subjects were dispensed study products per randomization, either an ADA reference manual toothbrush alone twice daily, or an ADA reference manual toothbrush in addition to once daily use of string floss or Sonicare AirFloss Pro with rinse (either Philips BreathRx or Listerine Cool Mint) dispensed to the interproximal space via the device. Subjects were instructed on product use technique and were to utilize the prescribed regimen for the following 28 days. Subjects returned to clinic at an interim time point of 14 days, and finally at 28 days for efficacy and safety evaluations following the 2–6 hour plaque accumulation period. Efficacy measures included gingival inflammation (MGI), gingival bleeding (GBI) and surface plaque (MPI). Safety was assessed per subject report and intraoral examination. Study products were collected from study participants at Day 28 and they were dismissed from study.

The Science Behind Sonicare AirFloss

PHILIPS
sonicare
sense and simplicity

Introduction from Dr. Joerg Strate

Vice President, Philips Oral Healthcare,
Clinical & Scientific Affairs

Philips Sonicare AirFloss

The name of our latest innovation is ambitious: Sonicare AirFloss. For decades, floss was the only widely recommended way to manage interdental oral hygiene in addition to the regular use of a toothbrush. Floss may be considered to be a functional solution, but patients find it difficult to use, resulting in infrequent use or complete omission.

Sonicare AirFloss replaces traditional flossing with micro bursts of water and air. Since the technological breakthrough of the first Sonicare power toothbrush, we have learned a lot about fluid forces and their ability to remove plaque biofilm. Sonicare AirFloss is a new technology chapter in the field of oral healthcare. It uses a unique spray of micro bubbles and a small dose of fluid to generate a gentle and convenient, yet highly effective, interdental cleaning action. Not only does it disrupt plaque biofilm structures in critical and hard-to-reach areas, it promotes healthy gums with the targeted release of water/air spray.

Sonicare AirFloss continues the Sonicare legacy of technology leadership within the oral healthcare segment. And while everything about Sonicare AirFloss seems quite different from the design and function of Sonicare toothbrushes, there is one area where AirFloss was submitted to the same rigorous criteria established for all Sonicare products: the meticulous clinical validation and verification of performance and safety requirements. The design and the concept are intriguing in themselves – but our clinical data are extremely convincing. With Sonciare AirFloss, interdental cleaning has just been reinvented.

Safety

in vivo study

Evaluation of surface wear by Philips Sonicare AirFloss and Waterpik Water Flosser on dental restorative materials

Yapp R, Powers JM, Jain V, de Jager M. Data on file, 2010

Objective

To investigate potential surface wear caused by Philips Sonicare AirFloss and the Waterpik Water Flosser on a dental restorative material with a relatively low surface hardness.

Methodology

To make this study a worst-case scenario for evaluating erosion of dental materials caused by pressurized water sprays, Durelon polycarboxylate cement (3M ESPE) was chosen because it is a popular luting cement and one of the softest (Vickers hardness of 20).

The Durelon specimens were flat discs, 10 mm in diameter and 3 mm thick, lightly polished to create flat surfaces and cleaned in an ultrasonic bath to remove any loose particles. Specimens were capped with soft impression material except in their center, where a round opening 2 mm in diameter allowed exposure to the sprays, such that the unexposed areas would serve as a control.

Eight Durelon test specimens were exposed to a total of 2,000 spray pulses with either Sonicare AirFloss or Waterpik Water Flosser (at pressure setting 5). Specimens were positioned at 1 mm distance from the nozzle and perpendicular to the spray, in such a way that water would run off the specimens to avoid interference with successive sprays.

Environmental scanning electron microscope (ESEM) inspection was used to determine if there was any visual evidence of erosion.

Results

Visual analysis with ESEM at 8X and 50X magnification did not disclose any difference between the erosion zones and non-erosion zones of any of the specimens, suggesting that neither the Sonicare AirFloss nor the Waterpik Water Flosser produced any obvious surface damage to the Durelon specimens, through 2,000 spray pulses.

