



The Science Behind Sonicare

PHILIPS
sonicare



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.

Finally, I would like to draw your attention to a topic that has become more important in our efforts to truly engage patients: aesthetics and beauty.

Philips Sonicare products have always been perfectly suited to support both oral health and beauty, and with the addition of Zoom whitening, Philips now offers you complete and comprehensive patient solutions. And there is the same clinical rigor supporting this ambition. The breadth of research supporting our Philips Zoom products is impressive and warrants its own Clinical Proof Brochure, which we would be pleased to share with you.

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

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Gingivitis Reduction and Plaque Removal

in vivo study

Effect of Philips Sonicare AirFloss on interproximal plaque and gingivitis

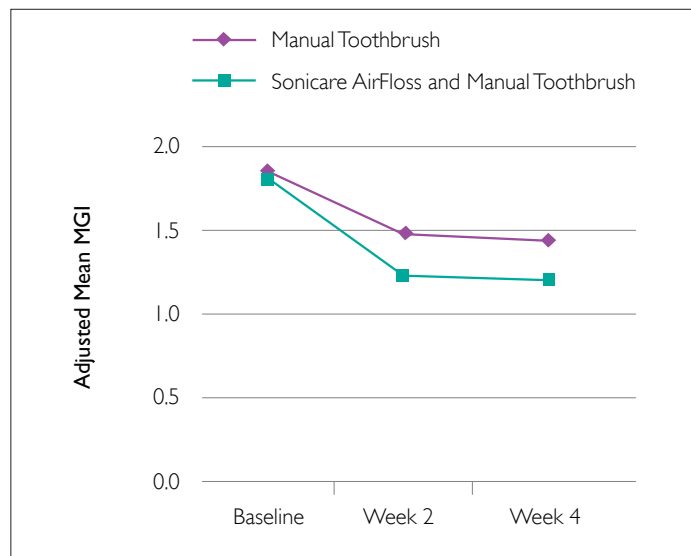
de Jager M, Jain V, Schmitt P, DeLaurenti M, Jenkins W, Milleman J, Milleman K, Putt M.
J Dent Res 90 (spec iss A), 2011

Objective	Philips Sonicare AirFloss is a rechargeable interproximal cleaning device that uses micro-droplets of water accelerated by pressurized air 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 (two minutes, twice a day) plus Sonicare AirFloss (once daily, evening). Changes in gingival inflammation were measured using the 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 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.

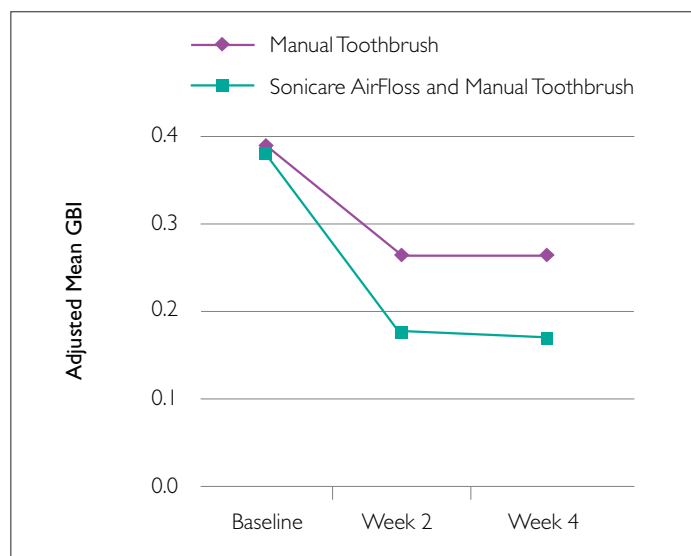
Conclusion

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.

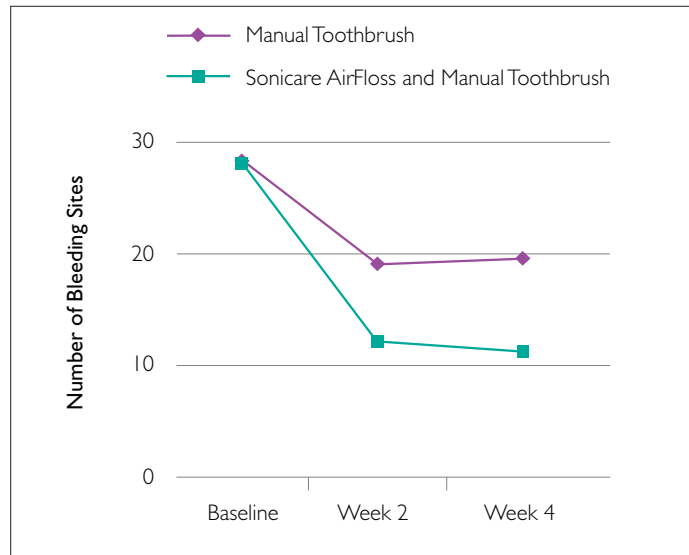
Modified Gingival Index



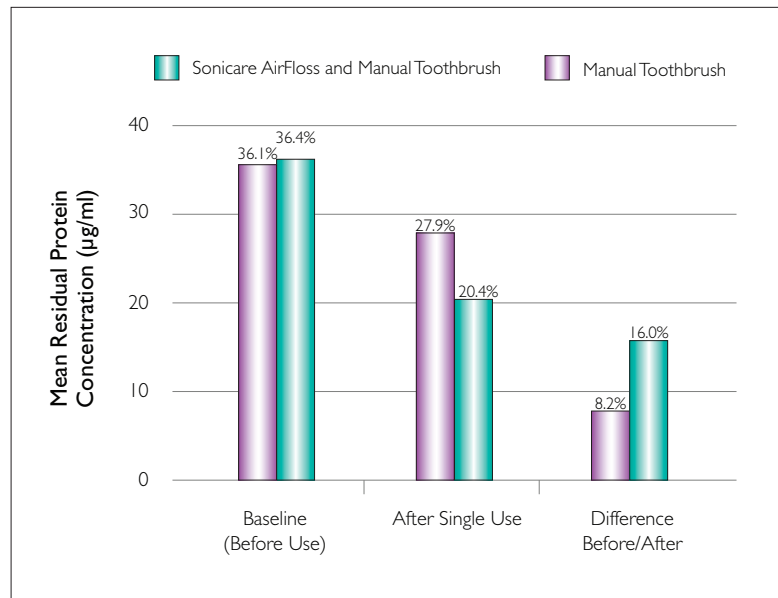
Gingival Bleeding Index



Bleeding Sites



Interproximal Plaque (RPC)



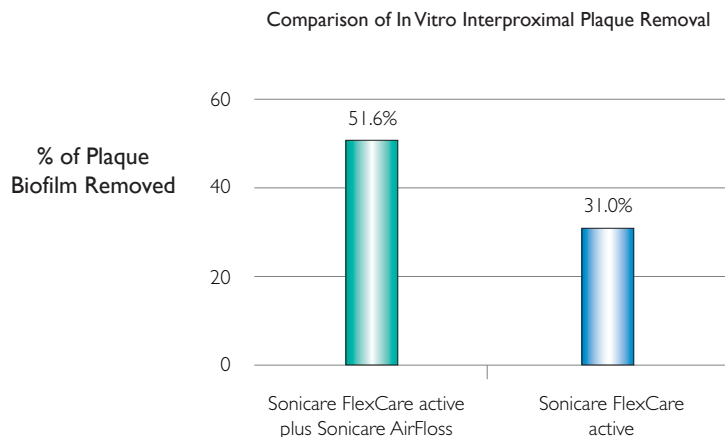
Plaque Biofilm Disruption

*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.



*Results will vary with actual use

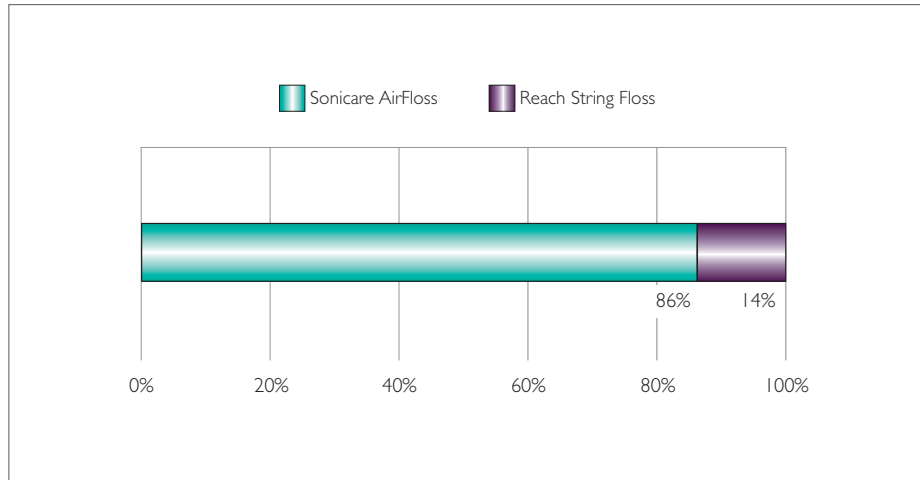
Preference

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

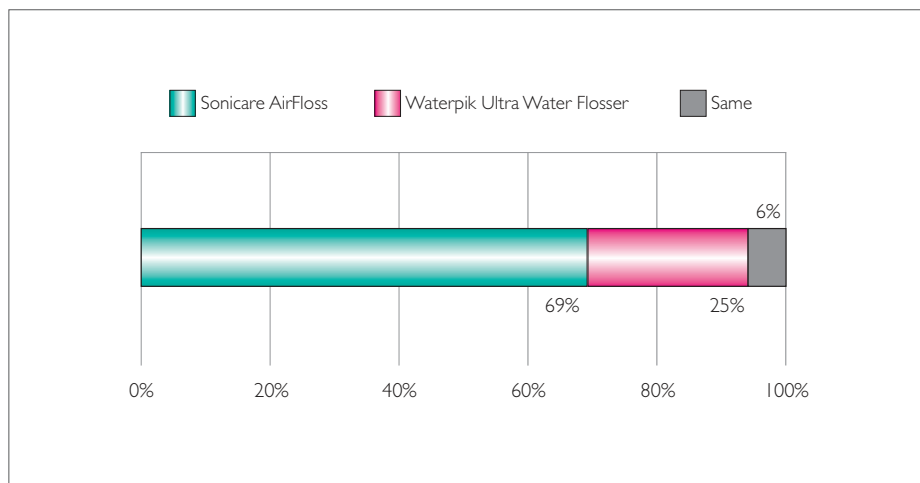
Krell S, Kaler A, Wei J. Data on file, 2010

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.

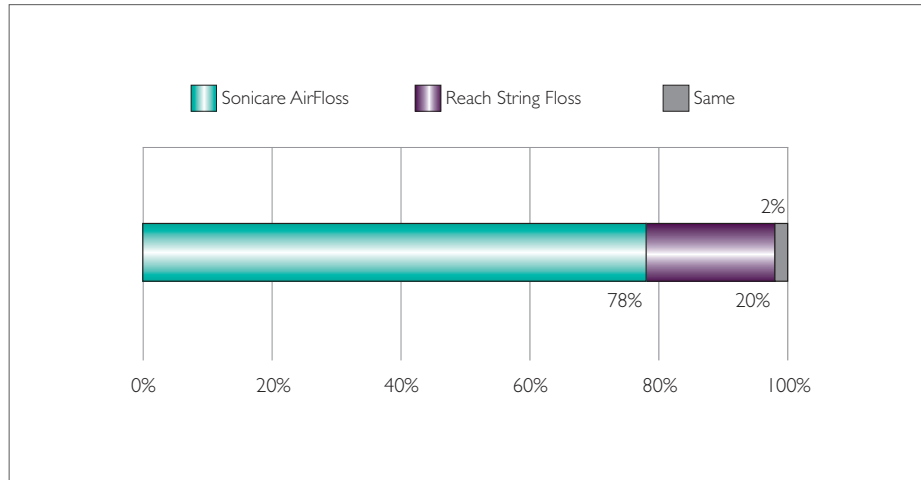
Which product was easier to use?



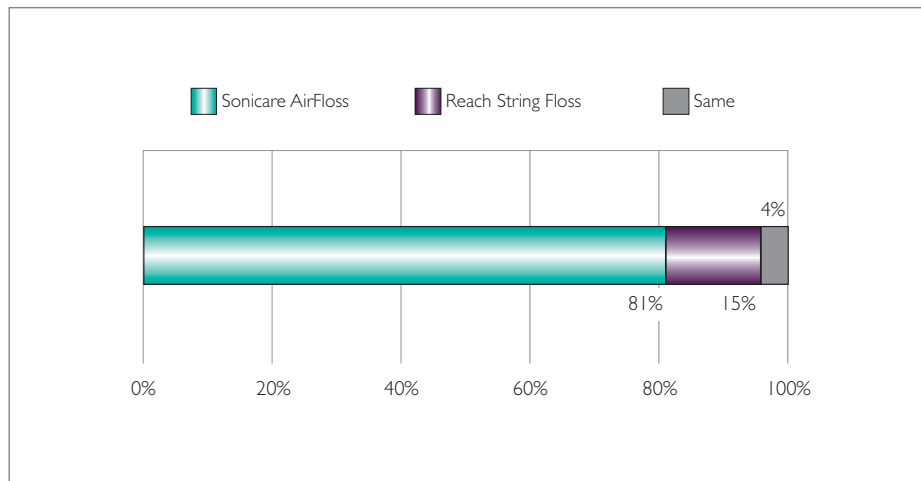
Which product was easier to use?



Which product was gentler on your teeth and gums?



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



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 Sonicare AirFloss in a sample of irregular flossers after three months 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 three months. 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 three months 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.

Safety

*in vitro 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	<p>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).</p> <p>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.</p> <p>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.</p> <p>Environmental scanning electron microscope (ESEM) inspection was used to determine if there was any visual evidence of erosion.</p>
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.

**Results will vary with actual use*

Gingival Health

in vivo study

Comparison of gingivitis and plaque reduction over time by Philips Sonicare FlexCare Platinum and a manual toothbrush

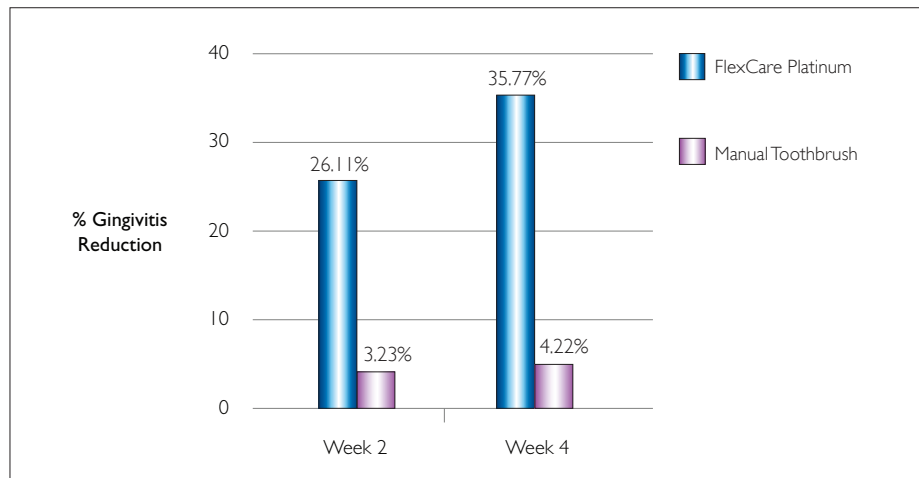
Ward M, Argosino K, Jenkins W, Milleman J, Milleman K, Nelson M, Souza S. Data on file, 2012.

Objective	To evaluate the ability of the Sonicare FlexCare Platinum toothbrush to reduce gingivitis, gingival bleeding and plaque versus a manual toothbrush following two and four weeks of product use.
Methodology	One hundred forty-eight adults (101 females; 47 males) with mild to moderate gingivitis, aged 18-65 years (mean, 42.5 years) participated in a single-blind, randomized, parallel-design IRB-approved clinical study. Eligible subjects were routine manual toothbrush users with a minimum Modified Quigley-Hein Plaque Index of ≥ 1.8 following three to six hours of plaque accumulation, and a Gingival Bleeding Index of ≥ 1 on at least 20 sites. Eligible subjects were randomized to either Sonicare FlexCare Platinum with InterCare standard brush head or ADA reference manual toothbrush (MTB) use. Subjects were instructed to brush twice daily for a four-week period. Efficacy and safety evaluations occurred at Weeks 2 and 4, in which gingivitis, bleeding and plaque levels were reassessed. Compliance was tracked at each follow-up visit by subject diary review. Safety was assessed by intraoral exam and subject report.
Results	<p>Sonicare FlexCare Platinum significantly reduced gingivitis, gingival bleeding and plaque following two and four weeks of product use.</p> <p>Sonicare FlexCare Platinum group was significantly superior to MTB on all clinical metrics as follows:</p> <p>For gingivitis reduction, FlexCare Platinum with InterCare standard brush head was superior to MTB at two and four weeks ($p < 0.0001$)</p> <p>For gingival bleeding reduction, FlexCare Platinum with InterCare standard brush head was superior to MTB at two and four weeks ($p < 0.0001$)</p> <p>For plaque reduction, FlexCare Platinum with InterCare standard brush head was superior to MTB at two and four weeks, overall and in all sub-regions ($p < 0.0001$)</p> <p>There were no adverse events reported.</p>

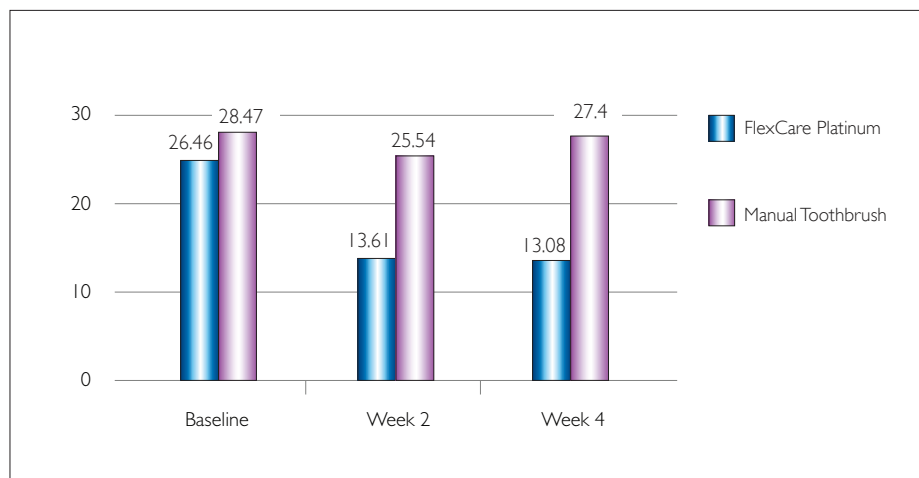
Conclusion

Sonicare FlexCare Platinum was significantly superior to a manual toothbrush in reducing gingivitis, sites of gingival bleeding and plaque at two and four weeks in a population of subjects with mild to moderate gingivitis. The products were safe for use, including for subjects with functional and cosmetic restorations.

