



PHILIPS

sonicare

Clinical studies

Our latest clinical evidence

As featured in a Special Issue of *The Journal of Clinical Dentistry*®



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At Philips Sonicare, we take tremendous pride in the quality of our work. Behind every Philips Sonicare product is a global team of dedicated and experienced people collaborating across a spectrum of disciplines, including research and development, product design and engineering, quality testing, clinical evaluation, manufacturing and fulfillment and distribution. With each innovation, our collective efforts have an overriding goal: to provide your patients the very best tools to optimize their oral health.

As we mark the 25th anniversary of Sonicare, it is with great pleasure that we share with you the publication of our latest clinical evidence in a Special Issue of *The Journal of Clinical Dentistry*® (Vol XXVIII, No.1, Spec Iss A). Following is a curated synopsis of the studies to provide you a sense of the clinical performance we demand of the products that your patients use to improve their oral health every single day.

As we look ahead to the next 25 years, be assured that Philips Sonicare will continue to challenge the status quo, combining the best of dental science, design and technology to provide innovative, safe and effective oral care solutions.

You are a valued partner and we hope you enjoy reading the scientific evidence provided in this brochure. On behalf of our entire team, **thank you for your support and partnership.**



Dr. Maha Yakob
Global Director, Professional Relations & Scientific Affairs
Philips Oral Healthcare

An Evidence-based Approach to Daily Plaque Control and Gingival Health

New Philips Sonicare clinical studies in brief

Study 1

Comparison of Gingivitis Reduction and Plaque Removal by Philips Sonicare DiamondClean and a Manual Toothbrush

DeLaurenti M, Ward M, Souza S, Jenkins W, Putt MS, Milleman KR, Milleman JL. *J Clin Dent* 2017;28(Spec Iss A):A1-6.



Key conclusion

Twice daily brushing with Philips Sonicare DiamondClean is significantly better than using a manual toothbrush for reducing plaque and improving gingival inflammation and gingival bleeding within just two weeks, persisting to four weeks.

Study 2

Comparison of Plaque and Gingivitis Reduction by Philips Sonicare FlexCare Platinum with Premium Plaque Control Brush Head and a Manual Toothbrush

Jenkins W, Souza S, Ward M, Defenbaugh J, Milleman KR, Milleman JL. *J Clin Dent* 2017;28(Spec Iss A):A7-12.



Key conclusion

Twice daily brushing with Philips Sonicare FlexCare Platinum with Premium plaque control* brush head is significantly better than using a manual toothbrush for reducing plaque and improving gingival inflammation and gingival bleeding within just two weeks. Statistically significant differences in all metrics persisted until study completion at Week 6.

*Brush head formerly called AdaptiveClean

Study 3

The Effectiveness of Manual versus High-Frequency, High-Amplitude, Sonic-Powered Toothbrushes for Oral Health: A Meta-Analysis

de Jager M, Rmaile A, Darch O, Bikker JW. *J Clin Dent* 2017;28(Spec Iss A):A13-28.



Key conclusion

Results of this comprehensive meta-analysis showed that high-frequency, high-amplitude, sonic-powered toothbrushes decrease plaque and gingivitis significantly more effectively than manual toothbrushes in everyday use, in studies lasting up to three months.

Study 4

An Assessment of Gingivitis Reduction and Plaque Removal by Philips Sonicare DiamondClean with Premium Plaque Control Brush Head and Oral-B 7000 with CrossAction Brush Head

Starke M, DeLaurenti M, Ward M, Souza S, Milleman KR, Milleman JL. *J Clin Dent* 2017;28(Spec Iss A):A29-35.



Key conclusion

Philips Sonicare DiamondClean with Premium plaque control* brush head is statistically superior to Oral-B 7000® with CrossAction™ brush head and SmartGuide accessory in reducing gingival inflammation, gingival bleeding and surface plaque.

*Brush head formerly called AdaptiveClean

Study 5

A Study to Assess the Effects of Philips Sonicare AirFloss Pro, when Used with Antimicrobial Rinse, on Gum Health and Plaque Removal

Mwatha A, Olson M, Souza S, Ward M, Jenkins W, Amini P, Gallob J, Fafard T. *J Clin Dent* 2017;28(Spec Iss A):A36-44.



Key conclusion

Daily use of Philips Sonicare AirFloss Pro with antimicrobial rinse as an adjunct to manual toothbrushing was shown to improve gum health and reduce plaque significantly better than manual toothbrushing alone. Moreover, a non-inferiority test showed AirFloss Pro to be similar to string floss in reducing plaque and gingivitis.