Conclusion

Sonicare AirFloss is safe to use with dental restorative materials.

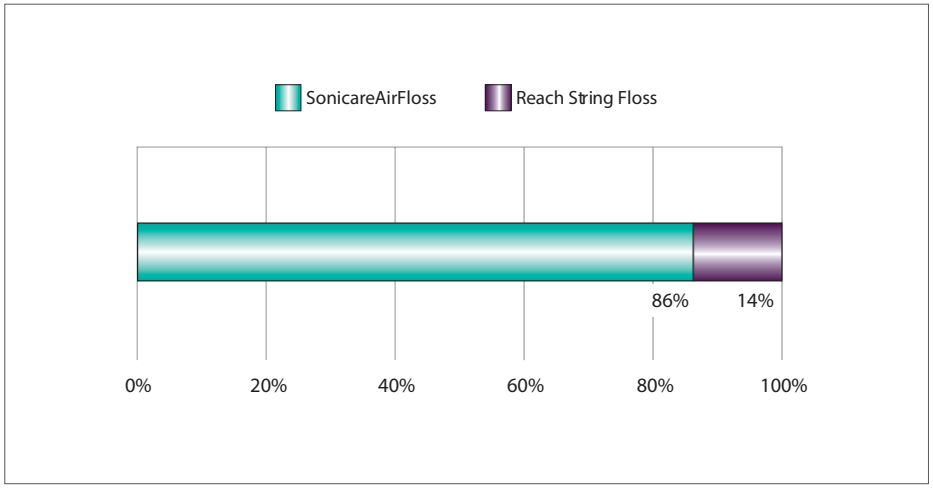
Preference

In-home use test to evaluate ease of use for Philips Sonicare AirFloss versus Reach string floss and Waterpik Ultra Water Flosser

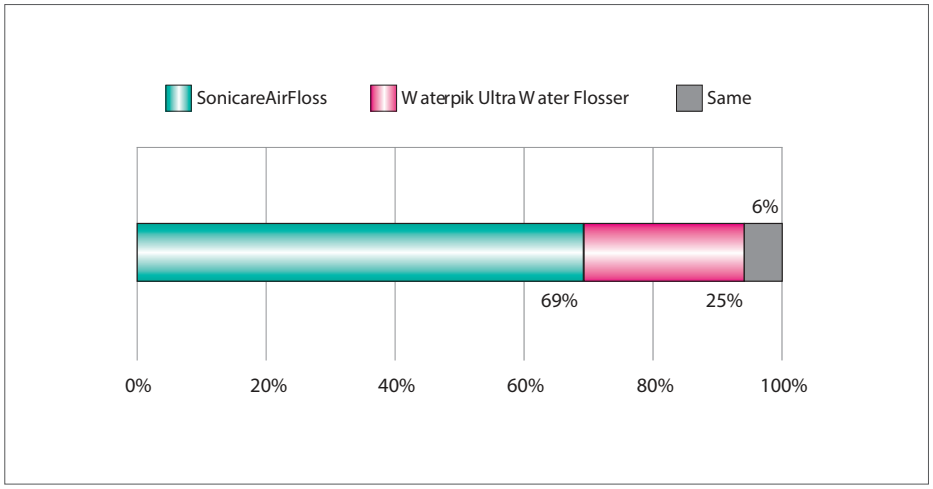
Krell S, Kaler A, Wei J. Data on file, 2010