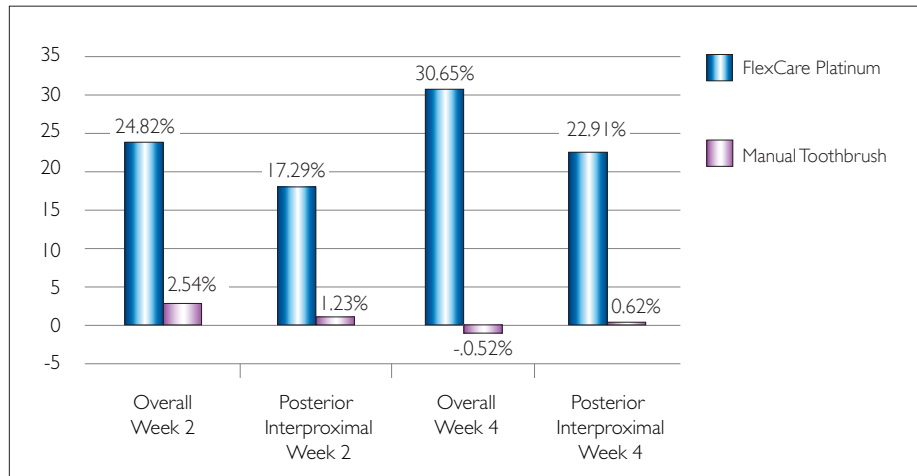
Percent Gingivitis Reduction from Baseline Overall



Number of Sites with Gingival Bleeding



Percent Plaque Reduction from Baseline, Overall and Posterior Interproximal



Gingival Health

in vivo study

Comparison of gingivitis and plaque reduction over time by Philips Sonicare FlexCare Platinum with compact brush head and a manual toothbrush

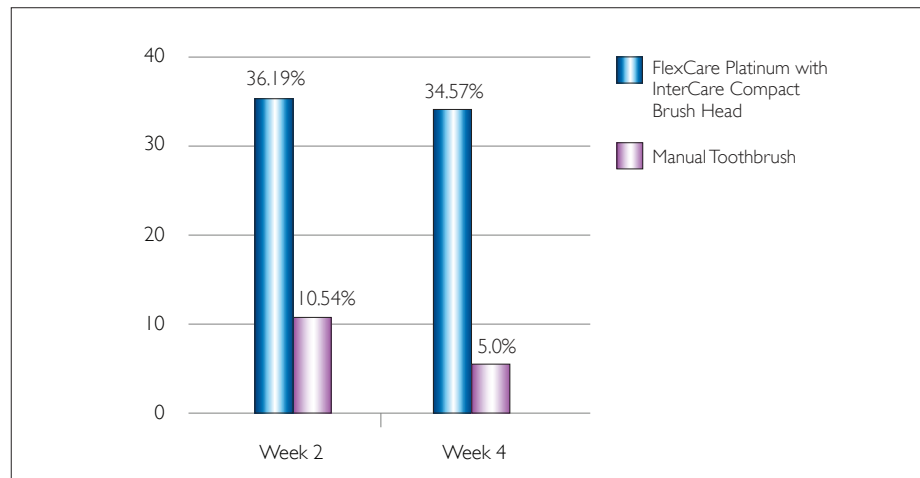
Ward M, Argosino K, Jenkins W, Milleman J, Milleman K, Nelson M, Souza S, Data on file, 2012.

Objective	To evaluate the ability of the Sonicare FlexCare Platinum toothbrush with InterCare compact brush head to reduce gingivitis, gingival bleeding and plaque versus a manual toothbrush following two and four weeks of product use.
Methodology	One hundred fifty adults (104 females; 46 males) with mild to moderate gingivitis, aged 18-65 years (mean age, 42.2 years), participated in a single-blind, randomized, parallel-design IRB-approved clinical study. Eligible subjects were routine manual toothbrush users with a minimum Modified Quigley-Hein Plaque Index of ≥ 1.8 following three to six hours of plaque accumulation and a Gingival Bleeding Index of ≥ 1 on at least 20 sites. Eligible subjects were randomized to either Sonicare FlexCare Platinum with compact brush head or ADA reference manual toothbrush (MTB) use. Subjects were instructed to brush twice daily for a four-week period. Efficacy and safety evaluations occurred at Weeks 2 and 4, in which gingivitis, bleeding and plaque levels were reassessed. Compliance was tracked at each follow-up visit by subject diary review. Safety was assessed by intraoral exam and subject report.
Results	<p>Sonicare FlexCare Platinum group significantly reduced gingivitis, gingival bleeding and plaque following two and four weeks of product use.</p> <p>Sonicare FlexCare Platinum with InterCare compact brush head was significantly superior to MTB on all clinical metrics as follows:</p> <p>For gingivitis reduction, FlexCare Platinum with InterCare compact brush head was superior to MTB at two and four weeks ($p < 0.0001$)</p> <p>For gingival bleeding reduction, FlexCare Platinum with InterCare compact brush head was superior to MTB at two and four weeks ($p < 0.0001$)</p> <p>For plaque reduction, FlexCare Platinum with InterCare compact brush head was superior to MTB at two and four weeks overall and in all sub-regions ($p < 0.0001$)</p> <p>There were no adverse events reported.</p>

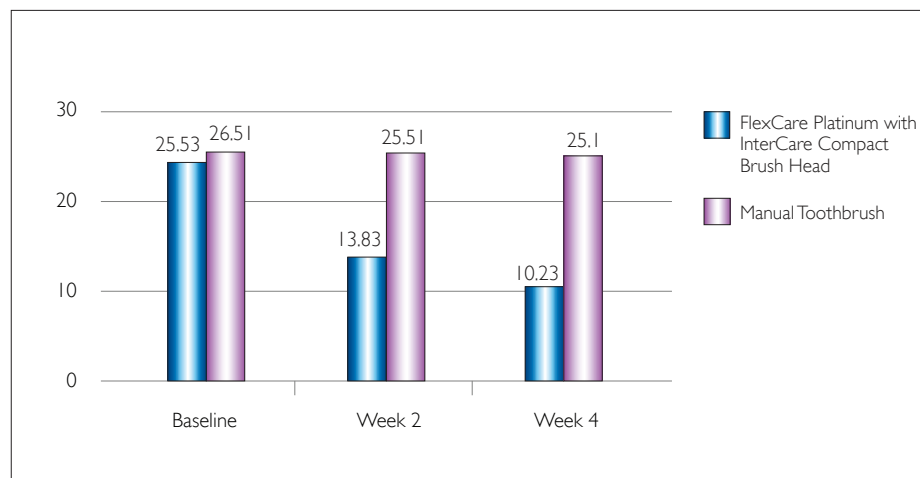
Conclusion

Sonicare FlexCare Platinum with InterCare compact brush head was significantly superior to a manual toothbrush in reducing gingivitis, sites of gingival bleeding and plaque at two and four weeks in a population of subjects with mild to moderate gingivitis. Both products were safe for use, including for subjects with functional and cosmetic restorations.

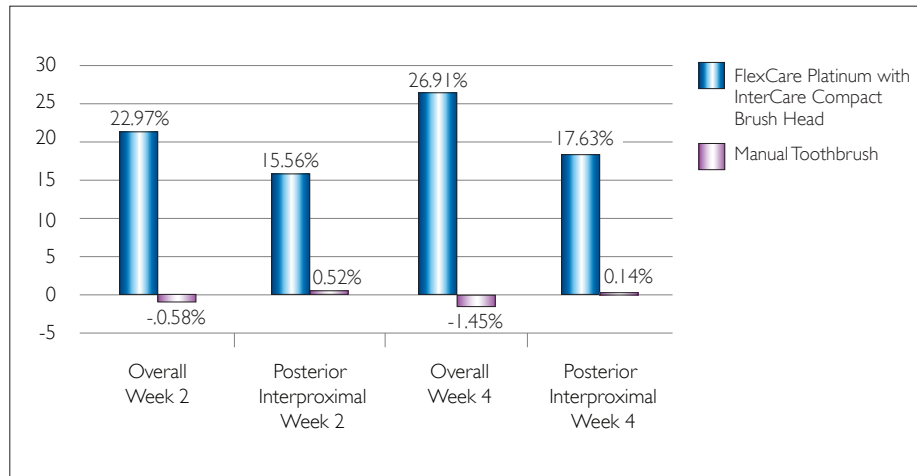
Percent Gingivitis Reduction from Baseline Overall



Number of Sites With Gingival Bleeding



Percent Plaque Reduction from Baseline, Overall and Posterior Interproximal



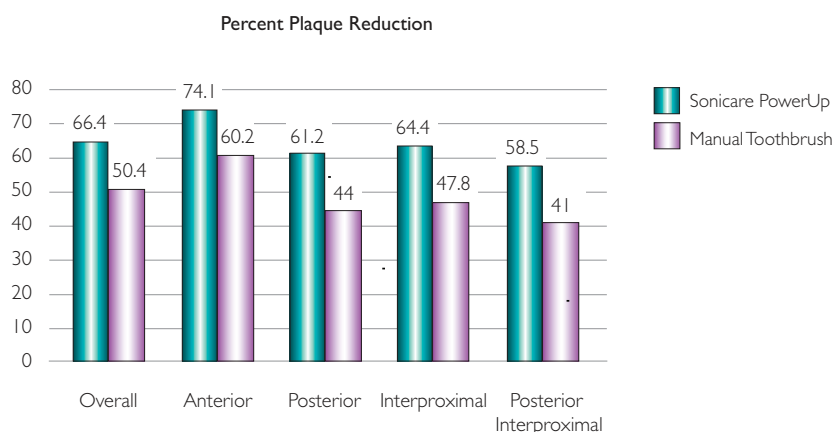
Plaque Removal

in vivo study

Comparison of plaque removal efficacy by Philips Sonicare PowerUp with ProResults standard brush head and a manual toothbrush

Argosino K, Jenkins W, Milleman, J, Nelson M, Souza S, Ward M. Data on file, 2012.

Objectives	To compare the overall plaque removal effects of a Sonicare PowerUp with ProResults standard brush head versus a manual toothbrush.
Methodology	A randomized, examiner-blinded, parallel-design, IRB-approved clinical study was conducted in 152 healthy adults (100 females; 52 males) aged 18-65 years (mean 42.6 years). Subjects presented to the clinic with 24 (+/- 4) hours of oral hygiene abstinence and were randomized to one of two treatment groups for one week. One treatment group used a Philips Sonicare PowerUp toothbrush with ProResults standard brush head at home for three days (twice daily) of technique familiarization, followed by four days of 'wash-out' with an ADA reference manual toothbrush; a second treatment group used only the ADA reference manual toothbrush. Compliance was tracked using verbal interviews and review of subject diaries. Single-use plaque removal efficacy was assessed by scoring before and after brushing using the Turesky-Modified Quigley-Hein Plaque Index. Safety was assessed in an intraoral examination.
Results	The Sonicare PowerUp with ProResults standard brush head removed significantly more plaque than a manual toothbrush overall (66.4% vs 50.4%, $P < 0.0001$) and in all sub regions, including hard-to-reach areas. Both products were safe for use.
Conclusion	The Sonicare PowerUp with ProResults standard brush head was found to be superior to a manual toothbrush in removing plaque when assessed over the entire dentition (overall) as well as in hard-to-reach areas.



Plaque Removal

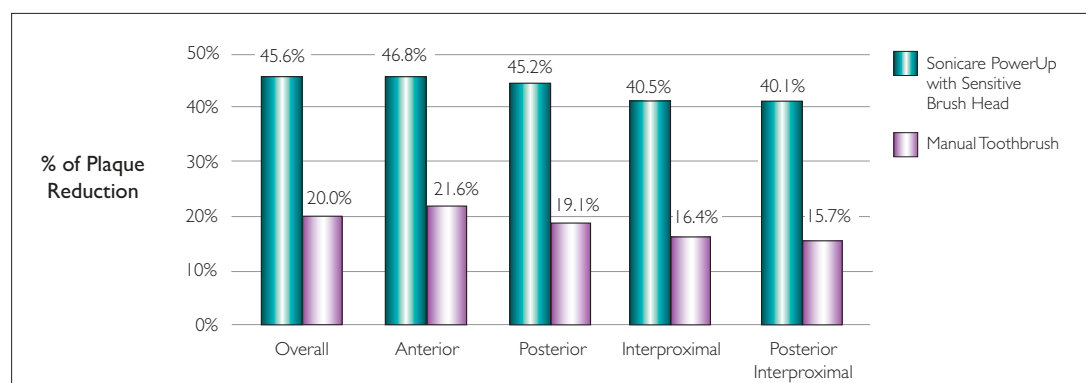
in vivo study

Comparison of plaque removal by Sonicare PowerUp with sensitive brush head and a manual toothbrush

Liu T, Souza S, Milleman J, Argosino K, Jenkins W, Ward M. Data on file, 2012.

Objective	To compare the plaque removal efficacy of Sonicare PowerUp with standard sensitive brush head versus a manual toothbrush.
Methodology	A randomized, examiner-blinded parallel design, two-visit study was conducted in healthy volunteers aged 18-65 (mean age 40.4). All 129 enrolled subjects provided informed consent and completed the IRB-approved study. Subjects presented to clinic at Visit 1 with 24 (+/- 4) hours of plaque accumulation. Eligible subjects were randomized to one of two treatment groups: Sonicare PowerUp with Sensitive brush head or ADA reference manual toothbrush for a three-day technique familiarization phase. Thereafter, all subjects used manual toothbrush for a three-day wash-out period. Subjects presented to clinic for Visit 2 on Day 7 with 24 hours of plaque accumulation. A pre-brushing plaque score was assessed upon entry using the Modified Quigley-Hein Plaque Index, followed by supervised brushing per randomization by unblinded study personnel. A second plaque score was assessed post-brushing and subjects were dismissed from study. Safety was assessed via intraoral examination and per subject report during the at-home product use period.
Results	Sonicare PowerUp with standard sensitive brush head removed significantly more plaque than a manual toothbrush overall (45.6% versus 20%, $p < 0.0001$) and in all sub-regions, including hard-to-reach areas.
Conclusion	Sonicare PowerUp with sensitive brush head was found to be superior to a manual toothbrush in removing plaque when assessed over the entire dentition (overall), as well as in hard-to-reach areas. Both products were safe for use.

Percent Plaque Reduction, Sonicare PowerUp vs. Manual Toothbrush



Gingival Health

in vivo study

Comparison of gingivitis reduction and plaque removal by Sonicare DiamondClean and a manual toothbrush

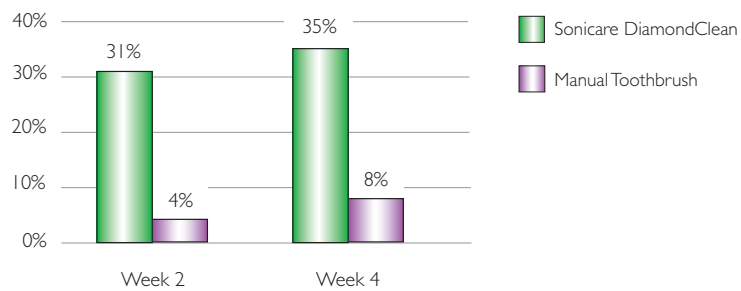
Delaurenti M, et al. An Evaluation of Two Toothbrushes on Plaque and Gingivitis. *Journal of Dental Research*. 2012, 91 (Special Issue B):522.

Objectives	<p>To evaluate the ability of the Sonicare DiamondClean to reduce gingivitis and gingival bleeding versus a manual toothbrush over time.</p> <p>To compare the plaque removal ability of the Sonicare DiamondClean to a manual toothbrush over time.</p>
Methodology	<p>One hundred forty-two healthy adults aged 18-64 years participated in a single-blind, randomized, parallel group clinical study assessing gingivitis and plaque over time for the Sonicare DiamondClean and an ADA reference manual toothbrush. Eligible subjects were routine manual toothbrush users with a minimum Turesky Quigley-Hein Plaque Index of ≥ 1.8 presented following three to six hours plaque accumulation, with at least 20 sites graded ≥ 1 by the Modified Gingival Index. Eligible subjects were randomized and trained on product usage twice daily. Subjects retained the assigned product for four weeks. Efficacy and safety evaluations occurred at Weeks 2 and 4, in which gingivitis and plaque levels were reassessed.</p>
Results	<p>The Sonicare DiamondClean showed significant reduction from baseline in gingivitis after two and four weeks of product use ($p < 0.0001$).</p> <p>The Sonicare DiamondClean showed significant reduction from baseline in the number of sites with gingival bleeding over two and four weeks ($p < 0.0001$).</p> <p>The Sonicare DiamondClean was significantly superior to a manual toothbrush in reducing gingivitis and the number of sites with gingival bleeding over two and four weeks ($p < 0.0001$).</p> <p>The Sonicare DiamondClean showed significant reduction from baseline in plaque after two and four weeks of product use ($p < 0.0001$).</p> <p>The Sonicare DiamondClean was significantly superior to a manual toothbrush in overall percent plaque reduction over two and four weeks ($p < 0.0001$).</p> <p>The Sonicare DiamondClean was superior to a manual toothbrush in plaque reduction in all sub-regions of the mouth over two and four weeks ($p < 0.0001$).</p>

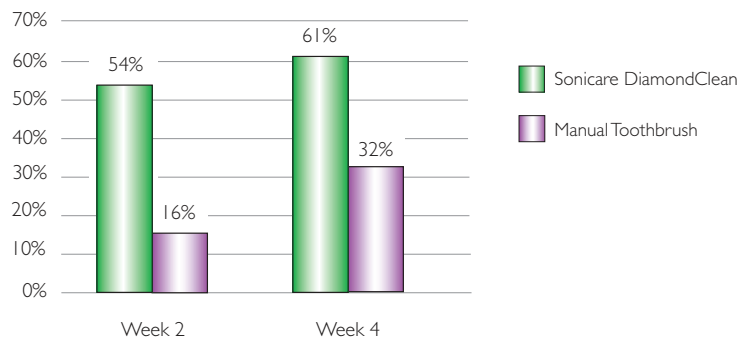
Conclusion

Sonicare DiamondClean was demonstrated to be up to two times more effective at reducing gingivitis and gingival bleeding relative to a manual toothbrush, and up to five times more effective at removing plaque. Both products were safe for use.