Gingival health

in vivo study

Comparison of Gingivitis Reduction and Plaque Removal by Sonicare DiamondClean and a Manual Toothbrush

DeLaurenti M, Ward M, Souza S, Jenkins W, Putt MS, Milleman KR, Milleman JL.

J Clin Dent 2017;28(Spec Iss A):A1-6.

University Park Research Center, USA

Objective

To evaluate the effect of use of Philips Sonicare DiamondClean and a manual toothbrush on gingivitis, gingival bleeding and surface plaque following a home-use period of four weeks.

Methodology

One hundred forty-one healthy adults aged 18-70 years (mean age 42.1 years) completed this single-blind, randomized, parallel group clinical trial. Eligible subjects were non-smokers who were routine manual toothbrush users. Those enrolled on study exhibited mild to moderate gingivitis upon study entry and had a minimum surface plaque score, per Lobene and Soparker Modified Plaque Index, of >1.8 following a 3 to 6 hour plaque accumulation period. Subjects with severe gingivitis or who exhibited periodontal disease were excluded from participation. Those enrolled on study received an examination to chart dental restorations for subsequent safety tracking and were then randomized to a treatment assignment. Subjects were dispensed either a Philips Sonicare DiamondClean (SDC) power toothbrush with standard size brush head, or an ADA reference manual toothbrush (MTB) for twice daily home use. All subjects received a standard fluoride-containing dentifrice and were to abstain from all other oral hygiene interventions during the study period. Subjects returned to clinic at two weeks for an interim efficacy and safety assessment, and then at four weeks for final examinations and release from study.

Results

Gingival Inflammation per Modified Gingival Index (MGI)

At Baseline, the MGI LS Mean (SE) outcome for SDC was 2.08 (0.05), and for MTB it was 2.14 (0.05), p-value = 0.3660.

Following two weeks of product use, LS Mean (SE) for the SDC group was 1.6 (0.03), and for MTB it was 1.83 (0.03), p-value <0.0001. Expressed as percent reduction versus Baseline, this is 24.5% reduction for SDC, and 13.7% for MTB.

Following four weeks of product use, LS Mean (SE) for the SDC group was 1.57 (0.04), and for MTB it was 1.71 (0.04), p-value = 0.0106. Expressed as percent reduction versus Baseline, this is 25.5% reduction for SDC, and 19.1% for MTB.

Gingival Bleeding per Gingival Bleeding Index (GBI)

At Baseline, GBI, number of bleeding sites, the LS Mean (SE) for SDC was 28.5 (1.13), and was 29.7 (1.12) for MTB, p-value 0.4232.

Following two weeks of product use, LS Mean (SE) for the SDC group was 14.1 (0.92), and for MTB it was 24.2 (0.91), p-value <0.0001. Expressed as percent reduction versus Baseline, this is 52.2% reduction for SDC, and 17.0% for MTB.

Following four weeks of product use, LS Mean (SE) for the SDC group was 12.4 (0.89) and was 20.0 (0.88) for MTB, p-value <0.0001. Expressed as percent reduction versus Baseline, this is 57.4% reduction for SDC, and 31.4% for MTB.

Surface Plaque per Modified Plaque Index (MPI)

At Baseline, the LS Mean (SE) outcome for SDC was 2.77 (0.05), and for MTB it was 2.85 (0.05), p-value 0.2481.

Following two weeks of product use, LS Mean (SE) for the SDC group was 1.93 (0.04), and for MTB it was 2.7 (0.04), p-value <0.0001. Expressed as percent reduction versus Baseline, this is 31.4% reduction for SDC, and 3.8% for MTB.

Following four weeks of product use, LS Mean (SE) for the SDC group was 1.84 (0.05), and for MTB it was 2.58 (0.05), p-value <0.0001. Expressed as percent reduction versus Baseline, this is 34.9% reduction for SDC, and 8.0% for MTB.

Safety

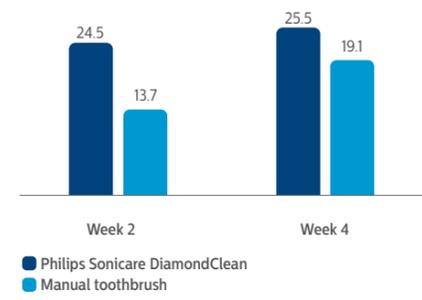
There were eight reported safety events from three study subjects, none of which were serious. There were no observed adverse effects to restorative materials, including crowns, composites or veneers.