Objective	To assess ease of use of Philips Sonicare AirFloss and two commercially available interproximal cleaning devices after using each device at home for one week.
Methodology	Eligible participants included 59 adult irregular flossers (floss from one time per month to three times per week).The study utilized a three-period, randomized crossover design.The three interproximal cleaning products tested were Sonicare AirFloss, Johnson & Johnson Reach unwaxed string floss and Waterpik Ultra Water Flosser (an oral irrigator). The study included four weekly, on-site visits, during which a new device was exchanged for the previous device until all of the three interproximal cleaning products were used, per randomized assignment. Participants were given a survey to report their feedback for the use of each product at the fourth visit. Feedback was recorded through an online questionnaire (Survey Monkey).
Results	All of the 59 participants completed the study and survey. Overall, participants were highly satisfied with the use of the Sonicare AirFloss. 86% and 69% of study participants reported Sonicare AirFloss as easier to use than string floss or an oral irrigator, respectively. 78% reported Sonicare AirFloss as gentler on the teeth and gums than string floss. 81% reported that Sonicare AirFloss provided better access to the back of the mouth than string floss.
Conclusion	Among a sample of irregular flossers, Sonicare AirFloss was reported by users to be a preferred alternative for cleaning between teeth, relative to other commonly used modalities. It elicited significantly higher scores for ease of use than floss or an oral irrigator, and Sonicare AirFloss rated higher for gentleness on teeth and gums and its ability to provide better access to the back of the mouth compared to string floss.

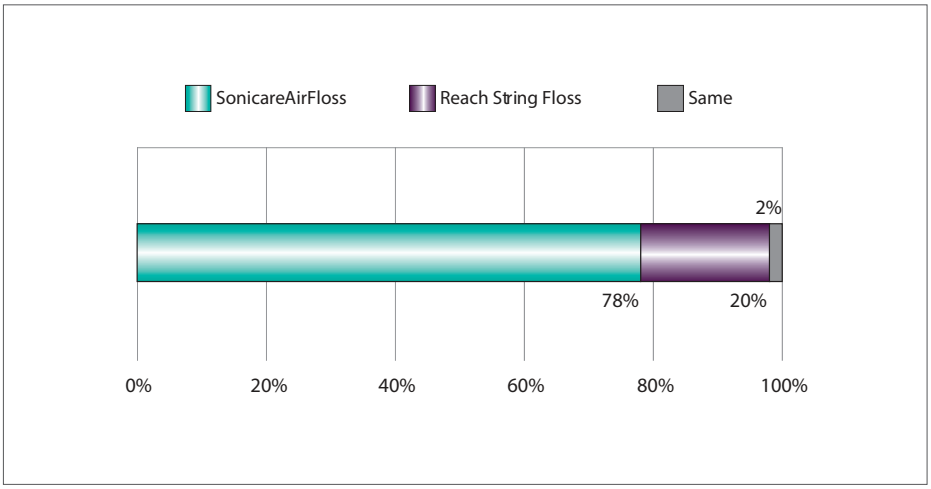
Which product was easier to use?



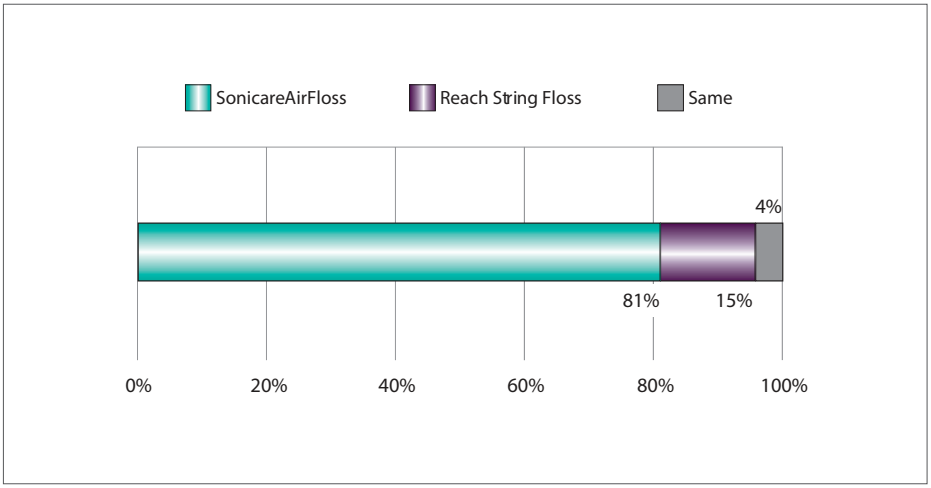
Which product was easier to use?



Which product was gentler on your teeth and gums?