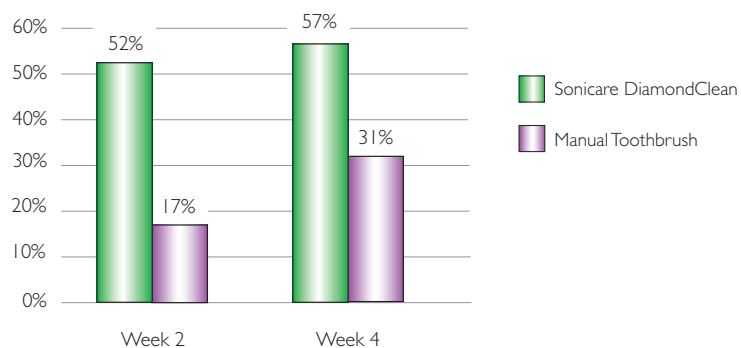
Percent Plaque Reduction from Baseline Overall



Percent Gingivitis Reduction from Baseline Overall



Percent Reduction in Sites of Gingival Bleeding from Baseline



Plaque Removal

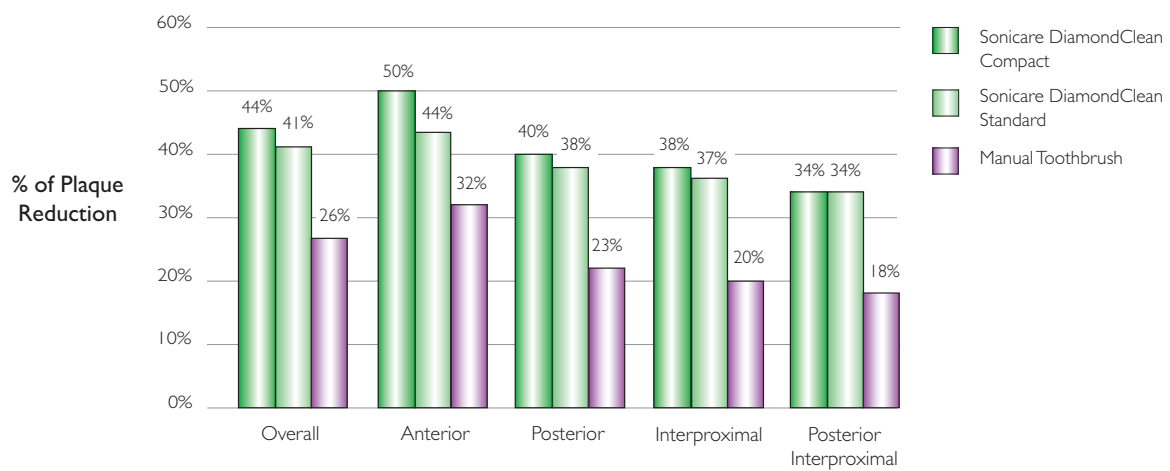
in vivo study

Plaque removal efficacy of two novel Philips Sonicare DiamondClean brush heads

Putt M, Milleman J, DeLaurenti M, Schmitt P. Data on file, 2010

Objective	To evaluate the plaque removal efficacy and safety of the Philips Sonicare DiamondClean standard and compact brush heads, the Sonicare ProResults brush head and a manual toothbrush.
Methodology	A randomized, examiner-blinded, parallel-design study was conducted in a population of 106 healthy adults (81 females, 25 males) aged 18-60 years (mean age: 37) who have been using Philips Sonicare FlexCare with ProResults brush head at home for technique familiarization. These subjects presented to the clinic with 24 (+/- 4) hours of plaque growth and were randomized to use one of the four different test devices. The test devices were ProResults standard brush head, Sonicare DiamondClean standard or compact brush head and ADA reference manual toothbrush. To assess single-use efficacy in plaque removal, plaque scores were assessed before and after brushing using the Turesky-Modified Quigley-Hein Plaque Index. Safety was assessed in an oral soft tissue examination.
Results	Sonicare DiamondClean brush head (standard and compact) removed significantly more plaque than a manual toothbrush overall and in all other regions, including hard-to-reach areas. Sonicare DiamondClean compact brush head removed 100% more plaque in hard-to-reach areas than a manual toothbrush. All products were safe for use.
Conclusion	Both Sonicare DiamondClean brush heads (standard and compact) were found to remove significantly more plaque than a manual toothbrush.

Region	Device	Mean plaque reduction scores	Performance improvement vs Sonicare ProResults (%)
Overall	Sonicare DiamondClean Compact	1.29	45%
	Sonicare DiamondClean Standard	1.19	33%
	Sonicare ProResults Standard	0.89	



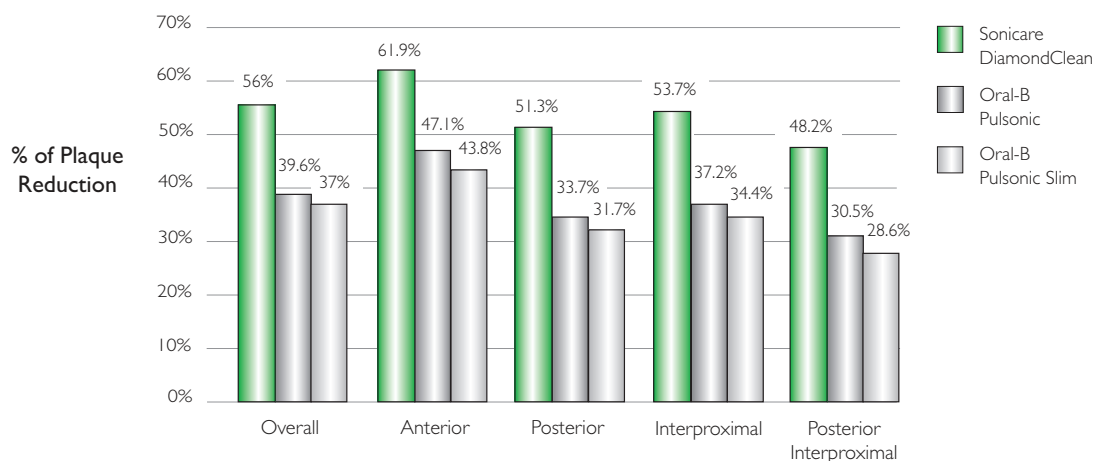
Plaque Removal

in vivo study

Comparison of plaque removal by Philips Sonicare DiamondClean and Oral-B Pulsonic

Amini P, Goyal C R, Strate J. Data on File, 2011

Objective	To compare the plaque removal ability of Sonicare DiamondClean to Oral-B Pulsonic (S26.523.3) and Oral-B Pulsonic Slim (S15.513.2).
Methodology	Fifty healthy adults completed a randomized, cross-over design study to evaluate the plaque removal effects of brushing in a single-use model with Sonicare DiamondClean, Oral-B Pulsonic and Oral-B Pulsonic Slim. Eligible subjects were randomized to a sequence of product home use for familiarization followed by a manual toothbrush wash-out. Subjects were to brush for two minutes, twice daily, for each brushing encounter. Compliance was tracked by subjects in a home-use diary. For the efficacy evaluation, subjects presented to clinic with 24 hours of plaque accumulation and were dispensed a new brush head for use in a supervised brushing encounter by clinic staff per the randomization assignment. Plaque was assessed before and after the supervised brushing encounter using the Turesky-Modified Quigley-Hein Plaque Index by a blinded examiner. Safety was assessed by intra-oral examination.
Conclusion	Philips Sonicare DiamondClean removed statistically significantly more plaque than Oral-B Pulsonic and Oral-B Pulsonic Slim overall and in all sub-regions of the mouth ($p < 0.001$). Both products were safe for use.



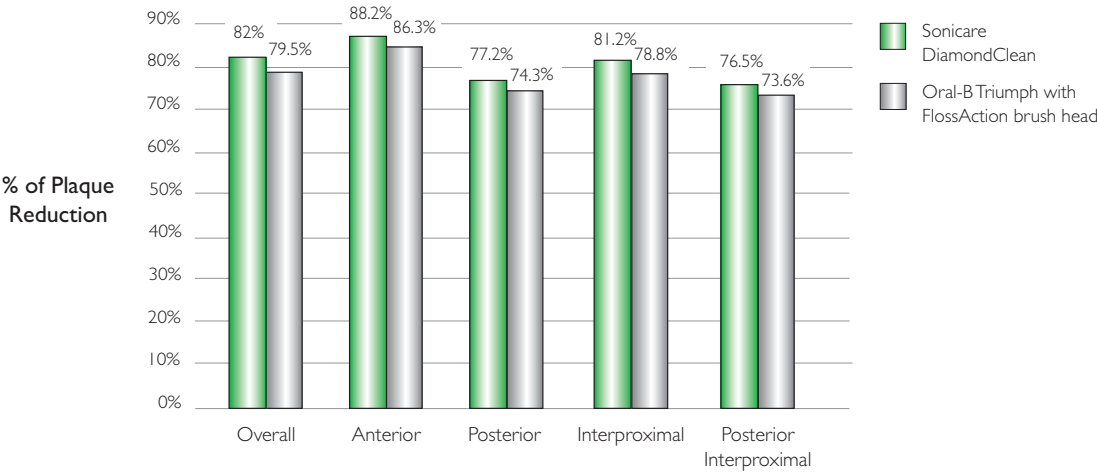
Plaque Removal

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.



Plaque Removal

in vivo study

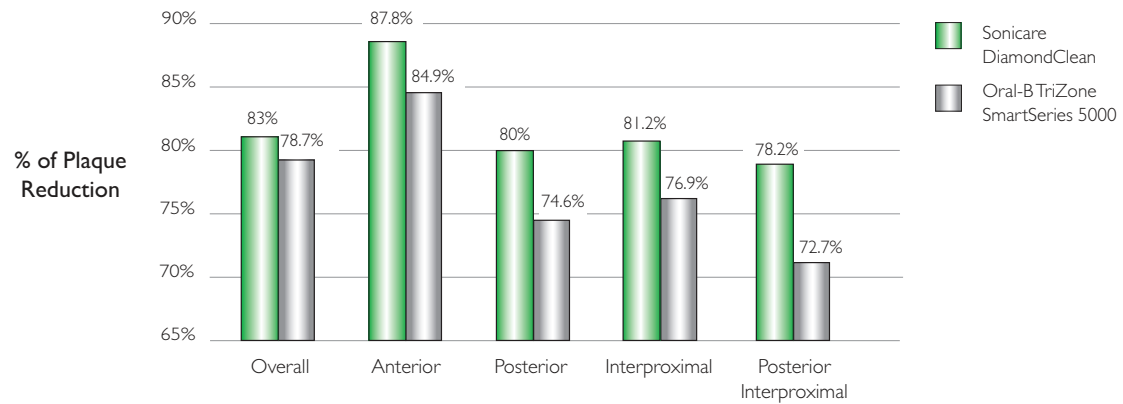
Comparison of plaque removal by Sonicare DiamondClean and Oral-B TriZone SmartSeries 5000 with SmartGuide

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.



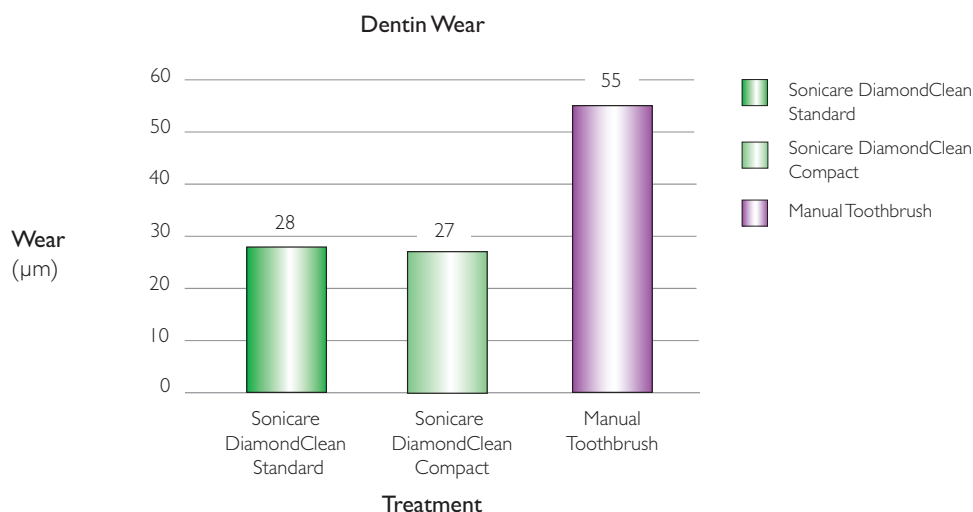
Gentleness

*in vitro study**

In vitro assessment of dentin wear resulting from the use of the Philips Sonicare DiamondClean power toothbrush

Moore M, Putt M, Jain V, de Jager M. Data on file, 2010

Objective	To evaluate dentin wear associated with the use of Philips Sonicare DiamondClean standard and compact brush heads compared to a manual toothbrush using simulated clinical conditions.
Methodology	Twenty-four human dentin slices with a surface of 3x10 mm were embedded in temporary crown and bridge material and polished to render a smooth surface as starting condition. Samples were brushed either with Sonicare DiamondClean standard and compact brush heads using externally powered Sonicare handles at 100 grams or with an ADA reference manual toothbrush at 250 grams brushing load. These brushing loads represent clinical use conditions. All specimens were brushed using toothpaste slurry for a period representing six months (3,000 strokes) of clinical brushing. Dentin wear was determined before and after brushing using surface profilometry to establish the mean depth of induced surface wear from toothbrushing.
Results	Both Sonicare DiamondClean standard and compact brush heads resulted in significantly less dentin abrasion than the manual toothbrush ($p < 0.05$). There was no significant difference between Sonicare DiamondClean standard and compact brush heads.
Conclusion	In this in vitro study, the Sonicare DiamondClean standard and compact brush heads were found to cause about 50% less dentin wear than a manual toothbrush.



*Results will vary with actual use

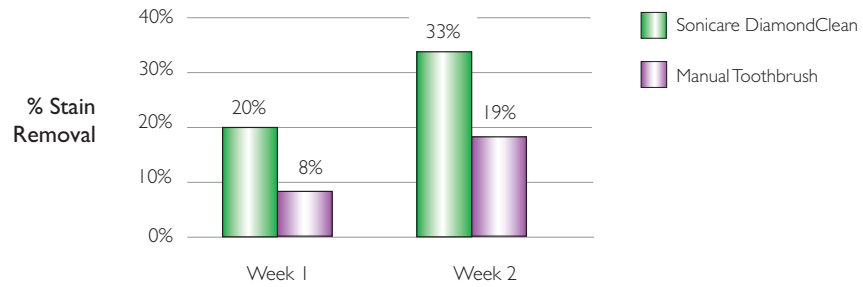
Stain Removal

in vivo study

Evaluation of stain removal by Philips Sonicare DiamondClean power toothbrush and manual toothbrushes

Colgan P, DeLaurenti M, Johnson M, Jenkins W, Strate J. Data on file, 2010

Objective	To evaluate the reduction of naturally occurring tooth stain for Philips Sonicare DiamondClean and manual toothbrushes over two weeks of product use.
Methodology	A randomized, multicenter, examiner-blinded, parallel, two-stage group, sequential-design study was conducted in a population of 179 healthy adults (124 females, 55 males) aged 18-65 years (mean age: 40) who had naturally occurring tooth stain on the buccal surface of the anterior teeth. The subject population included smokers and consumers of coffee, tea and red wine. The subjects were screened and consented at Visit 1 for qualification to enroll in the study. Subjects were instructed to abstain from smoking, eating or drinking fluids other than water for two hours prior to clinical visits and presented to the clinic within three to six hours of their last toothbrushing encounter. At Visit 2 (day 7 to day 1), stain was re-evaluated to confirm eligibility and participants were randomized either to the Sonicare DiamondClean power toothbrush or to the ADA reference manual toothbrush. Subjects were instructed on product usage and brushed at home twice daily using Crest Cool Mint Gel dentifrice. At Visit 3 (day 7) and Visit 4 (day 14), subjects returned to the clinic for safety and stain evaluations. Stain was assessed by using Modified Lobene Stain Index (MLSI).
Results	All 179 subjects completed the study. Sonicare DiamondClean power toothbrush removed significantly more surface stain than a manual toothbrush. The mean baseline overall MLSI score for Sonicare DiamondClean was 0.55 and 0.56 for a manual toothbrush. The mean percent reduction in MLSI for Sonicare DiamondClean following one and two weeks of use was 20% and 33% respectively ($p < 0.0001$ at each time point). The Sonicare DiamondClean power toothbrush was significantly superior to a manual toothbrush, reducing surface stain by 137% following one week of product use and by 67% following two weeks ($p < 0.01$ /week 1; $p < 0.01$ /week 2). Both products were safe for use.
Conclusion	Sonicare DiamondClean power toothbrush effectively removed extrinsic tooth stain within one and two weeks of use, and it was significantly superior to a manual toothbrush at both time points.



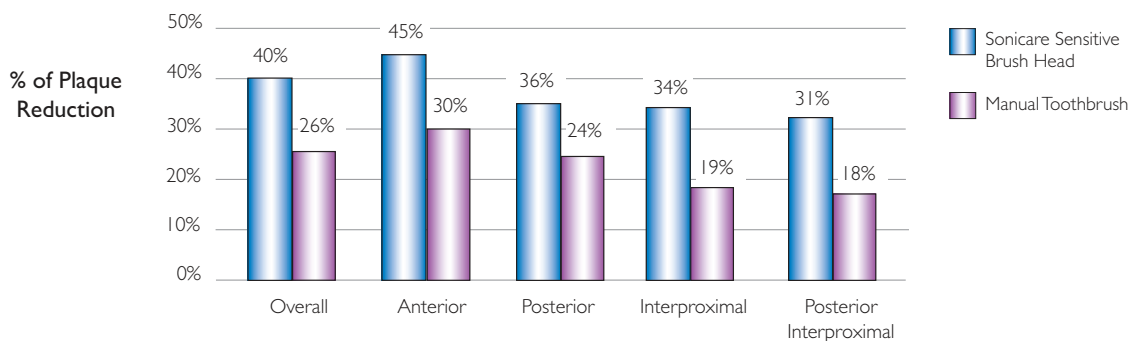
Plaque Removal

in vivo study

Comparison of plaque removal by novel Philips Sonicare sensitive brush head and a manual toothbrush

Putt M, Milleman J, Jenkins W, Schmitt P. Data on file, 2010

Objective	To evaluate the plaque removal efficacy and safety of the Sonicare sensitive brush head and a manual toothbrush.
Methodology	A randomized, examiner-blinded, parallel-design study was conducted in a population of 60 healthy adults (45 females, 15 males) aged 18-63 years (mean age: 39.4) who have been using Philips Sonicare FlexCare with ProResults brush head at home for technique familiarization. These subjects presented to the clinic with 24 (+/- 4 hours of plaque growth and were randomized to use one of the two test devices. The test devices were Sonicare sensitive brush head and ADA reference manual toothbrush. To assess single-use efficacy in plaque removal, plaque scores were assessed before and after brushing using the Turesky-Modified Quigley-Hein Plaque Index. Safety was assessed in an oral soft tissue examination.
Results	The Sonicare sensitive brush head removed significantly more plaque than a manual toothbrush overall and in all sub regions, including hard-to-reach areas. The Sonicare sensitive brush head removed 54% more plaque overall than a manual toothbrush. Both products were safe for use.
Conclusion	The Sonicare sensitive brush head was found to remove significantly more plaque than a manual toothbrush when assessed over the entire dentition (overall) as well as in hard-to-reach areas.



Plaque Removal

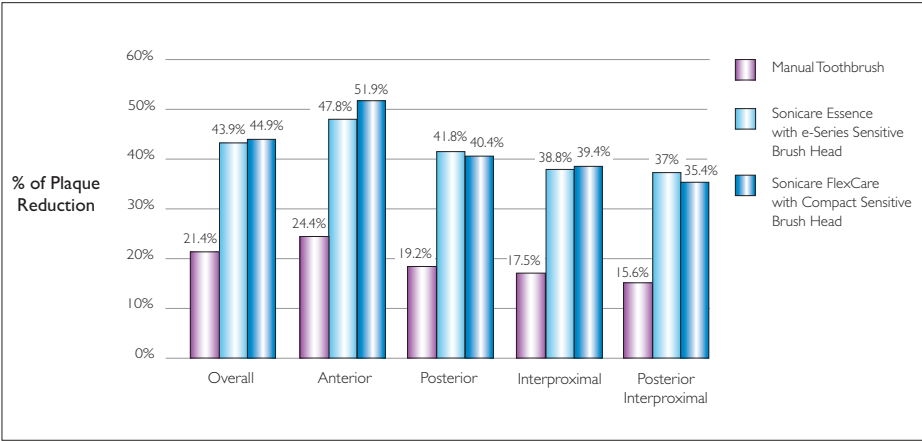
in vivo study

Comparison of plaque removal by two Philips Sonicare power toothbrushes with sensitive brush heads and a manual toothbrush

Argosino K, Jenkins W, Milleman J, Nelson M, Souza S, Ward M. Data on file, 2012.