Conclusions:

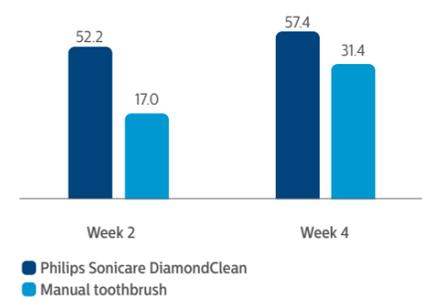
Philips Sonicare DiamondClean was statistically significantly more effective than a manual toothbrush at reducing gingival inflammation, gingival bleeding and surface plaque following two and four weeks of home use.

Both products were safe for home use.

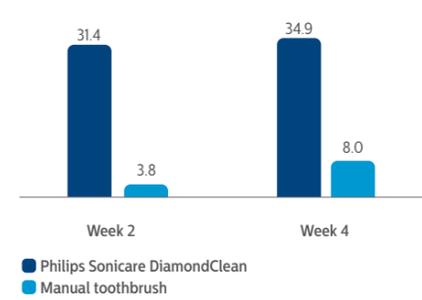
Least Squares Mean for Modified Gingival Index
Percent Reduction from Baseline to Week 2 and Week 6



Least Squares Mean for Gingival Bleeding Index
Percent Reduction from Baseline to Week 2 and Week 6



Least Squares Mean for Modified Plaque Index
Percent Reduction from Baseline to Week 2 and Week 6



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DRC-0790



Gingival health

in vivo study

Comparison of Plaque and Gingivitis Reduction by Philips Sonicare FlexCare Platinum with Premium Plaque Control Brush Head and a Manual Toothbrush

Jenkins W, Souza S, Ward M, Defenbaugh J, Milleman KR, Milleman JL.

J Clin Dent 2017;28(Spec Iss A):A7-12.

Salus Research, Ft. Wayne IN, USA

Objective

To compare the effects of Philips Sonicare FlexCare Platinum with Premium plaque control* brush head and an ADA reference manual toothbrush on plaque and gingivitis following two and six weeks of home use.

Methodology

One hundred fifty-four adults (mean age 40.62; 111 female/43 male) were consented, enrolled and randomized in this IRB-approved, single-center, examiner-blinded, parallel-design clinical trial. One hundred forty-three subjects completed the study. Eligible subjects were routine manual toothbrush users who were non-smokers, aged 18-65 with a minimum plaque score of ≥ 1.8 per Lobene and Soparker Modified Plaque Index (MPI) following 3-6 hours of plaque accumulation, and a Gingival Bleeding Index (GBI) of ≥ 1 on at least 20 sites. Eligible subjects were randomly allocated to utilize either a Philips Sonicare FlexCare Platinum with Premium plaque control brush head in Deep Clean mode and high intensity twice daily, or an ADA reference manual toothbrush twice daily per their usual technique. Gingivitis (GBI and Modified Gingival Index (MGI)) and MPI efficacy metrics were assessed at Baseline, and following two and six weeks of home use of the study products. Subjects presented to clinic for all visits with 3-6 hours of plaque accumulation. Safety was assessed by intraoral exam and per subject report.

Results

Gingival Inflammation per Modified Gingival Index (MGI)

At Baseline, the MGI LS Mean (SE) outcome for Philips Sonicare FlexCare Platinum with Premium plaque control brush head was 2.16 (0.05), and for manual toothbrush it was 2.27 (0.05), p-value = 0.1282.

Following two weeks of product use, LS Mean (SE) for the Sonicare group was 1.32 (0.04), and for manual toothbrush it was 2.05 (0.04), p-value <0.0001. Expressed as percent reduction versus Baseline, this is 41.73% reduction for Philips Sonicare FlexCare Platinum with Premium plaque control brush head, and 7.38% for manual toothbrush.

Following six weeks of product use, LS Mean (SE) for the Sonicare group was 1.23 (0.04), and for manual toothbrush it was 2.22 (0.04), p-value <0.0001. Expressed as percent reduction versus Baseline, this is 45.79% reduction for Philips Sonicare FlexCare Platinum with Premium plaque control brush head, and -0.71% for manual toothbrush.

Gingival Bleeding per Gingival Bleeding Index (GBI)

At Baseline, the GBI LS Mean (SE) outcome for Philips Sonicare FlexCare Platinum with Premium plaque control brush head was 0.40 (0.03), and for manual toothbrush it was 0.39 (0.03), p-value = 0.7934.

Following two weeks of product use, LS Mean (SE) for the Sonicare group was 0.19 (0.01), and for manual toothbrush it was 0.34 (0.01), p-value <0.0001. Expressed as percent reduction versus Baseline, this is 47.97% reduction for Philips Sonicare FlexCare Platinum with Premium plaque control brush head, and 8.64% for manual toothbrush.