Which product provided better access to the back of your mouth?



Plaque Biofilm Disruption

in vitro study

In vitro evaluation of interproximal biofilm removal with Philips Sonicare AirFloss

de Jager M, Hix J, Aspiras M, Schmitt P. Data on file, 2010

Objective

To evaluate, in vitro, the additional removal of interproximal plaque biofilm of Philips Sonicare AirFloss when used in combination with Philips Sonicare FlexCare.

Methodology

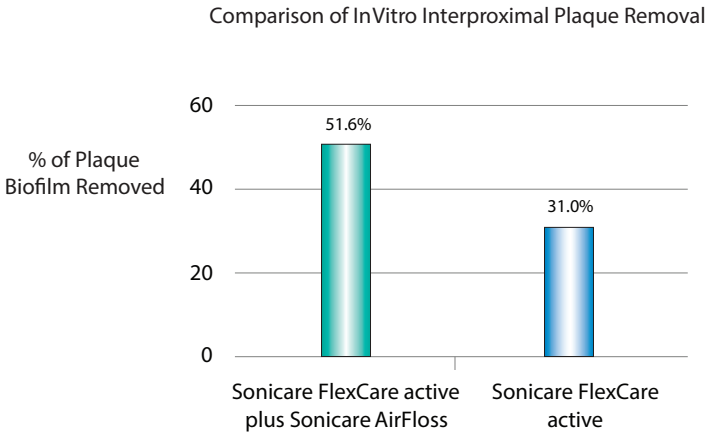
This study evaluated interproximal biofilm removal of Sonicare FlexCare with or without subsequent use of Sonicare AirFloss. An in vitro tooth model was used to assess the efficacy in removing dental plaque biofilm from the interproximal spaces of molar teeth. The dental plaque model was a multispecies oral biofilm grown on hydroxyapatite discs. In a typodont, the discs with biofilm were located on interproximal sites of molar teeth at a distance of 2-4 mm from the tip of the bristles or the nozzle. The typodont was exposed to the dynamic fluid activity generated by the high-frequency bristle movement from the activated Sonicare FlexCare (15 seconds) and by the high-velocity droplet air spray from Sonicare AirFloss (single shot). An inactivated Sonicare FlexCare was used as a control. Plaque removal efficacy was determined by enumeration of the percentage of viable bacteria removed from the discs as a result of these exposures.

Results

Sonicare AirFloss in conjunction with Sonicare FlexCare removed 66% ($p<0.0001$) more interproximal biofilm than the active Sonicare FlexCare alone. Sonicare FlexCare active removed significantly more biofilm than Sonicare FlexCare inactive ($p<0.0001$).

Conclusion

Sonicare AirFloss removed 66% more interproximal plaque biofilm than Sonicare FlexCare alone.



Gingivitis Reduction and Plaque Removal

in vivo study

Effect of Philips Sonicare AirFloss on interproximal plaque and gingivitis

de Jager M, Jain V, Schmitt P, DeLaurenti M, Jenkins W, Milleman J, Milleman K, Putt M.
J Dent Res 90 (spec iss A), 2011

Objective

Philips Sonicare AirFloss is a rechargeable interproximal cleaning device that uses a high-velocity burst of air and water droplets to clean between teeth.The objective of this study was to evaluate the effect of Sonicare AirFloss on interproximal plaque and gingivitis when used in addition to manual toothbrushing.

Methodology

One hundred forty-eight adults (98 females, 50 males; mean age 39.5 years) with moderate gingivitis participated in this single-blind, four-week, parallel, randomized controlled clinical trial. Ethical approval and written informed consent were obtained. Subjects were randomized either to a manual toothbrush (two minutes, twice a day) or to a manual toothbrush plus Sonicare AirFloss (once daily, evening). Changes in gingival inflammation were measured using the Modified Gingival Index (MGI) and Gingival Bleeding Index (GBI) at baseline, two weeks and four weeks.The amount of interproximal plaque was evaluated by analyzing the residual protein concentration (RPC) of six plaque samples collected from four posterior sextants (one interproximal site per sextant) and two anterior sextants (three interproximal sites per sextant). Baseline plaque samples were collected prior to any intervention. At two weeks, the plaque removal efficacy from a single use of Sonicare AirFloss was assessed by collecting interproximal plaque samples immediately after subjects used their assigned treatment regimen. Safety of the products was assessed through oral examination, prior to all other assessments.