Objective	To evaluate the overall plaque removal efficacy and safety of the Sonicare Essence with e-Series sensitive brush head, Sonicare FlexCare with compact sensitive brush head and a manual toothbrush.
Methodology	A randomized, examiner-blinded, three-arm parallel-design IRB-approved clinical study was conducted in 155 healthy adults (103 females; 52 males) aged 18-65 years (mean, 41.8 years). Eligible subjects were randomized to one of three treatment groups: Sonicare Essence with e-Series sensitive brush head, Sonicare FlexCare with compact sensitive brush head or ADA reference manual toothbrush (MTB). Subjects were instructed to brush twice daily with the assigned product for three days to acclimate to product-use technique. Thereafter, all subjects entered an MTB washout phase for three days. Subjects then returned to clinic with 24 (+/-4) hours plaque accumulation. Efficacy was assessed using the Modified Quigley Hein Plaque Index, where plaque status was assessed before and after a supervised brushing encounter with the assigned device. Compliance was tracked using verbal interviews and review of subject diaries. Safety was assessed in an intraoral examination.
Results	Sonicare Essence with e-Series sensitive brush head removed 43.9% plaque overall, Sonicare FlexCare with compact sensitive brush head removed 44.9% and MTB removed 21.4%. The differences between the power toothbrushes versus manual toothbrush are statistically significant ($p < 0.001$). There was no statistical difference between power toothbrushing groups. There were no adverse events reported.
Conclusion	Both Sonicare Essence with e-Series sensitive brush head and Sonicare FlexCare with compact sensitive brush head were found to be superior to a manual toothbrush in removing plaque when assessed over the entire dentition (overall) as well as in hard-to-reach areas. All products were safe for use.

Percent Plaque Reduction



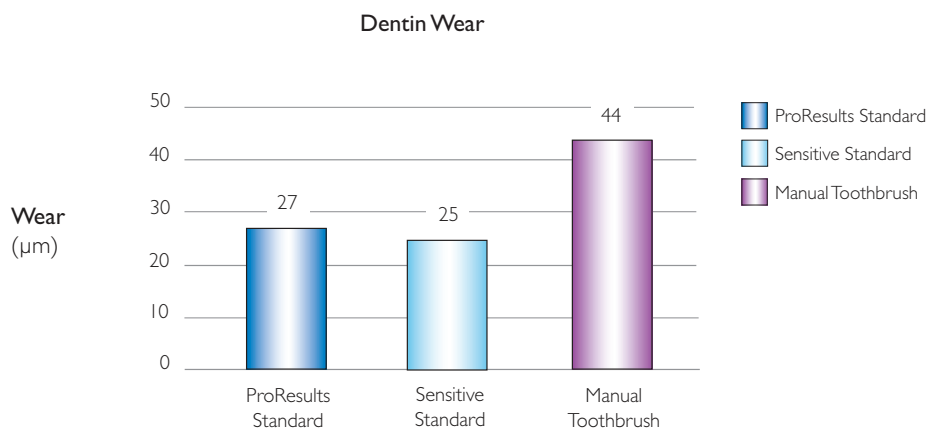
Gentleness

*in vitro study**

In vitro assessments of dentin wear resulting from the use of the Sonicare sensitive brush head

Hix J, de Jager M, Contracted Dental Research Laboratory. Data on file, 2011

Objective	To evaluate dentin wear associated with the use of Sonicare sensitive and ProResults brush heads compared to a manual toothbrush using simulated clinical conditions.
Methodology	Twenty-four human dentin slices with a surface of 3x10 mm were embedded in temporary crown and bridge material and polished to render a smooth surface as starting condition. Samples were brushed with a sensitive or a ProResults brush head using externally powered Sonicare handles at 100 grams or brushed with an ADA reference manual toothbrush at 250 grams brushing load. (These brushing loads represent clinical use conditions.) All specimens were brushed using toothpaste slurry for a period representing six months (3,000 strokes) of clinical brushing. Dentin wear was determined before and after brushing using surface profilometry to establish the mean depth of induced surface wear from toothbrushing.
Results	The sensitive brush head resulted in significantly less dentin abrasion than the manual toothbrush ($p < 0.05$).
Conclusion	In this in vitro study, the sensitive brush head was found to cause about 56% less dentin abrasion than a manual toothbrush.



*Results will vary with actual use

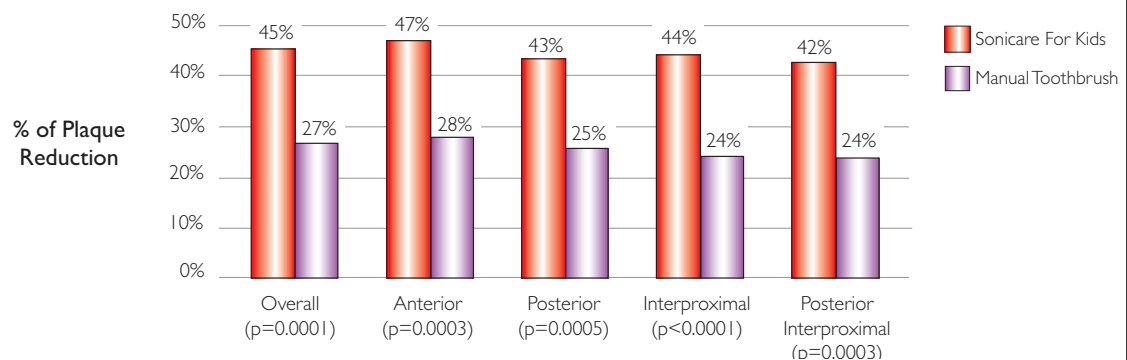
Plaque Removal

in vivo study

Comparison of plaque removal by Sonicare For Kids and a manual toothbrush in children aged 7–10 years

Milleman J, Putt M, Olson M, Master A, Jenkins W, Schmitt P, Strate J. *International J Pediatric Dent.* 2009; 19:s1

Objective	To compare the plaque removal efficacy and safety of Sonicare For Kids at “high” setting and Oral-B Stages 4® manual toothbrush (MTB) in children aged 7–10 years.
Methodology	Fifty-eight healthy children enrolled in and four withdrew from an IRB-approved single-blind, randomized, parallel-design study (totaling 32 females, 22 males; mean age 8.3 years). Informed consent/assent (with parent) was obtained. All subjects abstained from brushing for 26 ± 6 hours prior to examination visits. At Visit 1, subjects were screened for eligibility (Turesky-Modified Quigley-Hein Plaque Index (TPI) >1.8). Eligible subjects were enrolled and instructed on use of both devices (Sonicare For Kids and MTB) in alternating manner at home (twice daily for two minutes) for a one-week familiarization period. At Visit 2, baseline TPI was performed followed by a randomization and supervised two-minute brushing session with the assigned device. Post-brushing TPI scores were then obtained. Safety was assessed in oral soft tissue examinations at Visit 2. ANOVA was used for the primary statistical analysis.
Results	Sonicare For Kids removed significantly more plaque than a manual toothbrush from the dentition overall ($p=0.0001$) as well as in hard-to-reach areas, i.e., the posterior teeth ($p=0.0005$) and the interproximal spaces ($p<0.0001$) of children aged 7–10 years. Both toothbrushes were safe to use.
Conclusion	Sonicare For Kids was found to remove significantly more plaque than Oral-B Stages 4 manual toothbrush in children aged 7–10 years. It is also proven safe and gentle on oral tissues.



Plaque Removal

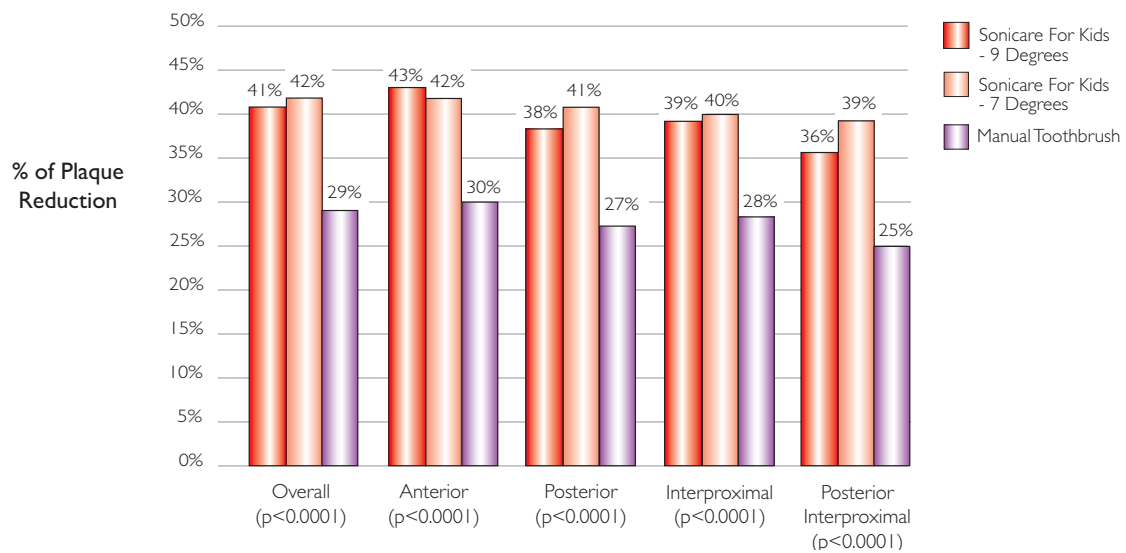
in vivo study

Comparison of plaque removal by Sonicare For Kids and a manual toothbrush in children aged 4–7 years in a professionally applied toothbrushing study

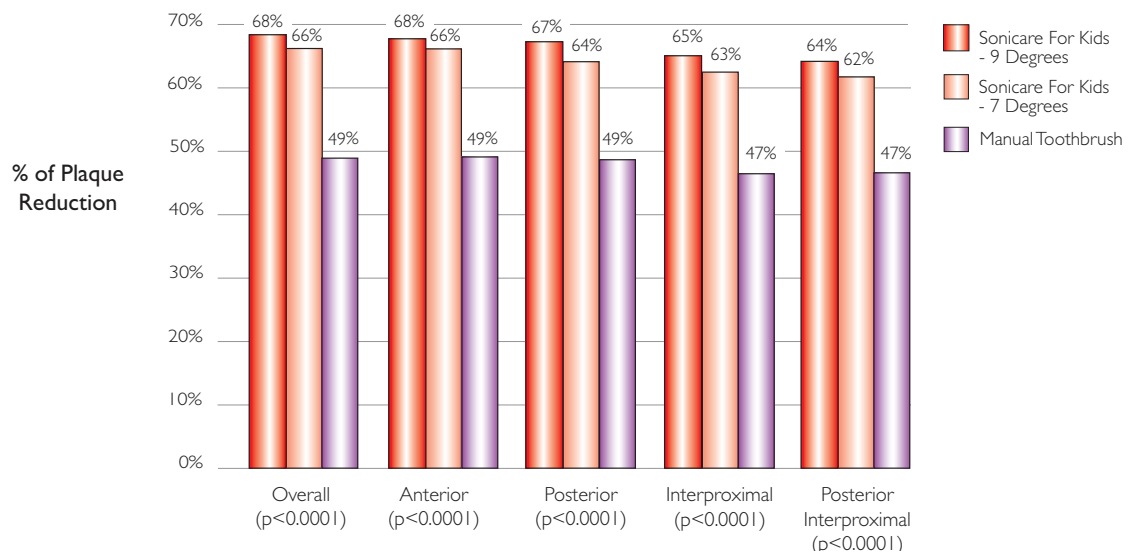
Pelka M, DeLaurenti M, Master A, Jenkins W, Strate J, Wei J, Schmitt P. *International J Pediatric Dent.* 2009; 19:s1

Objective	To compare the plaque removal efficacy of Philips Sonicare For Kids at “high” and “low” settings and Oral-B Stages 3® manual toothbrushes in a professionally applied brushing session simulating one and two minutes of brushing time in children aged 4–7 years.
Methodology	Sixty-eight healthy children (38 females, 30 males; mean age 5.3 years) participated in an IRB-approved single-blind, randomized, split-mouth-design study. Informed consent/assent (with parent) was obtained. Subjects were screened for eligibility (Turesky-Modified Quigley-Hein Plaque Index (TPI) >1.8). Eligible subjects were randomized to Sonicare For Kids “high,” Sonicare For Kids “low” and a manual toothbrush by quadrant and were brushed accordingly by clinical hygienists. TPI was scored at one- and two-minute interval equivalents by quadrant by a blinded examiner. Safety was assessed in oral soft tissue examinations. For statistical analysis, MANOVA for a split-mouth-design was applied and P-values were adjusted using the Dunnett-Hsu adjustment.
Results	Sonicare For Kids (in “high” and “low” settings) removed significantly more plaque than a manual toothbrush from the dentition overall ($p < 0.0001$) as well as in hard-to-reach areas, i.e., the posterior teeth ($p < 0.0001$) and the interproximal spaces ($p < 0.0001$) at one- and two-minute brushing intervals in children aged 4–7 years with professionally applied brushing sessions. Both toothbrushes were safe to use.
Conclusion	Sonicare For Kids was found to remove significantly more plaque than Oral-B Stages 3 manual toothbrush in children aged 4–7 years with professionally applied brushing. It is also proven safe and gentle on oral tissues.

Adjusted Mean Percent Plaque Reduction, Squirt Prototype
7 and 9 Degrees vs. Manual Toothbrush, 1-Minute Equivalent



Adjusted Mean Percent Plaque Reduction, Squirt Prototype
7 and 9 Degrees vs. Manual Toothbrush, 2-Minute Equivalent



Preference

An observational in-home use test of children 4-10 years using Sonicare For Kids

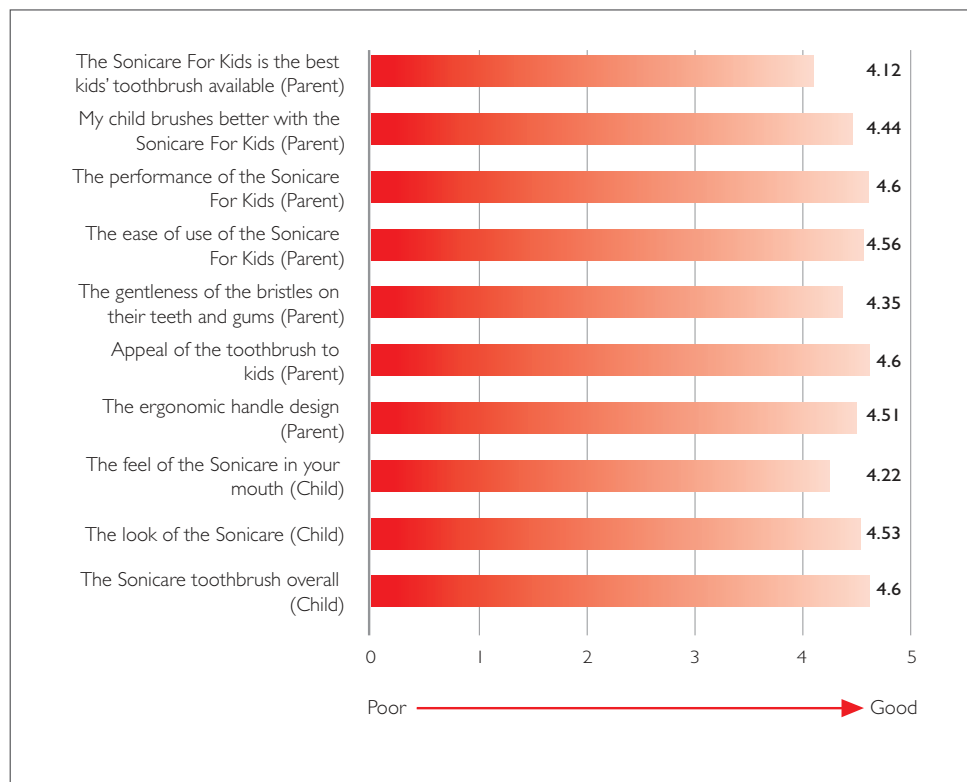
Jenkins W, Master A, Defenbaugh J, Wei J. Philips Oral Healthcare, Snoqualmie, WA; *J Dent Res* 89 (spec iss B); Abstract 3696, 2010

Introduction	The performance of an oral care product is fundamentally limited to the user's willingness to accept it into their regimen. In a product designed for children, the suitability of the experience (in all its dimensions) is as much a barrier to success as any primary metric of effective performance. Therefore, we conducted an in-home use study with a novel power toothbrush for children.
Objective	To evaluate whether the Philips Sonicare For Kids toothbrush, designed to positively influence engagement, experience and motivation, results in an acceptable and successful home toothbrushing experience between parents and children.
Methodology	Eligible participants included dental professional (DP) adults (from across North America) with children aged 4-10 years. All children received the Philips Sonicare For Kids toothbrush. A total of 75 DP parents with 105 participating children (51 girls, 54 boys) completed the three-week survey. Parents were asked to introduce the Philips Sonicare For Kids to their child/children for routine use at home per the manufacturer's instructions. Participants were not restricted from use of any other oral care products. Parents were asked to report observations of the child's use patterns, attitudes and behaviors through online questionnaires (Survey Monkey).
Results	<p>In a survey of DP parents where the Philips Sonicare For Kids toothbrush was used by their 4-10 year-old children for a three-week period, respondents observed:</p> <ul style="list-style-type: none"> • greater motivation brushing with Sonicare For Kids compared to their prior toothbrush, 90% • better brushing with Sonicare For Kids compared to their prior toothbrush, 88% • that their child brushed longer with Sonicare For Kids (mean: 104 seconds, median: 120 seconds) compared to their prior toothbrush (mean: 64 seconds, median: 60 seconds) <p>In addition:</p> <ul style="list-style-type: none"> • 81% of DP parents would recommend Sonicare For Kids to their patients • 91% of DP parents prefer Sonicare For Kids for use as their children's primary toothbrush • 93% of DP parents were highly satisfied with the cleaning performance of Sonicare For Kids • 84% of DP parents were highly satisfied with the gentleness of Sonicare For Kids • 91% of DP parents were highly satisfied with the ease of use of Sonicare For Kids

- 84% of DP parents reported that their children were highly satisfied with the in-mouth feel when using Sonicare For Kids
- 92% of DP parents reported that their children were highly satisfied with the look of Sonicare For Kids
- 93% of DP parents reported that their children were highly satisfied with the overall experience of using Sonicare For Kids
- 89% of DP parents reported that their children preferred Sonicare For Kids to their prior toothbrush

Conclusion The Philips Sonicare For Kids toothbrush positively influences engagement and promotes healthy brushing behavior in children 4-10 years old.