Following six weeks of product use, LS Mean (SE) for the Sonicare group was 0.15 (0.01), and for manual toothbrush it was 0.38 (0.01), p-value <0.0001. Expressed as percent reduction versus Baseline, this is 58.36% reduction for Philips Sonicare FlexCare Platinum with Premium plaque control brush head, and -3.14% for manual toothbrush.

Surface Plaque per Modified Plaque Index (MPI)

At Baseline, the MPI LS Mean (SE) outcome for Philips Sonicare FlexCare Platinum with Premium plaque control brush head was 2.84 (0.06), and for manual toothbrush it was 2.90 (0.06), p-value = 0.4159.

Following two weeks of product use, LS Mean (SE) the Sonicare group was 1.42 (0.06), and for manual toothbrush it was 2.77 (0.06), p-value <0.0001. Expressed as percent reduction versus Baseline, this is 50.59% reduction for Philips Sonicare FlexCare Platinum with Premium plaque control brush head, and 3.08% for manual toothbrush.

Following six weeks of product use, LS Mean (SE) for the Sonicare group was 1.55 (0.07), and for manual toothbrush it was 2.91 (0.07), p-value <0.0001. Expressed as percent reduction versus Baseline, this is 46.55% reduction for Philips Sonicare FlexCare Platinum with Premium plaque control brush head, and -1.58% for manual toothbrush.

Safety

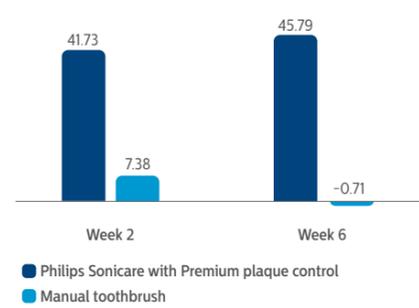
There were two adverse events reported, both of which were reported as unlikely related to the study.

Conclusions:

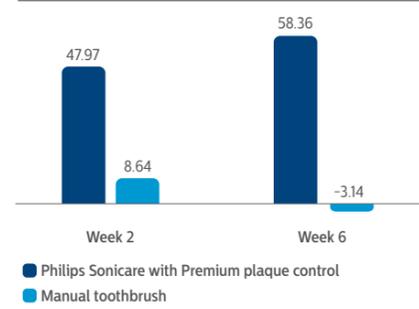
Philips Sonicare FlexCare Platinum with Premium plaque control brush head was statistically superior to an ADA reference manual toothbrush in reducing gingivitis, gingival bleeding and surface plaque following two and six weeks of home use.

Both products were safe for home use.

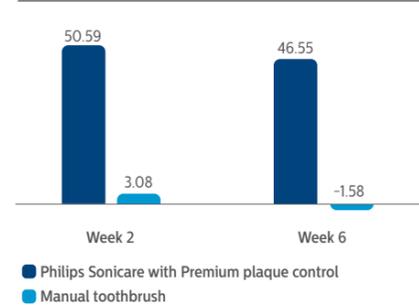
Least Squares Mean for Modified Gingival Index
Percent Reduction from Baseline to Week 2 and Week 6



Least Squares Mean for Gingival Bleeding Index
Percent Reduction from Baseline to Week 2 and Week 6



Least Squares Mean for Modified Plaque Index
Percent Reduction from Baseline to Week 2 and Week 6



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*Brush head formerly called AdaptiveClean

MAH-15-0181



Gingival health / plaque removal

The Effectiveness of Manual versus High-Frequency, High-Amplitude, Sonic-Powered Toothbrushes for Oral Health: A Meta-Analysis

Meta-analysis
de Jager M, Rmaile A, Darch O (Philips Research, Cambridge, UK), and Bikker JW (CQM, Eindhoven, Netherlands)
J Clin Dent 2017;28(Spec Iss A):A13-28.
Philips Research, Eindhoven, NL

Objective

To compare the everyday efficacy of high-frequency, high-amplitude, sonic-powered toothbrushes versus manual toothbrushes on plaque removal and gingivitis reduction through a meta-analysis of short-term clinical studies.

Methodology

Studies were eligible if they were randomized controlled clinical trials which evaluated both manual and sonic-powered toothbrushes on plaque or gingivitis reduction over a period of four weeks to three months in subjects without disability affecting toothbrushing. Single-use and clinician supervised studies were excluded. To identify eligible studies, searches were performed in databases of scientific publications (Embase, MEDLINE, BIOSIS, Inspec, PQ-SciTech, Compendex, SciSearch) as well as the electronic database of IADR abstracts. Data were extracted from qualifying studies, and investigators were contacted when insufficient information was available. To allow for the meta-analysis, data were pooled to compute standardized mean differences (SMD) and 95% confidence intervals (95% CI) using random-effects models to quantify differences in plaque removal or gingivitis reduction for each study as well as for the overall weighted average across included studies. Sources of heterogeneity and risk for bias were assessed.