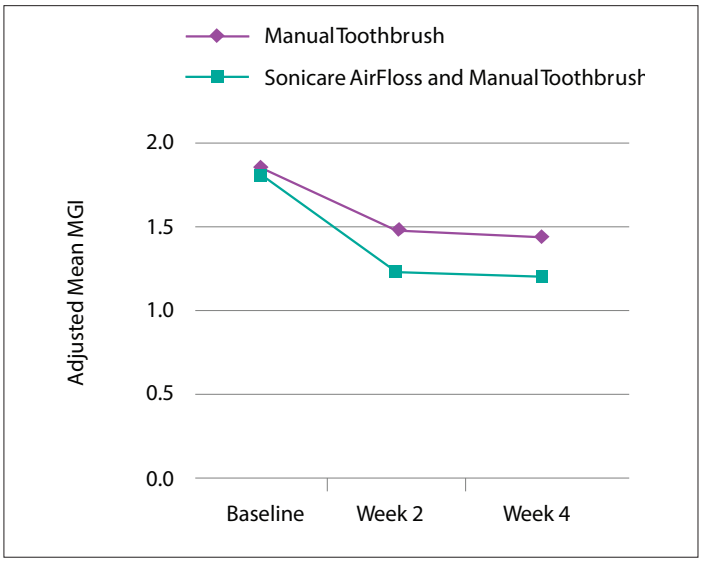
Results

Sonicare AirFloss, when used in addition to a manual toothbrush, provided significantly greater reductions in gingivitis and bleeding sites ($p<0.01$) than a manual toothbrush alone. After four weeks, Sonicare AirFloss reduced gingivitis by 33% more, gingival bleeding by 75% more and the number of bleeding sites by 86% more than a manual toothbrush alone. Interproximal plaque evaluated after a single use showed that Sonicare AirFloss removed significantly more plaque than a manual toothbrush alone ($p<0.01$). Both products were safe to use.

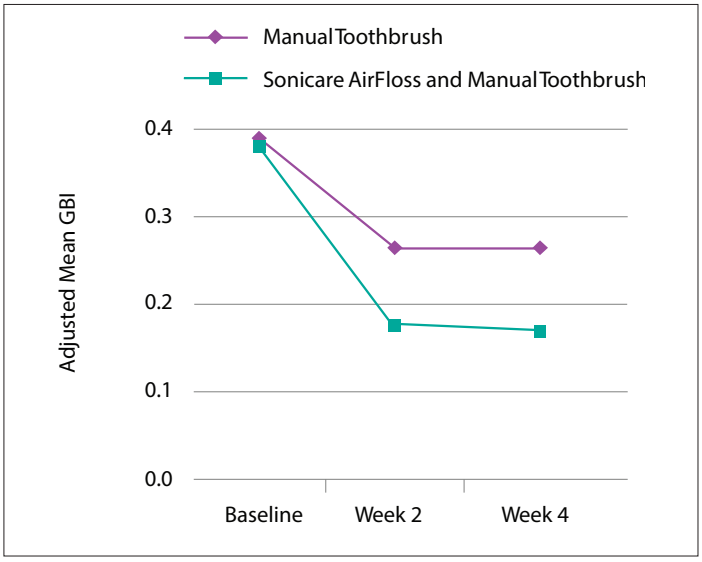
Conclusion

Sonicare AirFloss, when used in addition to manual brushing, removed significantly more interproximal plaque and resulted in significantly greater reductions of gingivitis after two weeks and four weeks of use, compared to manual brushing alone.