Toothbrush Attributes



Brushing Duration

Brushing Duration (Median)			
	Overall	4-6 Years	7-10 Years
Sonicare	120 sec	110 sec	120 sec
Previous Toothbrush	60 sec	60 sec	60 sec

Preference

An observational in-home use test of children 4-10 years using Sonicare For Kids

Jenkins W, Master A, Defenbaugh J, Wei J. Philips Oral Healthcare, Snoqualmie, WA; *J Dent Res* 89 (spec iss B); Abstract 3696, 2010

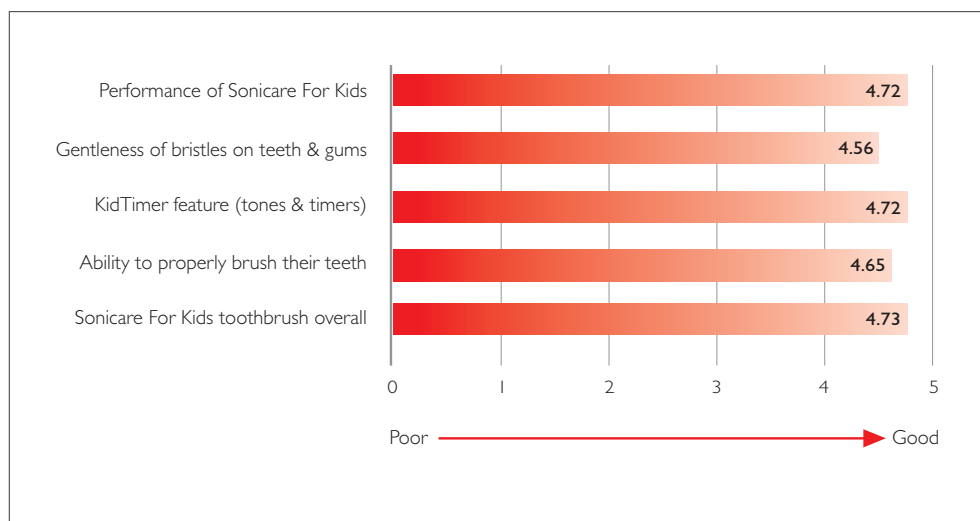
Introduction	The Sonicare For Kids toothbrush was specifically designed to grow with children 4-10 years old and suit their particular needs. In this population, the suitability of the toothbrushing experience (in all its dimensions) is as much a barrier to success as any primary metric of effective performance. This in-home use test was done with a group of hygienists because this population of trained dental professionals was expected to reflect the most critical and detailed feedback possible, not only in the dimension of the experience of introduction of the product, but also in characterization of its performance and ability to promote independent brushing of an acceptable standard.
Objective	To gain feedback and observe behavior changes in 4-10 year-old children or pediatric patients of registered dental hygienists (RDHs) after use of the Philips Sonicare For Kids toothbrush at home, in order to assess whether its introduction into the home toothbrushing regime promoted better oral health habits by positively influencing the child's motivation and experience.
Methodology	Eligible participants included adult RDHs (from RDH Under One Roof Conference who attended the course "New and Innovative Products of 2009") with a patient, child, friend or family member aged 4-10 years. All children received the Philips Sonicare For Kids toothbrush. A total of 131 RDHs with participating children (58 girls, 73 boys) completed the four-week survey. Parents were asked to introduce the Philips Sonicare For Kids to their child/children for routine use at home per the manufacturer's instructions. Participants were not restricted from use of any other oral care products. Parents were asked to report observations of the child's use patterns, attitudes and behaviors through online questionnaires (Survey Monkey).
Results	<p>Where the Philips Sonicare For Kids toothbrush was used by their 4-10 year-old children for a three-week period, study participants observed longer brushing time, willingness to brush and improved quality of brushing.</p> <p>In addition:</p> <ul style="list-style-type: none"> • 98% of RDHs would recommend Sonicare For Kids to their patients • 93% of RDHs noticed improvements in the child's brushing habits after use of Sonicare For Kids • 99% of RDHs were highly satisfied with the performance of Sonicare For Kids • 96% of RDHs were highly satisfied with the gentleness of Sonicare For Kids • 98% of RDHs reported that their children were highly satisfied with the overall experience of using Sonicare For Kids

- 97% of RDHs reported on their children's ability to properly brush their teeth with Sonicare For Kids
- 93% of RDHs reported that the child will continue to use Sonicare For Kids rather than their previous toothbrush

Conclusion

The Philips Sonicare For Kids toothbrush positively influences engagement and promotes healthy brushing behavior in children 4-10 years old.

Product Attributes (n=131)



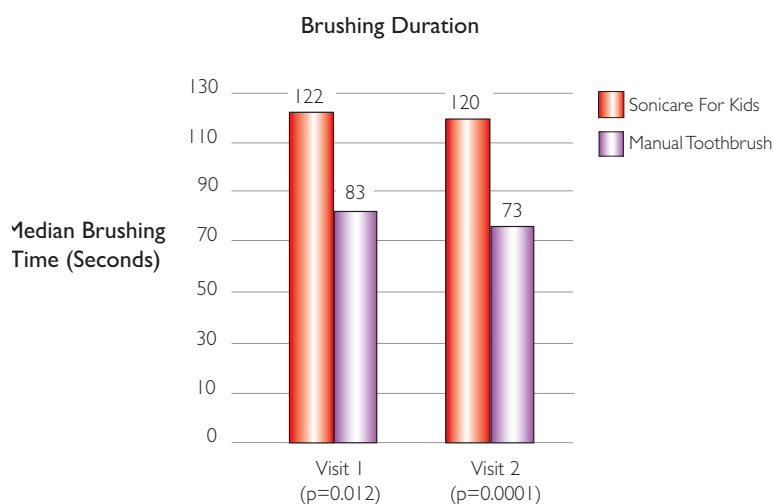
Compliance

in vivo study

Brushing duration and use interaction patterns of manual versus sonic toothbrushes in children aged 7–10 years

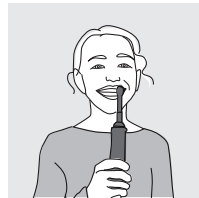
Defenbaugh J, Schmitt P, Master A, Jenkins W, Strate J. *International J Pediatric Dent* 2009; 19:s1

Objective	To compare the brushing duration and use interaction patterns in children aged 7–10 years using a Sonicare For Kids power toothbrush versus Oral-B Stages 4® manual toothbrush.
Methodology	Sixty healthy subjects (31 females, 29 males) were enrolled in an IRB-approved randomized, parallel-design two-week study. Informed consent/assent was obtained. At Visit 1, eligible subjects were randomized and provided brushing instructions. They performed an on-site brushing session immediately thereafter. It was timed and video recorded for duration and use interaction data collection. A home-use period of two weeks commenced with the assigned product in order for subjects to familiarize with the device. At Visit 2, the brushing and recording procedure was repeated and subjects were dismissed. Longitudinal and between-group comparisons were assessed for duration and ergonomic use interaction events. Statistical analysis was performed using the Wilcoxon Test.
Results	Thirty-one subjects were randomized to Sonicare For Kids and twenty-nine to a manual toothbrush. A longer median brushing duration was observed for Sonicare For Kids users at both time points. Sonicare For Kids (122 seconds) compared to manual toothbrush (83 seconds) at visit 1 ($p=0.012$). Sonicare For Kids (120 seconds) compared to manual toothbrush (73 seconds) at visit 2 ($p=0.0001$).



In video analysis review by an ergonomic expert, use interaction brush artifacts occurred more frequently with a manual toothbrush than with Sonicare For Kids, 1.56 compared to 0.80.

Use Interaction Brush Artifacts



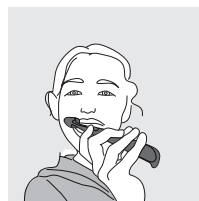
Vertical Brushing



Shoulder Abduction



Wrist Extension /
Hyperextension



Obvious Loose Grip

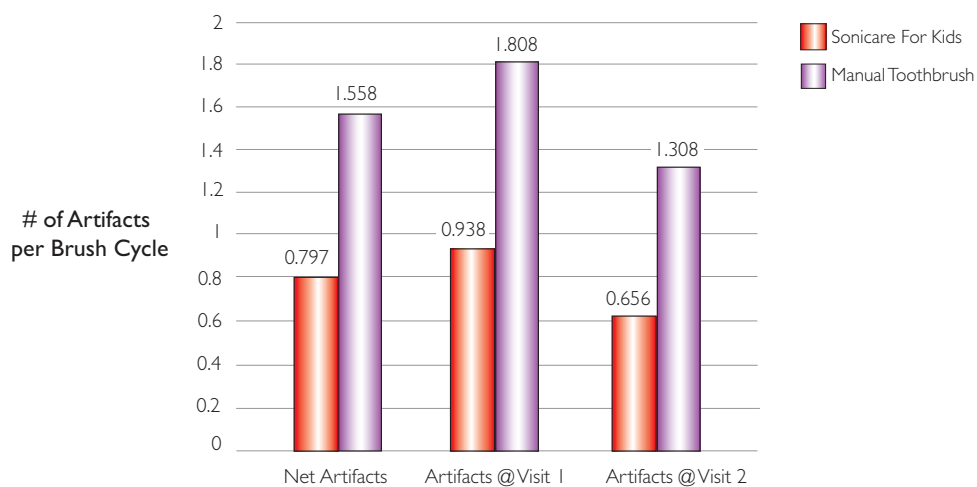


Obvious Over Grip



Finger Extension

Use Interaction Comparison

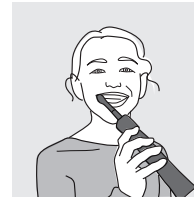


It was also observed that Sonicare For Kids toothbrush users prefer to grip with their fingertips, while manual toothbrush users prefer a power grip.

Grip Types

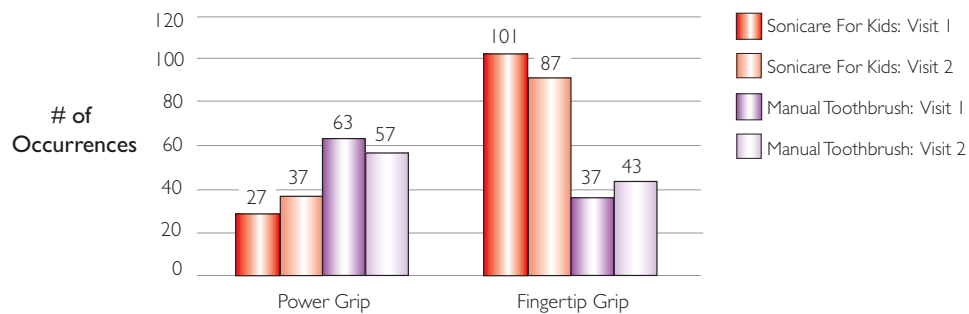


Power Grip Preferred
for Manual Toothbrush



Fingertip Grip Preferred
for Sonicare For Kids

Grip Type Comparison



For both types of brush, users prefer to grip in the center of the brush handle. Users did not typically switch between grips or hand location during brushing cycles or between brushing cycles.

Conclusion

Children aged 7–10 years brushed significantly longer with Sonicare For Kids than with a manual toothbrush following immediate product introduction and after a period of home use. Use interaction comparison suggests that form factor may influence the frequency of artifact occurrence.

Gingival Health

in vivo study

Comparison of gingivitis reduction and plaque removal by Sonicare FlexCare and a manual toothbrush

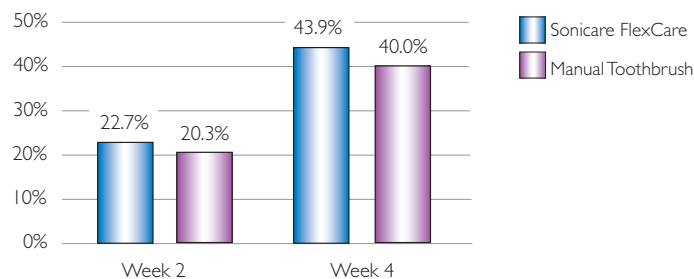
Holt J, Sturm D, Master A, Jenkins W, Schmitt P, Hefti A. A randomized, parallel-design study to compare the effects of the Sonicare FlexCare prototype and the Oral-B P-40 manual toothbrush on plaque and gingivitis. *Compend Contin Educ Dent*. 2007; 28 (suppl 1):35-41 4)

Objectives	<p>To evaluate the ability of the Sonicare FlexCare to reduce gingivitis and gingival bleeding over time.</p> <p>To compare the plaque removal ability of the Sonicare FlexCare to a Oral-B P-40® manual toothbrush over time.</p>
Methodology	<p>One hundred seventy-five healthy adults aged 18-64 years, participated in a single blind, randomized, parallel group clinical study assessing gingivitis and plaque over time for the Sonicare FlexCare and a manual toothbrush. Eligible subjects were routine manual toothbrush users with a minimum Silness and Løe plaque index of >0.8 presented following three-six hours plaque accumulation, with at least 20 sites graded >2 by the Løe and Silness Gingival Index. Eligible subjects were randomized and trained on product usage, two minutes twice daily. Subjects retained the assigned product for four weeks. Efficacy and safety evaluations occurred at Weeks 2 and 4 in which gingivitis and plaque levels were reassessed.</p>
Results	<p>The Sonicare FlexCare showed significant reduction from baseline in gingivitis after two and four weeks of product use ($p<0.0001$).</p> <p>The Sonicare FlexCare showed significant reduction from baseline in the number of sites with gingival bleeding over two and four weeks ($p<0.0001$).</p> <p>The Sonicare FlexCare was superior to a manual toothbrush in reducing the number of sites with gingival bleeding over four weeks ($p=0.0293$).</p> <p>The Sonicare FlexCare showed significant reduction from baseline in plaque after two and four weeks of product use ($p<0.0001$).</p> <p>The Sonicare FlexCare was superior to a manual toothbrush in overall percent plaque reduction over four weeks ($p=0.015$).</p> <p>The Sonicare FlexCare was superior to a manual toothbrush in plaque reduction in hard-to-reach areas over four weeks [posterior $p=0.002$, interproximal $p=0.02$, posterior interproximal $p=0.007$].</p>

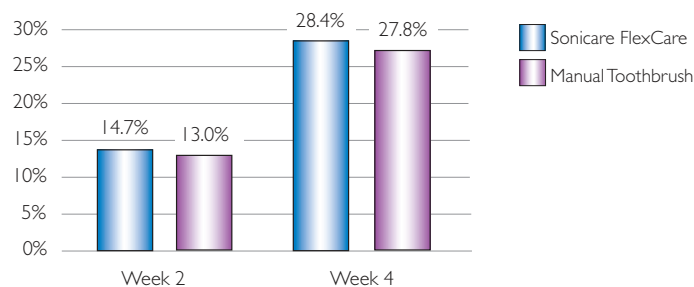
Conclusion

Sonicare FlexCare was found to be safe and effective in reducing gingivitis and plaque. FlexCare was found to be superior to a manual toothbrush in reducing plaque and sites of gingival bleeding over time.

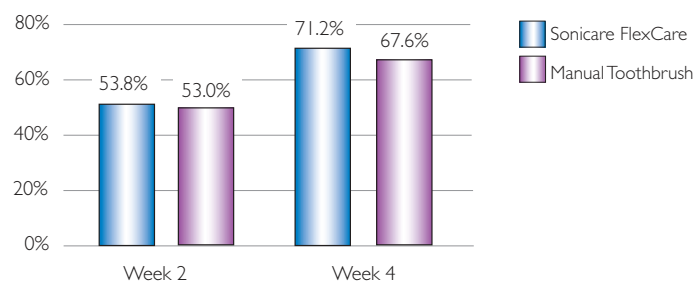
Percent plaque reduction from baseline overall



Percent gingivitis reduction from baseline overall



Percent reduction in sites of gingival bleeding from baseline



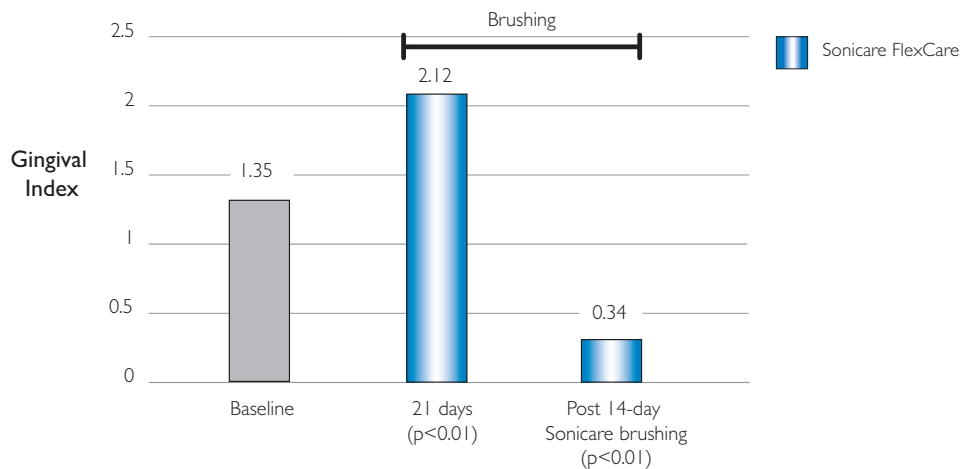
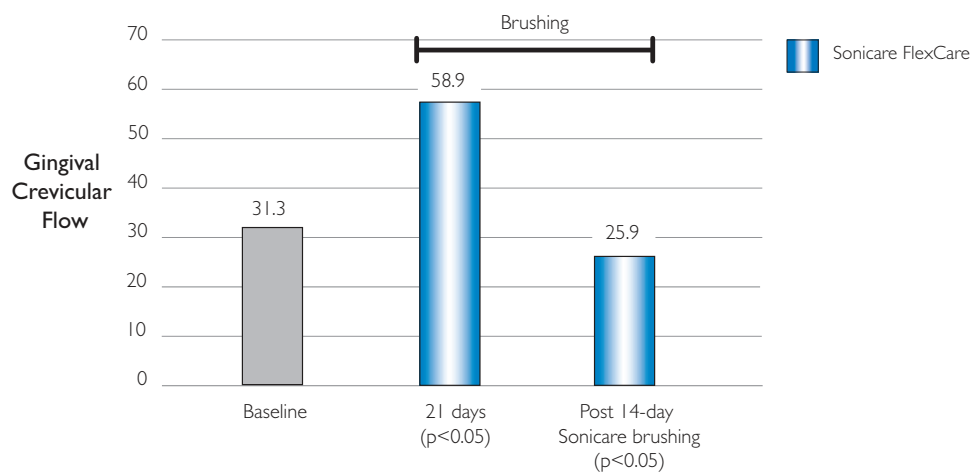
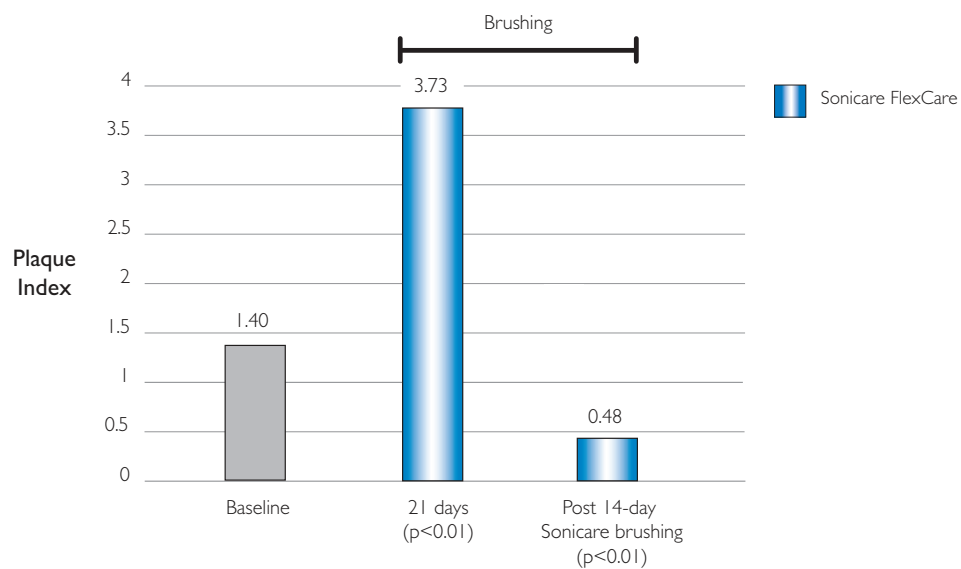
Gingival Health

in vivo study

Efficacy of Sonicare FlexCare in reducing gingivitis in smokers

Kumar P, De Jager M, Aspiras M., *J Dent Res* 88 (spec Iss A): 2585, 2009

Objective	To examine the efficacy of Sonicare FlexCare in reducing the clinical manifestations of experimental gingivitis in smokers.
Methodology	Fifteen subjects over 18 years of age who were current smokers participated in a single-blind study. All subjects received an initial evaluation and a baseline prophylaxis. Stents were fabricated to protect three adjacent teeth in two quadrants (one maxillary, one mandibular) during brushing for 21 days. Instructions were given to avoid mouthwash, flossing or other hygiene aides in the area. Turesky-Modified Quigley-Hein Plaque Index, Löe and Silness Gingival Index and Gingival Crevicular Fluid Flow were recorded for both baseline and 21-day accumulated plaque. Subjects were then given a Sonicare FlexCare toothbrush and instructed to use it for two weeks. At the conclusion of the two-week usage period, Turesky's plaque index, Löe and Silness Gingival Index and Gingival Crevicular Fluid Flow were once again recorded.
Results	Plaque index, gingival index and gingival crevicular flow increased in the induction phase and decreased considerably during the resolution phase following brushing with the Sonicare FlexCare. A significant reduction in 21-day plaque and gingival index scores was observed following two weeks of Sonicare FlexCare use ($p < 0.01$ and $p < 0.01$ for plaque and gingival index, respectively). Similarly, a significant reduction in 21-day gingival crevicular scores in induced gingivitis was observed after two weeks of Sonicare FlexCare use ($p < 0.05$). For all three parameters, post-brushing scores after the resolution phase were lower than initial baseline, suggesting marked improvement in gingival health.
Conclusion	Sonicare FlexCare significantly reduces induced gingivitis in smokers in two weeks.