Results

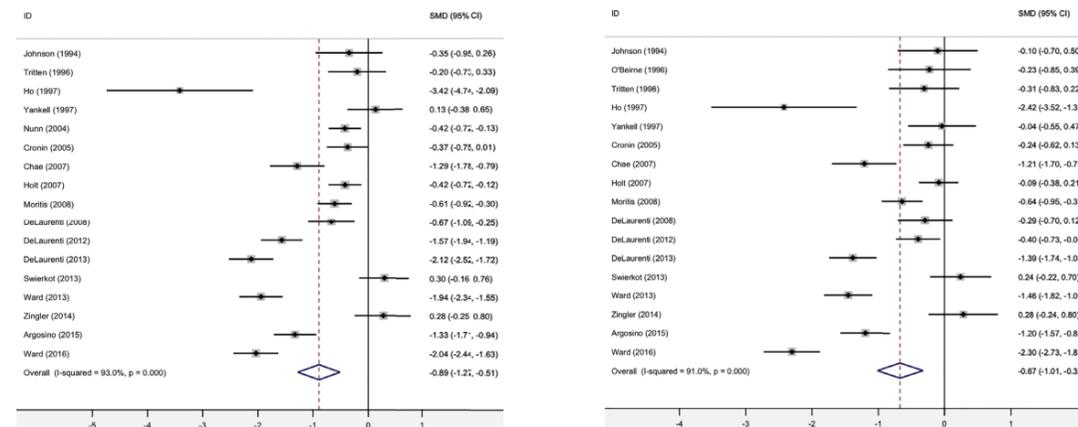
Overall, 18 studies comprising 1,870 subjects were included. The results demonstrated that high-frequency, high-amplitude sonic-powered toothbrushes resulted in statistically significantly greater reductions in plaque (SMD = -0.89, 95% CI = [-1.27, -0.51]) and gingivitis (-0.67, [-1.01, -0.32]) when compared to manual toothbrushes. In practical terms, this equates to approximately 20% more plaque removal and 10% greater decrease in gingivitis in everyday use. Although heterogeneity was large, sensitivity and subgroup analysis showed that outcomes were robust, and bias was not apparent.

Conclusion:

High-frequency, high-amplitude, sonic-powered toothbrushes decreased plaque and gingivitis significantly more effectively than manual toothbrushes in everyday use in studies lasting from four weeks up to three months.

Standardized Mean Difference and Confidence Intervals for plaque removal and gingivitis reduction

Results and forest plots for each study with Standardized Mean Difference (SMD) and 95% Confidence Intervals (95% CI) comparing sonic powered versus manual toothbrushes for (left) plaque removal and (right) gingivitis reduction. SMD<0 favors the powered toothbrush.



Key Characteristics of Included Studies

Reference	Subjects	Powered Toothbrush	Manual Toothbrush	Final Timepoint
Johnson 1994	Adults with gingivitis, 20-54 yrs	Sonicare Advance	Oral-B 30	4 weeks
O'Beirne 1996	Adults with periodontitis, 18-65 yrs	Sonicare Advance	Oral-B	8 weeks
Tritten 1996	Adults with gingivitis, 18-65 yrs	Sonicare Advance	Butler 311	12 weeks
Ho 1997	Orthodontic adolescents, 11-18 yrs	Sonicare Advance	Oral-B P 35	4 weeks
Yankell 1997	Adults, 18-50 yrs	Sonicare Advance	Oral-B P 35	30 days
Nunn 2004	Adults, 18-68 yrs	Sonicare Crest IntelliClean	Oral-B P 35	4 weeks
Cronin 2005	Not specified	Oral-B Sonic Complete	Not provided	3 months
Chae 2007	Adults with mild-moderate periodontitis, 25-55 yrs	Sonicare Elite	Butler 311	12 weeks
Holt 2007	Adults with moderate gingivitis, 18-64 yrs	Sonicare FlexCare	Oral-B P40	4 weeks
Moritis 2008	Adults with moderate gingivitis, 19-62 yrs	Sonicare Elite	Oral-B P40	4 weeks
DeLaurenti 2008	Orthodontic subjects, 12-42 yrs	Sonicare FlexCare	Oral-B P40	4 weeks
DeLaurenti 2012	Adults with mild-moderate gingivitis, 20-70 yrs	Sonicare FlexCare+	ADA reference	4 weeks
DeLaurenti 2013	Adults with mild-moderate gingivitis, 18-64 yrs	Sonicare FlexCare Platinum	ADA reference	4 weeks
Swierkot 2013*	Partially edentulous with posterior implants, 45-78 yrs	Sonicare FlexCare	Oral-B P40	3 months
Ward 2013	Adults with mild-moderate gingivitis, 18-65 yrs	Sonicare FlexCare Platinum	ADA reference	4 weeks
Zingler 2014	Orthodontic adolescents, 11-15 yrs	Sonicare FlexCare	Elmex	12 weeks
Argosino 2015	Adults with mild-moderate gingivitis, 18-64 yrs	Sonicare 3 Series	ADA reference	4 weeks
Ward 2016	Adults with mild-moderate gingivitis, 19-64 yrs	Sonicare FlexCare Platinum	ADA reference	6 weeks