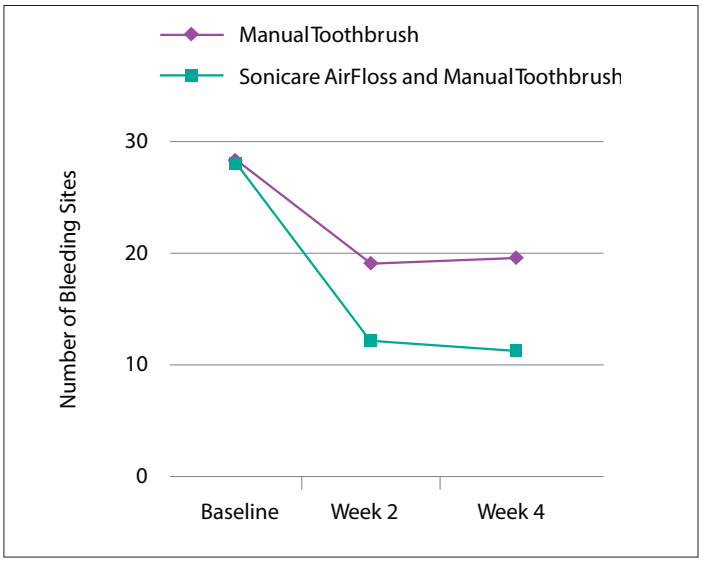
Modified Gingival Index



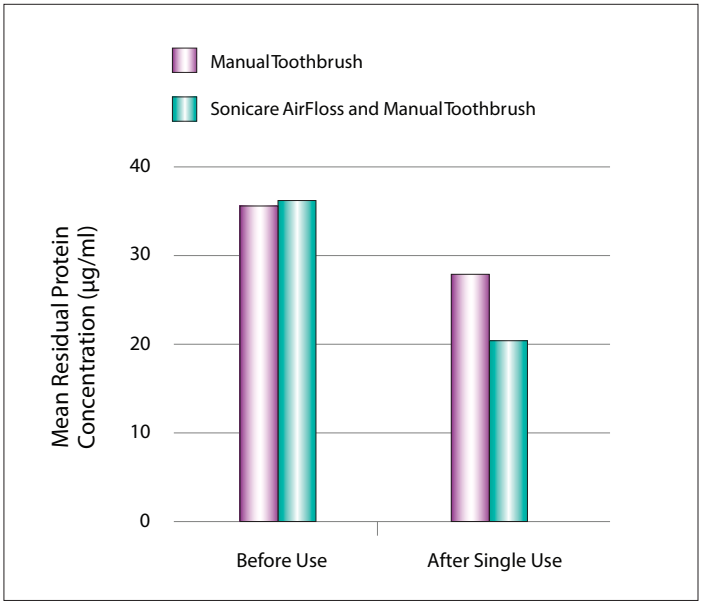
Gingival Bleeding Index



Bleeding Sites



Interproximal Plaque (RPC)



Compliance

in vivo study

In-home use test to assess compliance of Philips Sonicare AirFloss

Krell S, Kaler A, Wei J. Data on file, 2010

Objective	To assess compliance of Philips SonicareAirFloss in a sample of irregular flossers after one month of home use.
Methodology	Eligible participants included 56 adult irregular flossers (floss from one time per month to three times per week). Participants were given a product-usage diary to self report the frequency of usage of the product.The study utilized a single-arm design. All participants received the Sonicare AirFloss with a nozzle and travel charger, a daily-usage diary and product instructions. Per the study instructions, each participant used the Sonicare AirFloss at home and recorded his or her usage in the diary. In addition, feedback was recorded using an online questionnaire (Survey Monkey) at the end of one month. Participants were not restricted from using any other flossing products but were advised to use Sonicare AirFloss in their regular flossing routine.
Results	Fifty-one participants completed and returned their daily-usage diary after the first month of use. On average, irregular flossers used Sonicare AirFloss 1.3 times a day. 96.1% of the participants used Sonicare Airfloss four or more days per week.
Conclusion	96% of irregular flossers reported use of Sonicare AirFloss four or more days per week.

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