Gingival Health

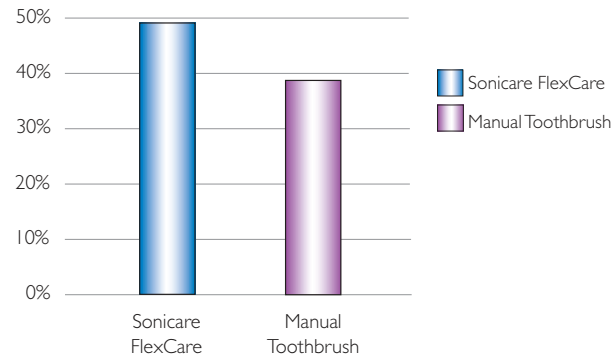
in vivo study

Effect of power brushing on clinical indices in periodontitis patients

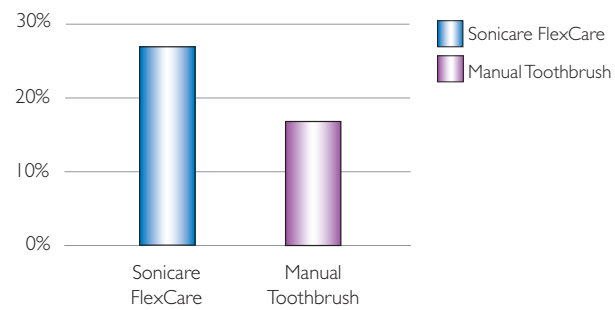
Offenbacher S, Barros SP, Aspiras M, De Jager M. *J Dent Res* 90 (Spec Iss A): 0807, 2011

Objective	To determine the clinical benefits of Sonicare FlexCare powered toothbrush following experimental induction of biofilm overgrowth in subjects with mild, moderate and severe periodontitis.
Methodology	97 healthy adults, 18-75 years of age, completed a single-blind randomized study assessing changes in clinical indices indicative of the biofilm-induced gingival inflammation in 3 groups of patients with mild, moderate or severe periodontitis (32-35 patients in each group). To qualify, all subjects had at least one site with probing pocket depth >3mm. The 3 groups were defined according to the extent of gingival bleeding on probing: ≤10% (mild), 10-50% (moderate), >50% (severe). For 21 days, subjects received an experimentally induced gingivitis challenge using oral stents. Subjects were then randomized in equal allocation to receive either a manual toothbrush or a Sonicare FlexCare powered toothbrush with the compact ProResults brush head to use for a four week resolution phase. During the induction and resolution phases, plaque index (PI), gingival index (GI), bleeding on probing (BOP), pocket depth (PD) and clinical attachment loss (CAL) were recorded at days 0, 7, 14, 21 (end of induction phase, beginning of resolution phase), 35 and 49 (end of resolution phase).
Results	During the induction phase, PI, GI and BOP increased 1.8, 1.2 and 1.4 fold, respectively, for all 3 periodontitis groups, though no significant changes were observed for PD and CAL. After 4 weeks of resolution, Sonicare FlexCare resulted in significantly greater improvements ($p<0.05$) in interproximal scores for all indices, except CAL, for all 3 groups. In particular, Sonicare FlexCare resulted in a significantly greater reduction ($p<0.01$) in the prevalence of deep pockets ($PD\geq 4\text{mm}$) with 35.8% compared to 2.8% for the manual toothbrush. Consequently, Sonicare FlexCare significantly reduced mean probing pocket depth by 6.5% compared to 1.0% for the manual toothbrush ($p<0.01$).
Conclusion	Sonicare FlexCare significantly reduced interproximal plaque, gingivitis and pocket depths in patients with mild, moderate and severe periodontal disease within 4 weeks of regular use when compared to a manual toothbrush.

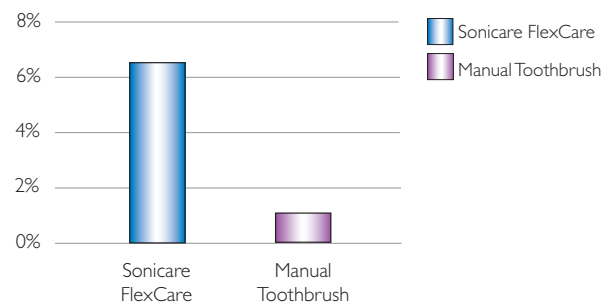
Plaque Reduction



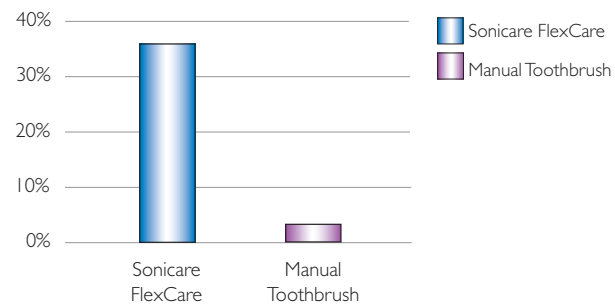
Gingival Inflammation Reduction



Pocket Depth Reduction



Reduction of Prevalence of Deep Pockets



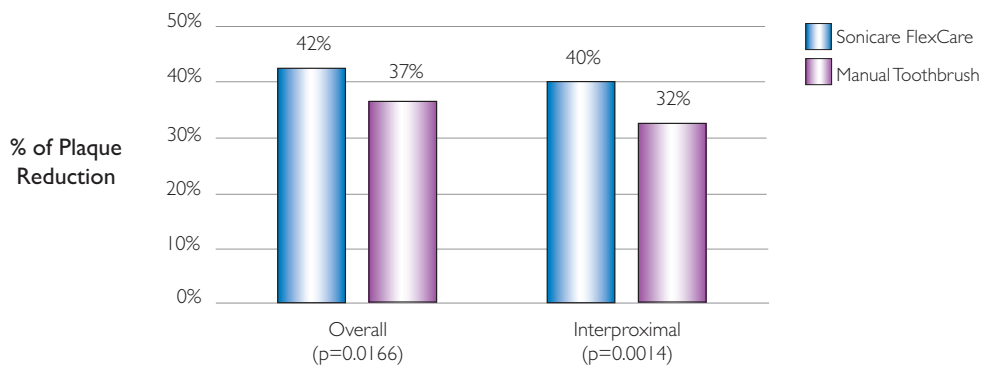
Plaque Removal

in vivo study

Comparison of plaque removal for one minute brushing by Sonicare FlexCare and a manual toothbrush

Platt K, Jenkins W, Schmitt P, Sturm D, Hefti A. Data on file, 2007

Objective	To compare the plaque removal efficacy and safety of the Sonicare FlexCare and a manual toothbrush when used for one minute of brushing.
Methodology	Thirty-five healthy adults aged 19-65 years, participated in a single-blind, randomized, crossover-design study assessing the plaque removal efficacy and safety of the Sonicare FlexCare and a manual toothbrush (Oral-B P-35). Subjects were trained on usage in a one minute session per encounter (15 seconds per quadrant, four times daily). Each toothbrush was used for one week at home for familiarization. At the end of each period, subjects presented with 24 hours of plaque accumulation and then had an assessment of plaque using the Turesky-Modified Quigley-Hein Plaque Index before and after a one minute supervised brushing with the assigned toothbrush. Safety was assessed in oral soft tissue examinations prior to all assessments of plaque.
Results	Sonicare FlexCare removed significantly more plaque than the manual toothbrush from the dentition overall ($p=0.0166$) as well as in hard-to-reach areas, i.e., the interproximal spaces ($p=0.0014$). Both toothbrushes were safe to use.
Conclusion	Sonicare FlexCare was found to remove significantly more plaque than a manual toothbrush when used for one minute brushing when assessed over the entire dentition (overall) as well as in the hard-to-reach areas.



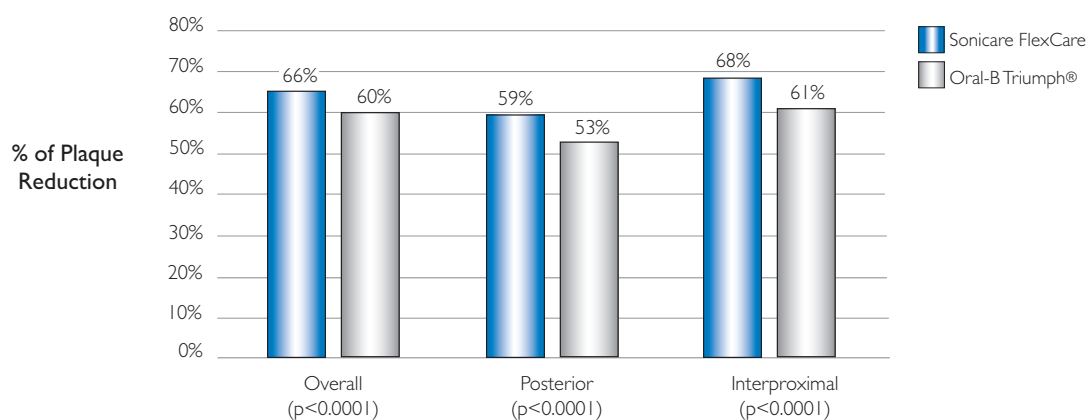
Plaque Removal

in vivo study

Comparison of plaque removal by Sonicare FlexCare and Oral-B Triumph®

Schaeken M, Sturm D, Master A, Jenkins W, Schmitt P. A randomized, single-use study to compare the plaque removal ability of two power toothbrushes, the Sonicare FlexCare and the Oral-B Triumph Professional Care 9000. *Compend Contin Educ Dent*. 2007;28 (suppl 1):29-34)

Objective	To compare the plaque removal efficacy of the Sonicare FlexCare and Oral-B Triumph toothbrushes.
Methodology	Ninety-one healthy subjects, aged 18-53 years participated in a single-blind, randomized, crossover-design study to assess the plaque removal efficacy and safety of the Sonicare FlexCare (ProResults brush head) and Oral-B Triumph (FlossAction brush head) power toothbrushes. Each toothbrush was used for one week at home for familiarization. At the end of each period, subjects presented with 24 hours plaque using the Turesky-Modified Quigley-Hein Plaque Index before and after a two-minute supervised brushing session with the assigned toothbrush. Safety was assessed in oral soft tissue examinations prior to all assessments of plaque.
Results	Sonicare FlexCare removed significantly more plaque than Oral-B Triumph from the dentition overall ($p < 0.0001$) as well as in hard-to-reach areas, i.e., the posterior teeth ($p < 0.0001$) and the interproximal spaces ($p < 0.0001$). Both toothbrushes were safe to use.
Conclusion	Sonicare FlexCare was found to remove significantly more plaque than Oral-B Triumph when assessed over the entire dentition (overall) as well as in hard-to-reach areas.



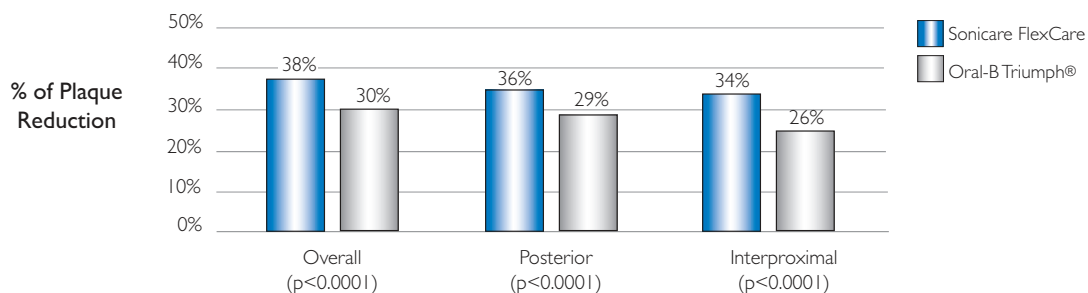
Plaque Removal

in vivo study

Comparison of plaque removal by Sonicare FlexCare and Oral-B Triumph®

Putt M, Milleman J, Jenkins W, Schmitt P, Master A, Strate J. A randomized crossover-design study to investigate the plaque removal efficacy of two power toothbrushes: Philips Sonicare Flexcare and Oral-B Triumph. *Compend Contin Educ Dent* 2008 Jan-Feb;29(1):56, 58-64

Objective	To compare the plaque removal efficacy of the Sonicare FlexCare and Oral-B Triumph toothbrushes.
Methodology	Ninety-three healthy subjects, aged 18-60 years, participated in a single-blind, randomized, crossover-design study to assess the plaque removal efficacy and safety of the Sonicare FlexCare (ProResults brush head) and Oral-B Triumph (FlossAction brush head) power toothbrushes. Each toothbrush was used for one week at home for familiarization. At the end of each period, subjects presented with 24 hours plaque and were assessed using the Turesky-Modified Quigley-Hein Plaque Index before and after a two-minute supervised brushing session with the assigned toothbrush. Safety was assessed in oral soft tissue examinations prior to all assessments of plaque.
Results	Sonicare FlexCare removed significantly more plaque than Oral-B Triumph from the dentition overall ($p<0.0001$) as well as in hard-to-reach areas, i.e., the posterior teeth ($p<0.0001$) and the interproximal spaces ($p<0.0001$). Both toothbrushes were safe to use.
Conclusion	Sonicare FlexCare was found to remove significantly more plaque than Oral-B Triumph when assessed over the entire dentition (overall) as well as in hard-to-reach areas.



Plaque Removal

in vivo study

Comparison of plaque removal in orthodontic subjects by Sonicare FlexCare and a manual toothbrush

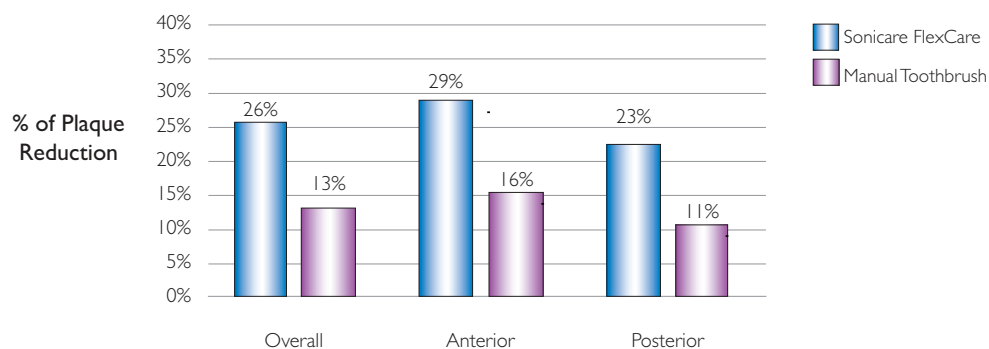
DeLaurenti M, Putt M, Milleman J, Jenkins W, Wei J, Strate J. Plaque Removal by Sonicare and Manual Toothbrushes in Orthodontic Subjects. *J Dent Res* 87 (spec Iss B): 2044, 2008

Objective	To compare the plaque removal and gingivitis reduction ability for the Sonicare FlexCare (ProResults brush head) and Oral-B P-40® manual toothbrush in orthodontic population.
Methodology	Ninety-five healthy orthodontic subjects aged 12 years and older participated in a single-blind, randomized, parallel group clinical study assessing gingivitis and plaque over time for the Sonicare FlexCare and a manual toothbrush. All subjects were routine manual toothbrush users. At Visit 1, subjects were screened for eligibility (Modified Bonded Bracket Index (BBI) >2.0; Pocket depth ≤ 4mm). At Visit 2, subjects received a prophylaxis and were randomized to a treatment arm. Subjects were trained and given brushing instructions to use the assigned test device twice daily at home for two minutes. Subjects abstained from oral hygiene for 12-24 hours before each visit. At subsequent visits, safety and BBI were assessed before and after a two minute supervised brushing. Secondary efficacy measurements included Turesky-Modified Quigley-Hein Plaque Index (TPI) on tooth surfaces without brackets and a full-mouth Löe and Silness Gingival Index (LSGI). ANOVA was used for statistical analysis.
Results	<p>The Sonicare FlexCare demonstrated superior plaque reduction in a single brushing on the buccal (bracketed) surfaces assessed by the Bonded Bracket Index compared to a manual toothbrush at the two-week and four-week evaluations (overall $p < 0.0001$ at two weeks, $p < 0.0001$ at four weeks).</p> <p>The Sonicare FlexCare demonstrated significantly superior reduction in plaque over time (two and four weeks) on the lingual surfaces assessed by the Turesky-Modified Quigley-Hein Plaque Index compared to a manual toothbrush (overall $p = 0.0221$ at two weeks and $p = 0.0025$ at four weeks).</p> <p>The Sonicare FlexCare demonstrated significantly superior plaque reduction in a single brushing on the lingual surfaces assessed by the Turesky-Modified Quigley-Hein Plaque Index compared to a manual toothbrush at the two-week and four-week evaluations (overall $p = 0.0001$ at two weeks, overall $p < 0.0001$ at four weeks).</p> <p>The mean scoring Löe and Silness Gingival Index value was low (1.14, std 0.10) indicating that the population presented with healthy gingivae. Both groups, however, were able to demonstrate statistically significant improvement vs. baseline over time (overall $p < 0.0001$).</p>

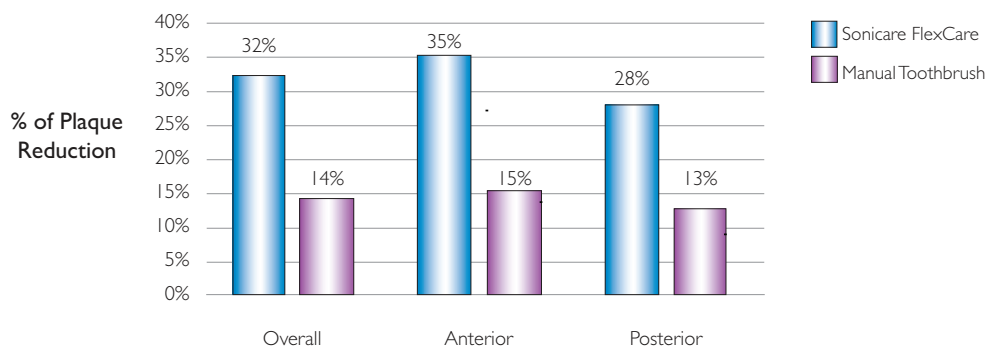
Conclusion

Sonicare FlexCare removed significantly more plaque than a manual toothbrush in a single brushing at two and four weeks on teeth with and without orthodontic brackets. Both toothbrushes were safe for use on oral soft tissues and orthodontic brackets.