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* Study reported data for natural teeth and implant sites separately.

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Gingival health

in vivo study

An Assessment of Gingivitis Reduction and Plaque Removal by Philips Sonicare DiamondClean with Premium Plaque Control Brush Head and Oral-B 7000 with CrossAction Brush Head

Starke M, Delaurenti M, Ward M, Souza S, Milleman KR, Milleman JL.

J Clin Dent 2017;28(Spec Iss A):A29-35.

Salus Research, Ft. Wayne IN, USA

Objective

To compare the effects of Philips Sonicare DiamondClean with Premium plaque control* brush head and Oral-B 7000® with CrossAction™ brush head and SmartGuide accessory on gingival inflammation, gingival bleeding and surface plaque following two and six weeks of home use.

Methodology

Two hundred eighty-four adults (mean age 38.6 years, 213 female/71 male) were consented, enrolled and completed this randomized, parallel-design study. Eligible subjects were routine manual toothbrush users who were non-smokers, aged 18-65 with a minimum plaque score of ≥ 1.8 per Lobene and Soparker Modified Plaque Index (MPI) following 3-6 hours of plaque accumulation, and a Gingival Bleeding Index (GBI) of ≥ 1 on at least 50 sites. Eligible subjects were randomly allocated to utilize either a Philips Sonicare DiamondClean with Premium plaque control brush head or an Oral-B 7000 with CrossAction brush head and SmartGuide accessory. Both products were used in their respective Deep Clean modes, and all subjects received a standard fluoride-containing dentifrice for home use. The use of any other oral hygiene products were prohibited for the study period. Gingivitis (Modified Gingival Index (MGI)), GBI and MPI efficacy metrics were assessed at Baseline, and following two and six weeks of home use. Subjects presented to clinic for all visits with 3-6 hours of plaque accumulation. Safety was assessed by intraoral exam and per subject report.

Results

Gingival Inflammation per Modified Gingival Index (MGI)

At Baseline, the MGI values between treatment groups were balanced, p-value = 0.7174.

Following two weeks of product use, LS Mean (SE) for the Sonicare group was 1.46 (0.04), and for the Oral-B group it was 1.89 (0.04), p-value <0.0001. Expressed as percent reduction versus Baseline, this is 44.73% reduction for Sonicare and 27.92% for Oral-B.

Following six weeks of product use, LS Mean (SE) for the Sonicare group was 1.43 (0.04), and for Oral-B it was 1.91 (0.04), p-value <0.0001. Expressed as percent reduction versus Baseline, this is 45.68% reduction for Sonicare, and 26.83% for Oral-B.

Gingival Bleeding per Gingival Bleeding Index (GBI)

At Baseline, the GBI values between treatment groups were balanced, p-value = 0.5986.

Following two weeks of product use, LS Mean (SE) for the Sonicare group was 0.18 (0.01), and for Oral-B 7000 it was 0.27 (0.01), p-value <0.0001. Expressed as percent reduction versus Baseline, this is 66.75% reduction for Sonicare and 49.38% for Oral-B.

Following six weeks of product use, LS Mean (SE) for the Sonicare group was 0.13 (0.01), and for Oral-B it was 0.22 (0.01), p-value <0.0001. Expressed as percent reduction versus Baseline, this is 75.81% reduction for Sonicare, and 58.76% for Oral-B.

Surface Plaque per Modified Plaque Index (MPI)

At Baseline, the MPI values between treatment groups were balanced, p-value = 0.9777.

Following two weeks of product use, LS Mean (SE) for the Sonicare group was 1.78 (0.04), and for Oral-B it was 2.36 (0.04), p-value <0.0001. Expressed as percent reduction versus Baseline, this is 38.68% reduction for Sonicare and 18.28% for Oral-B.

Following six weeks of product use, LS Mean (SE) for the Sonicare group was 1.80 (0.04), and for Oral-B it was 2.30 (0.04), p-value <0.0001. Expressed as percent reduction versus Baseline, this is 37.58% reduction for Sonicare, and 20.70% for Oral-B.

Safety

There were eight adverse events reported, six of which were assessed as mild in severity, two of which were moderate. The disposition of all eight events were indicated as resolved by the end of the study.

Conclusions:

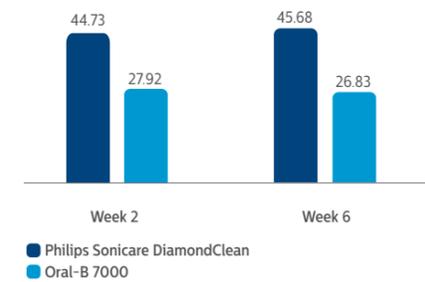
Philips Sonicare DiamondClean with Premium plaque control brush head was statistically superior to Oral-B 7000 with CrossAction brush head in reducing gingival inflammation, as measured by MGI, following 14 and 42 days of home use.

Philips Sonicare DiamondClean with Premium plaque control brush head was statistically superior to Oral-B 7000 with CrossAction brush head in reducing gingival bleeding, as measured by GBI, following 14 and 42 days of home use.

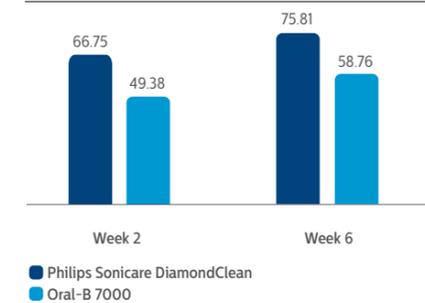
Philips Sonicare DiamondClean with Premium plaque control brush head was statistically superior to Oral-B 7000 with CrossAction brush head in reducing surface plaque, as measured by MPI, following 14 and 42 days of home use.

Both products were safe for home use.

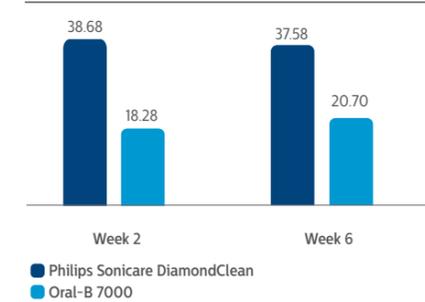
Least Squares Mean for Modified Gingival Index
Percent Reduction from Baseline to Week 2 and Week 6



Least Squares Mean for Gingival Bleeding Index
Percent Reduction from Baseline to Week 2 and Week 6



Least Squares Mean for Modified Plaque Index
Percent Reduction from Baseline to Week 2 and Week 6



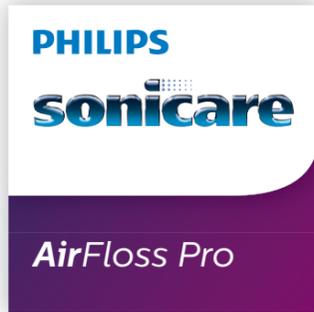
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*Brush head formerly called AdaptiveClean

MAH-16-0189



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

Mwatha A, Olson M, Souza S, Ward M, Jenkins W, Amini P, Gallob J, Fafard T.

J Clin Dent 2017;28(Spec Iss A):A36-44.

Silverstone Research, Las Vegas, NV 2014

Objectives

To compare the effect of four home use oral hygiene regimens on gum health and plaque reduction following two and four weeks of use.

Methodology

Two-hundred ninety healthy adults (mean age 35.6 years, 186 female/104 male) were enrolled in this IRB-approved, parallel, examiner-blinded clinical trial. Of these, 286 subjects completed the study. Eligible subjects were non-smokers, aged 18-65 years who were routine manual toothbrush users and irregular flossers (once per week, or less often). Enrolled participants had a minimum average plaque score of ≥ 0.5 per Rustogi Modified Navy Plaque Index (RMNPI) following 2-6 hours plaque accumulation, and a Gingival Bleeding Index (GBI) of ≥ 1 on at least 10 sites. All enrolled subjects were dispensed study products per randomization, either manual toothbrush (MTB) alone twice daily, or manual toothbrush in addition to once daily use of string floss (SF) or Philips Sonicare AirFloss with either BreathRx (AFBX) or Listerine CoolMint (AFL) rinse 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. Statistical methods included a comparison of interproximal cleaning devices to MTB alone, as well as a non-inferiority test between AFL and AFBX to SF. Study products were collected from study participants at Day 28 and they were dismissed from study.