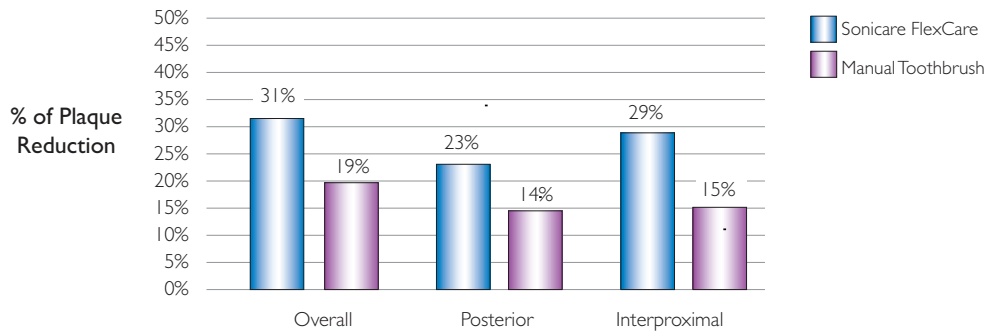
Percent Plaque Reduction Bonded Bracket Index Single Brushing Bracketed Surfaces at 2 Weeks



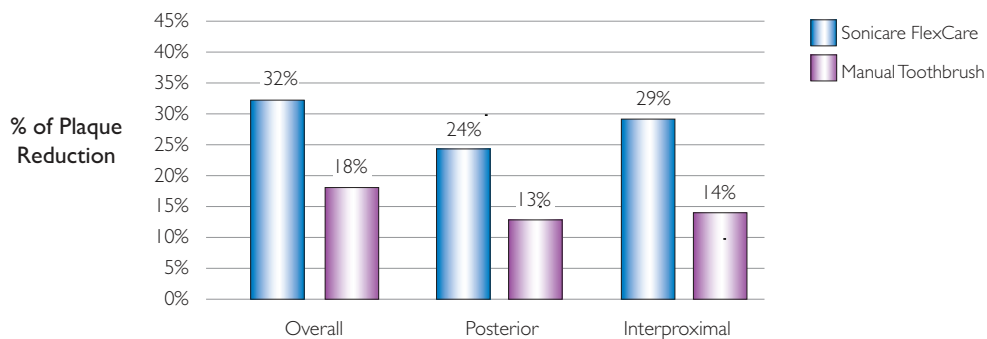
Percent Plaque Reduction Single Brushing Bonded Bracket Index Bracketed Surfaces at 4 Weeks



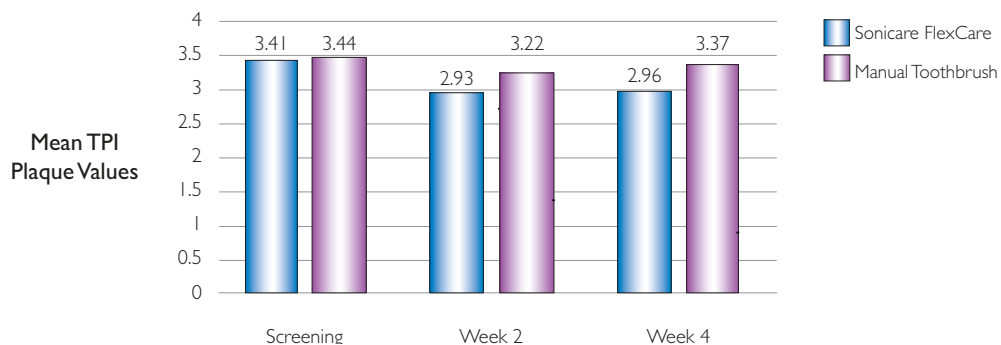
Percent Reduction Turesky Plaque Index Single
Brushing Lingual Surfaces at 2 Weeks



Percent Reduction Turesky Plaque Index Single
Brushing Lingual Surfaces at 4 Weeks



Reduction in Mean Turesky Plaque Index Over Time



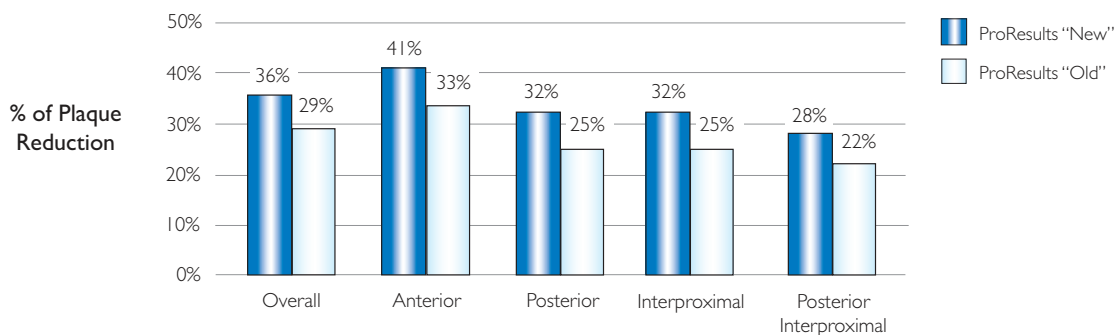
Plaque Removal

in vivo study

Plaque removal efficacy of "new" vs. "old" Philips Sonicare ProResults brush heads

Jenkins W, Schmitt P, Milleman J, Putt M and Strate J. Data on file, 2010

Objective	To compare the plaque removal efficacy and safety of an "old" (used for three months) Philips Sonicare ProResults brush head to a "new" ProResults brush head.
Methodology	A randomized, examiner-blinded, parallel-design study was conducted in a population of 72 healthy adults (56 females, 16 males) aged 18-60 years (mean age: 35) who were using Philips Sonicare FlexCare with ProResults brush head at home for three months, +/- 10 days. Following the three-month home-use period, subjects presented to the clinic with 24 hours of plaque growth and were randomized to utilize either a newly dispensed ProResults brush head or their home-use ProResults brush head from the preceding three-month period. Randomization was stratified by the pre-brushing plaque score (< 2.7 or ≥ 2.7) in an effort to mitigate treatment effect bias. A single-use pre and post-use plaque score was evaluated for each subject utilizing the Turesky-Modified Quigley-Hein Plaque Index. Safety was assessed in an oral soft tissue examination.
Results	A newly dispensed Philips Sonicare ProResults brush head removed more plaque than the brush head used at home for a three-month period for overall dentition and specifically in hard-to-reach areas. Both products were safe to use.
Conclusion	A new Philips Sonicare ProResults brush head is clinically proven to remove up to 28% more plaque as compared to a brush head that has been used for three months.



Plaque Biofilm Disruption

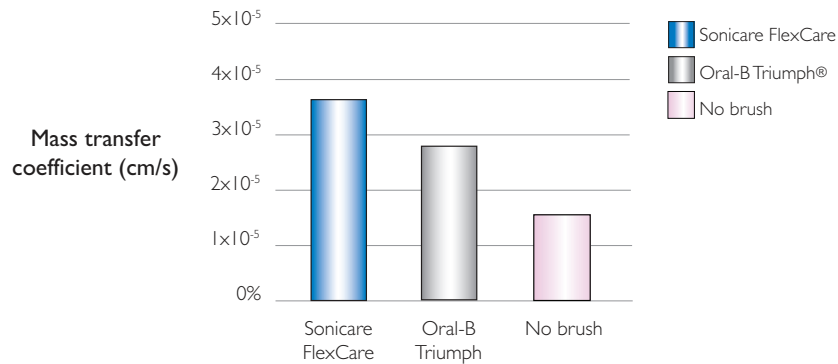
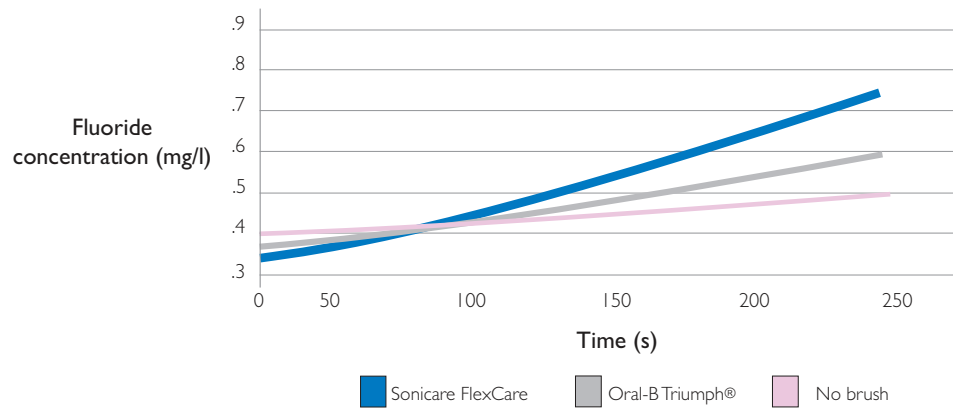
*in vitro study**

Effect of the Sonicare FlexCare power toothbrush on fluoride delivery through *Streptococcus mutans* biofilms

Stoodley P, Nguyen D, Longwell M, Nistico L, von Ohle Ch, Milanovich N, de Jager M. Effect of the Sonicare FlexCare power toothbrush on fluoride delivery through *Streptococcus mutans* biofilms. *Compend Contin Educ Dent*. 2007;28 (suppl 1):15-22)

Objective	Evaluate the ability of two power toothbrushes, the Sonicare FlexCare and the Oral-B Triumph®, to enhance the diffusion of fluoride through a biofilm by fluid dynamic action in vitro.
Methodology	Fluoride diffusion was established by an experimental system that measured the rate of fluoride diffusion through a membrane colonized with a <i>Streptococcus mutans</i> biofilm. In a fluid-filled container, the biofilm colonized membrane was contained in a water tight partition that separated the “brushing” chamber from the “measurement” chamber. Brushes were positioned perpendicular to the biofilm at 10 mm distance, then fluoride (1100 ppm NaF) was added to the brushing chamber and the brush activated to enhance fluoride penetration to the measurement chamber through fluid dynamic activity. Penetration of fluoride through the biofilm and membrane was measured with a fluoride electrode over a four minute period, and expressed as the “mass transfer coefficient.”
Results	The mass transfer coefficient (a measure of the rate of delivery of fluoride through the biofilm-colonized membrane) of fluoride generated by powered brushing was significantly greater ($p < 0.05$) than that from passive diffusion alone (no brushing): Sonicare FlexCare increased diffusion by 129% over no brushing. Sonicare FlexCare resulted in a significantly greater ($p < 0.05$) mass transfer coefficient than the Oral-B Triumph by 29%.
Conclusion	This study demonstrated that the fluid dynamic action of Sonicare FlexCare enhances the penetration of fluoride through biofilm which may, in turn, help increase the bioavailability of fluoride in residual dental plaque.

**Results will vary with actual use*



Plaque Biofilm Disruption

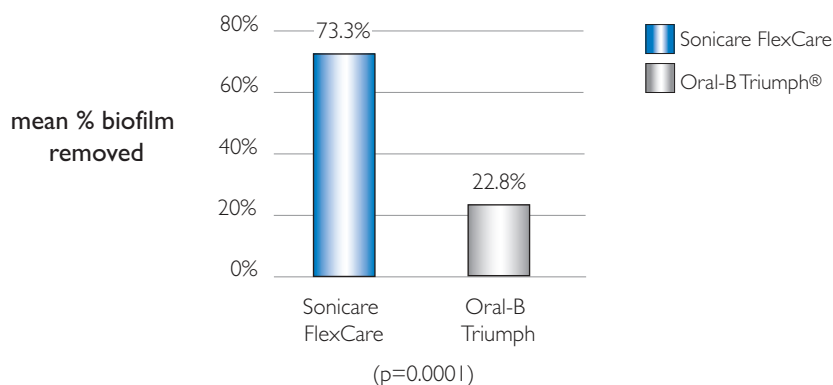
*in vitro study**

In vitro evaluation of interproximal biofilm removal with power toothbrushes

Aspiras M, Elliott N, Nelson R, Hix J, Johnson M, de Jager M. In vitro evaluation of interproximal biofilm removal with power toothbrushes. *Compend Contin Educ Dent*. 2007; 28 (suppl 1):10-14

Objective	To compare the removal of interproximal biofilm beyond the reach of the bristles of the Sonicare FlexCare and a rotating-oscillating power toothbrush, using an in vitro model.
Methodology	The ability of the Sonicare FlexCare and Oral-B Triumph® to remove biofilm without direct bristle contact was evaluated using a dental plaque model of a multispecies oral biofilm grown on hydroxyapatite discs. In a typodont model, the discs with plaque biofilm were located on interproximal sites of molar teeth at a distance of 2-4 mm from the bristles, and exposed to the fluid dynamic activity generated by the activated brushes. 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 brushing.
Results	The active Sonicare FlexCare toothbrush removed a significantly higher percentage of biofilm bacteria when compared to both the inactive state ($p < 0.0001$) and the active Oral-B Triumph toothbrush ($p = 0.0001$). Moreover, with 73% plaque biofilm removal, the Sonicare FlexCare removed three times the amount of plaque biofilm when compared to the Oral-B Triumph, with 23% removal.
Conclusion	Sonicare FlexCare removed significantly more biofilm 2-4 mm beyond the reach of the bristles than the Oral-B Triumph.

Removal of biofilm bacteria from HA discs
in an interproximal site model



*Results will vary with actual use

Plaque Biofilm Disruption

*in vitro study**

In vitro tooth-cleaning efficacy of electric toothbrushes around brackets

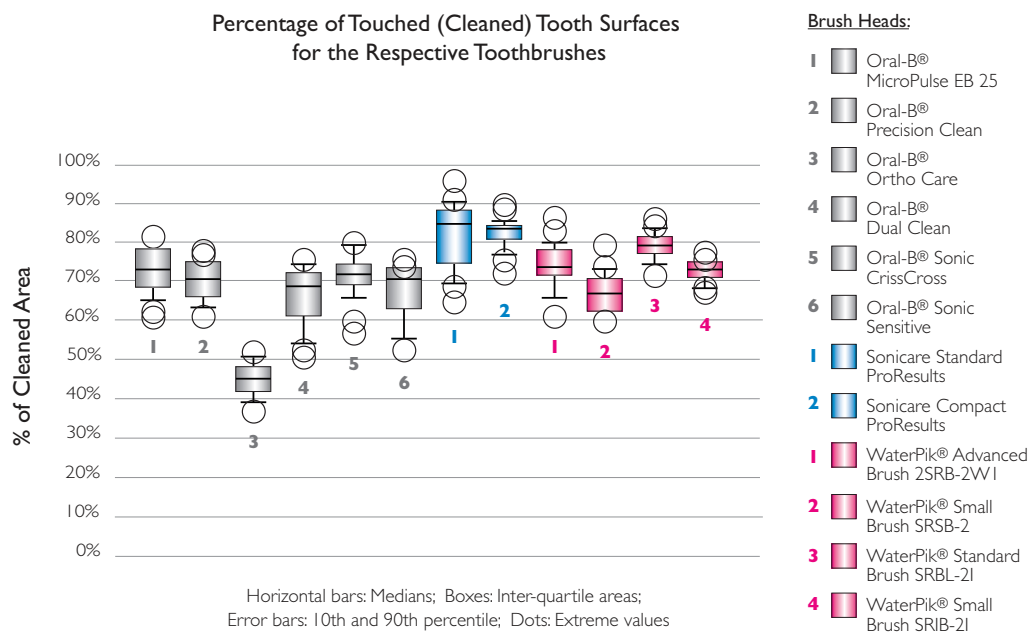
Schätzle M, Sener B, Schmidlin P, Imfeld T, Attin T. In vitro tooth-cleaning efficacy of electric toothbrushes around brackets. *Eur J Orthod*. Advance Access published on June 15, 2010; doi:10.1093/ejo/cjp166

Objective	To evaluate the cleaning efficacy of twelve different brush heads of two electric toothbrush actions (side-to-side and oscillating/rotating) around upper incisor brackets mounted on a custom model in a laboratory setting.	
Test Devices	<u>Oscillating / rotating toothbrushes</u> Oral-B Professional Care 9500 <ul style="list-style-type: none"> • MicroPulse EB 25 • Precision Clean • Ortho Care • Dual Clean <u>Side-to-side (sonic) toothbrushes</u> <div> <div> Oral-B Sonic Complete <ul style="list-style-type: none"> • Sonic CrissCross • Sonic Sensitive </div> <div> WaterPik SenSonic <ul style="list-style-type: none"> • Advanced Brush 2SRB-2WI • Small Brush SRSB-2 </div> </div> <div> <div> Philips Sonicare <ul style="list-style-type: none"> • Standard ProResults brush head • Compact ProResults brush head </div> <div> WaterPik SenSonic SR 800E <ul style="list-style-type: none"> • Standard Brush SRBL-2I • Small Brush SR1B-2I </div> </div>	
Methodology	Standard and Mini Diamond™ brackets were fixed on black-stained model teeth. The model teeth were then coated with white titanium oxide to simulate plaque accumulation and were brushed by a fixed, automated mechanism under constant conditions of load and equivalent duration of exposure. Twelve different brush heads with either side-to-side or oscillating-rotating action were tested. After brushing, the teeth were scanned, the images digitized and the surfaces re-appearing black were assessed utilizing custom software capable to detect gray-scale intensity. The quantification of the reduction of simulated plaque is expressed as a percentage of the total tooth area. ANOVA test was used for individual comparison of the brush types. Bonferroni/Dunn adjustment was applied for multiple testing.	
Results	The Sonicare power toothbrush with compact ProResults brush head and standard ProResults brush head were statistically significantly better than other brush heads in the test at removing simulated plaque, with 81.7% and 80.8% observed reduction overall, respectively.	