Results

Modified Gingival Index (MGI)

Following two weeks of product use, the LS Mean (SE) percent reduction from Baseline was 0.22% (0.55%) for MTB, 4.30% (0.44%) for SF, 4.55% (0.45%) for AFL and 4.20% (0.44%) for AFBX.

Following four weeks of product use, the LS Mean (SE) percent reduction from Baseline was 1.10% (0.72%) for MTB, 11.41% (0.58%) for SF, 9.54% (0.58%) for AFL and 8.52% (0.58%) for AFBX.

For both timepoints, the difference between MTB alone to MTB plus interproximal cleaning (SF, AFL, AFBX) was statistically significant, p-value <0.001.

Gingival Bleeding (GBI)

Following two weeks of product use, the LS Mean (SE) percent reduction from Baseline was -0.16% (2.81%) for MTB, 22.89% (2.26%) for SF, 26.90% (2.27%) for AFL and 24.61% (2.26%) for AFBX.

Following four weeks of product use, the LS Mean (SE) percent reduction from Baseline was 4.03% (2.85%) for MTB, 43.31% (2.31%) for SF, 40.49% (2.31%) for AFL and 36.79% (2.30%) for AFBX.

For both timepoints, the difference between MTB alone to MTB plus interproximal cleaning (SF, AFL, AFBX) was statistically significant, p-value <0.001.

Surface Plaque (RMNPI)

Following two weeks of product use, the LS Mean (SE) percent reduction from Baseline was 5.56% (1.00%) for MTB, 17.07% (0.80%) for SF, 15.95% (0.80%) for AFL and 14.33% (0.80%) for AFBX.

Following four weeks of product use, the LS Mean (SE) percent reduction from Baseline was 5.70% (1.08%) for MTB, 26.48% (0.87%) for SF, 23.96% (0.87%) for AFL and 22.41% (0.86%) for AFBX.

For both timepoints, the difference between MTB alone to MTB plus interproximal cleaning (SF, AFL, AFBX) was statistically significant, p-value <0.001.

Safety

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

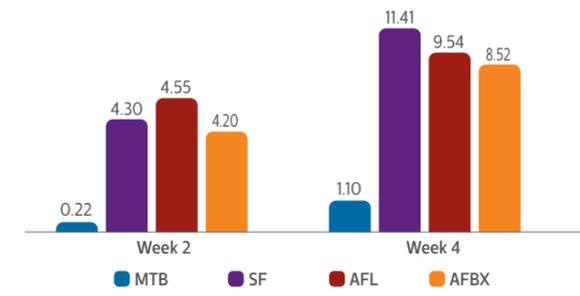
Conclusions

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.

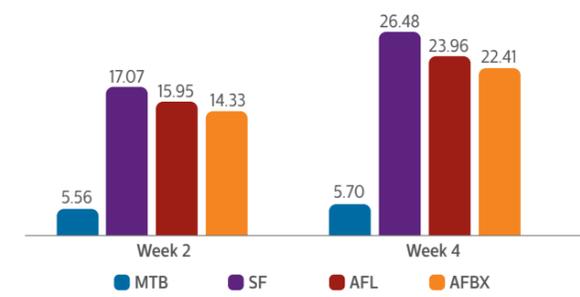
Among the adjunct interproximal cleaning regimens, a non-inferiority test comparing Philips Sonicare AirFloss Pro to string floss showed Philips Sonicare AirFloss Pro to be non-inferior to string floss, p-value <0.001, in reducing plaque and gingivitis.

All study products were safe for use.

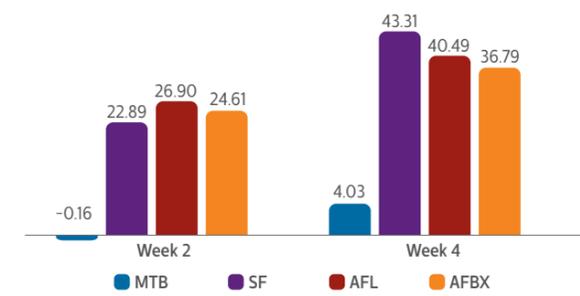
Least Squares Mean, Modified Gingival Index
Percent Reduction from Baseline to Week 2 and Week 4



Least Squares Mean, Rustogi Modified Plaque Index
Percent Reduction from Baseline to Week 2 and Week 4



Least Squares Mean, Gingival Bleeding Index
Percent Reduction from Baseline to Week 2 and Week 4



Key	
Manual toothbrush	MTB
String floss	SF
AirFloss Pro + Listerine	AFL
AirFloss Pro + BreathRx	AFBX

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