*Results will vary with actual use

Conclusion

In this in vitro experiment, the Sonicare power toothbrush with the compact ProResults brush head and the standard ProResults brush head provided superior cleaning efficacy of teeth with fixed orthodontic attachments.



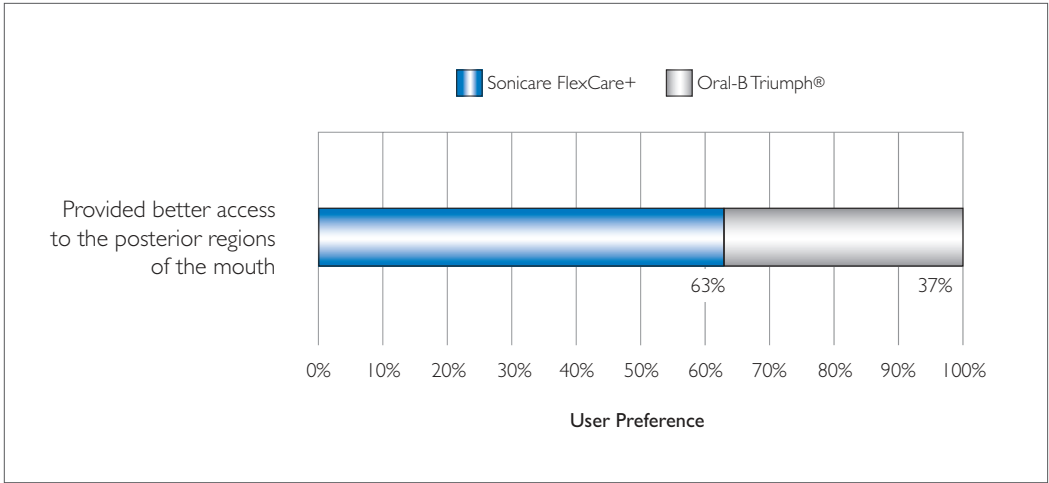
Preference

In-home use test by dental professionals evaluating the FlexCare+ with ProResults mini brush head and Oral-B Triumph with FlossAction brush head

Jenkins W, Defenbaugh J, Master A, Wei J. Data on file, 2010

Objective	To assess dental professionals' responses to an in-home use experience with the Philips Sonicare FlexCare+ with ProResults mini brush head and Braun Oral-B Triumph* with FlossAction brush head.
Methodology	Eligible participants included 267 dental professionals (DPs) (from Germany: 90, UK: 84, Netherlands: 93). The study utilized randomized, crossover, stratified design. All DPs received the Philips Sonicare FlexCare+ with ProResults mini brush head and Oral-B Triumph with FlossAction brush head according to a randomization assignment for routine use at home, per the manufacturer's instructions for a two-week period. Participants were not restricted from use of any other oral care products. DPs were then asked to report their feedback for each product use through online questionnaires (Survey Monkey) after the two-week use period.
Results	<p>Dental professionals were highly satisfied using Philips Sonicare FlexCare+ with ProResults mini brush head. They reported a significant preference for Sonicare FlexCare+ with ProResults mini brush head over Oral-B Triumph with FlossAction brush head for its ease of maneuverability and comfort on teeth and gums. DPs also rated better access to posterior regions of the mouth for Sonicare FlexCare+ with ProResults mini brush head over Oral-B Triumph with FlossAction brush head by a significant margin. Overall,</p> <ul style="list-style-type: none">• 81% of DPs were highly satisfied with the comfort of the FlexCare+ with ProResults mini brush head bristles on teeth and gums.• 75% of DPs were highly satisfied with the ability of the FlexCare+ with ProResults mini brush head to access hard-to-reach areas.• 80% of DPs were highly satisfied with the ability of the FlexCare+ with ProResults mini brush head to access posterior regions of the mouth.• 74% of DPs were highly satisfied with the maneuverability of this brush and would recommend the FlexCare+ with ProResults mini brush head to their patients.
Conclusion	Among a sample of dental professionals in Germany, the UK and the Netherlands, Philips Sonicare FlexCare+ with ProResults mini brush head elicited high satisfaction scores for its comfort on oral tissues, ability to access hard-to-reach areas and maneuverability. Significantly more DPs found Sonicare FlexCare+ with ProResults mini brush head easier to maneuver than with Oral-B Triumph with FlossAction brush head.

* Braun Oral-B Triumph IQ 4000, Braun Oral-B Triumph 5000



Satisfaction Indicators for FlexCare+ with ProResults Mini Brush Head	Highly Satisfied
Comfort of the bristles on your teeth and gums	81%
Size of the brush head overall	67%
Ability to access hard-to-reach areas	75%
Ability to access posterior regions of the mouth	80%
Maneuverability of the brush head	74%
Brush head overall	72%
Toothbrush weight	91%

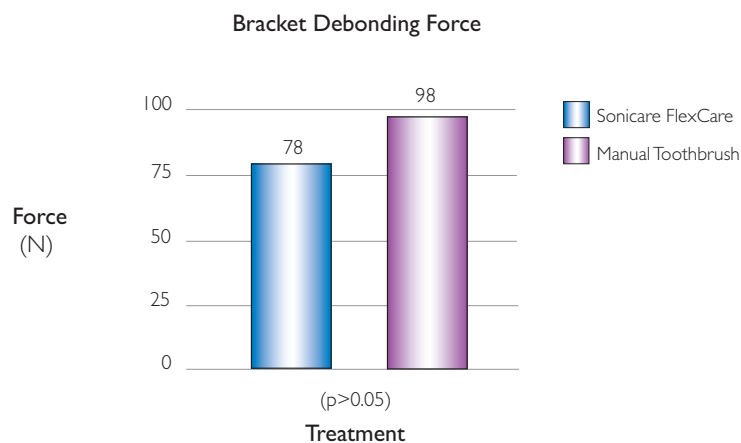
Gentleness

*in vitro study**

In vitro effect of power toothbrushes on orthodontic bracket bond strength

de Jager M, Nelson R, Schmitt P, Moore M, Putt M, Kunzelmann KH, Nyama I, Garcia-Godoy F, Garcia-Godoy C. In vitro assessment of toothbrushing wear on natural and restorative materials. *Compend Contin Educ Dent*. 2007; 28 (suppl 1):42-50

Objective	To evaluate the effect of two new power toothbrushes and a manual toothbrush on the bond strength of orthodontic brackets bonded to human enamel using simulated clinical conditions.
Methodology	Orthodontic brackets were bonded to 36 extracted teeth and exposed to Sonicare FlexCare power toothbrush or Oral-B P-35 Soft® manual toothbrush for the equivalent of a two-year exposure to brushing in the presence of a toothpaste slurry. After brushing, the force needed to debond the orthodontic brackets from the teeth was measured.
Results	There were no statistically significant differences in bracket debonding strength between any of the treatments ($p>0.05$).
Conclusion	This study demonstrated that the Sonicare FlexCare is safe to use for patients with orthodontic brackets compared to a manual toothbrush.



*Results will vary with actual use

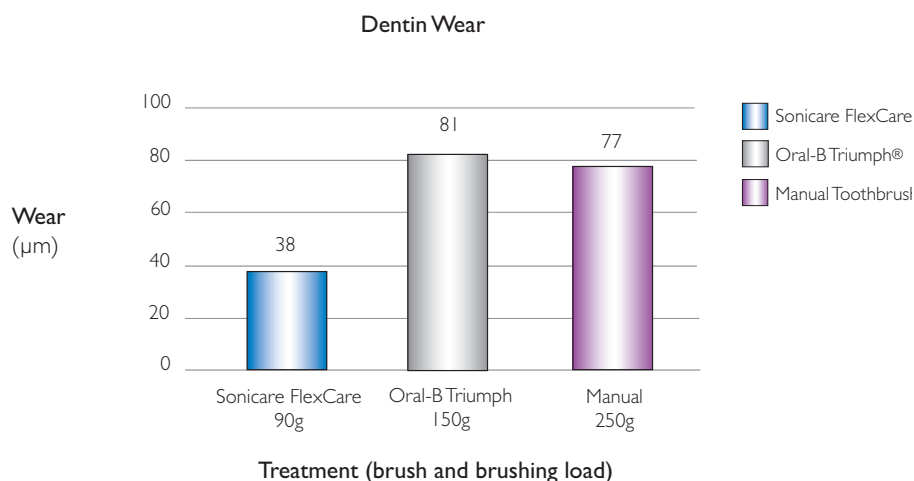
Gentleness

*in vitro study**

In vitro assessment of dentin wear resulting from the use of oral hygiene devices

de Jager M, Nelson R, Schmitt P, Moore M, Putt M, Kunzelmann KH, Nyama I, Garcia-Godoy F, Garcia-Godoy C. In vitro assessment of toothbrushing wear on natural and restorative materials. *Compend Contin Educ Dent*. 2007; 28 (suppl 1):42-50

Objective	To evaluate dentin wear associated with the use of the Sonicare FlexCare power toothbrush compared to Oral-B Triumph® and a manual toothbrush using simulated clinical conditions.
Methodology	Forty human dentin slices with a surface of 3x10 mm were embedded in temporary crown and bridge material and polished to render a smooth surface as starting condition. Samples were either brushed with Sonicare FlexCare at 90 grams, Oral-B Triumph at 150 grams or Oral-B P-35 Soft® manual toothbrush at 250 grams. These brushing loads are representing clinical use conditions. All specimens were brushed using a toothpaste slurry based on Crest Cool Mint Gel for a period representing two years of clinical brushing. Dentin wear was determined before and after brushing using 3D laser triangulation measurements to establish induced wear from toothbrushing.
Results	Sonicare FlexCare resulted in significantly less dentin wear than both the manual toothbrush ($p<0.05$) and the Oral-B Triumph ($p<0.05$). There was no significant difference between the manual and Oral-B Triumph brush.
Conclusion	In this in vitro study, Sonicare FlexCare was found to cause 50% less dentin wear than a manual toothbrush and a rotating-oscillating power toothbrush.



*Results will vary with actual use

Gentleness

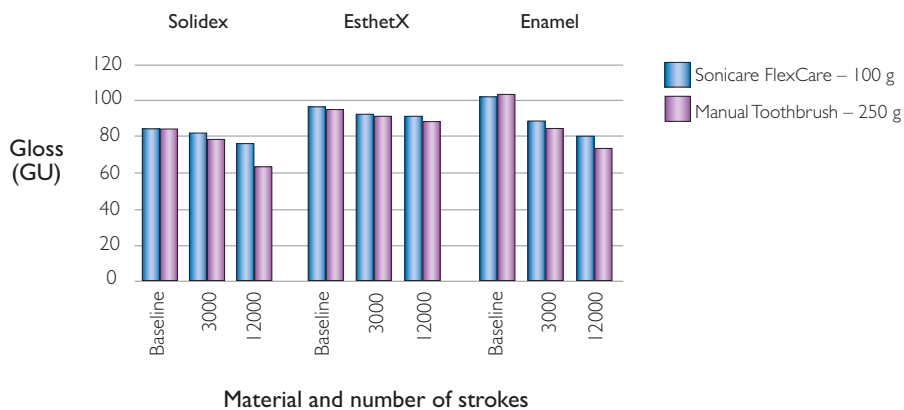
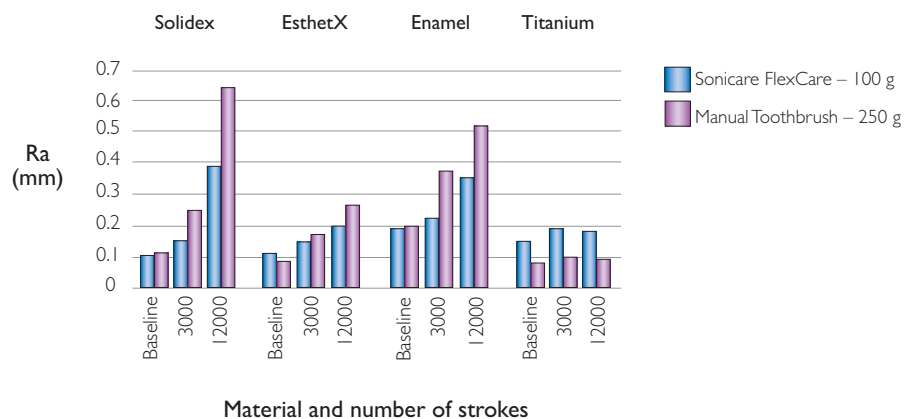
*in vitro study**

In vitro assessment of the effect of a manual and Sonicare FlexCare toothbrush on gloss and roughness of dental materials

de Jager M, Nelson R, Schmitt P, Moore M, Putt M, Kunzelmann KH, Nyama I, Garcia-Godoy F, Garcia-Godoy C. In vitro assessment of toothbrushing wear on natural and restorative materials. *Compend Contin Educ Dent*. 2007; 28 (suppl 1):42-50

Objective	To evaluate the effect on wear of dental materials of the Sonicare FlexCare power toothbrush and a manual toothbrush using simulated clinical conditions.
Methodology	Four different materials were investigated: the restorative composite materials Solidex and EsthetX, the implant material Titanium, and natural bovine enamel. For each material, 32 samples were embedded in acrylic mounts and polished to render a smooth surface as starting condition. Samples were either brushed with Sonicare FlexCare at 100 and 150 grams, or Oral-B P-35 Soft® manual toothbrush at 150 grams and 250 grams brushing load. All specimens were assessed after 3,000 and 12,000 brushing strokes, representing six months and two years of brushing, respectively, while using a toothpaste slurry based on Crest® Cool Mint Gel. Surface wear was determined before and after brushing using gloss meter and profilometry.
Results	In general, when differences were noted, they favored the Sonicare FlexCare over the manual toothbrush at clinically observed brushing forces (100 and 250 grams, respectively). For abrasion of Solidex, Sonicare FlexCare at 100 and 150 grams, and the manual brush at 150 grams all showed significantly less abrasion than the manual brush at 250 grams. For gloss of Solidex, Sonicare FlexCare at 100 grams, and the manual brush at 150 grams both retained significantly more gloss than the manual brush at 250 grams. For EsthetX and Titanium, no significant differences were observed. For gloss of bovine enamel, FlexCare at 100 grams retained significantly more gloss than the manual brush at 250g.
Conclusion	This study demonstrated that the Sonicare FlexCare is gentle for use on dental materials compared to a manual toothbrush for up to two years of simulated brushing with toothpaste.

**Results will vary with actual use*



Gentleness

in vivo study

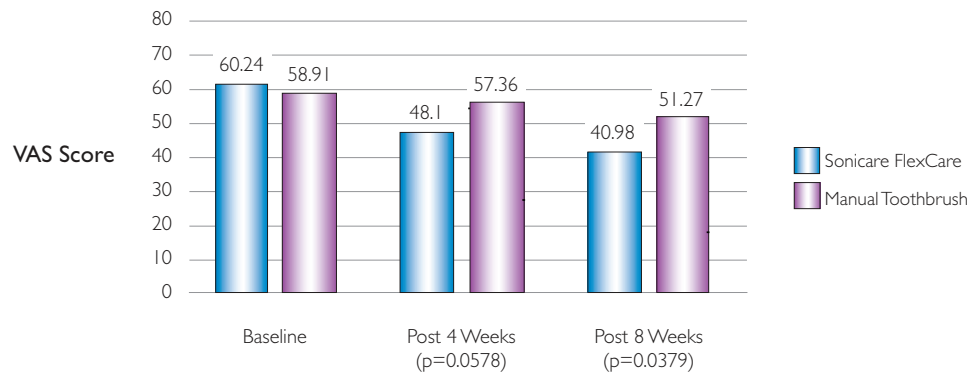
Comparison of Sonicare FlexCare power toothbrush and a manual toothbrush on dentin hypersensitivity

Frederick C, DeLaurenti M, Olson M, Jinling W, Jenkins J, Strate J. Data on file, 2009

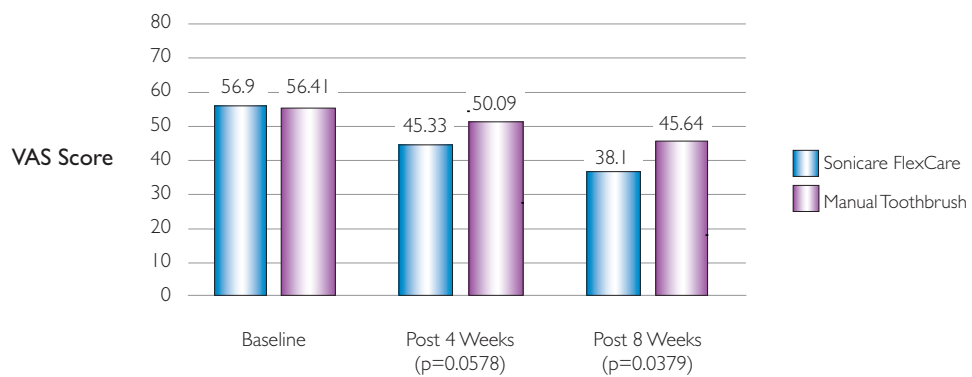
Objective	To investigate the effects of the Sonicare FlexCare power toothbrush and Oral-B P-40® manual toothbrush on dentin sensitivity.
Methodology	Forty-five healthy subjects, aged 24-63 years were enrolled in an IRB-approved randomized, parallel-design study to assess dentin sensitivity after four and eight weeks of use with Sonicare FlexCare or Oral-B P-40 manual toothbrush. In order to qualify for enrollment, subjects were required to have dentin sensitivity on the facial surface of at least one tooth and up to two teeth in different quadrants at screening and baseline on the same teeth. Sensitivity was assessed using evaporative and tactile stimulation and defined as experiencing discomfort using a Visual Analogue Scale (VAS) of 0–100 mm. Subjects returned to the research center at four and eight weeks for repeat assessments on sensitive teeth. At two and six weeks, subjects were contacted by phone for compliance checks and to answer study-related questions. The primary endpoint was the reduction in dentin sensitivity following eight weeks of product use.
Results	Forty-three subjects completed the study. The table provides a summary of the Global, Evaporative and Tactile VAS sensitivity mean scores measured at each of the three study examination visits. There was a statistically significant difference in the longitudinal VAS assessments of sensitivity for FlexCare post four and eight weeks of product use. Similar differences were observed for the manual toothbrush users except the evaporative stimulus scores, which were not significantly different post four weeks. Although no statistically significant difference was observed between groups when sensitivity was assessed after tactile stimulation at either time point, there was a statistically significant difference between FlexCare and a manual toothbrush following four weeks ($p=0.0578$) and eight weeks ($p=0.0379$) of product use after evaporative stimulation.
Conclusion	Philips Sonicare FlexCare showed significant reduction in pain associated with dentin hypersensitivity compared to a manual toothbrush following eight weeks of product use.

Examinations	Treatments	VAS Scores (Mean)		
		Global	Evaporative	Tactile
Screening	FlexCare	56.9	60.86	NA
	Manual	56.41	57.82	NA
Baseline	FlexCare	NA	60.24	53.57
	Manual	NA	58.91	54.98
4 Week	FlexCare	45.33	48.1	41.67
	Manual	50.09	57.36	36.57
8 Week	FlexCare	38.1	40.98	33.52
	Manual	45.64	51.27	34.57

Evaporative Stimulus



Global Assessment of Sensitivity



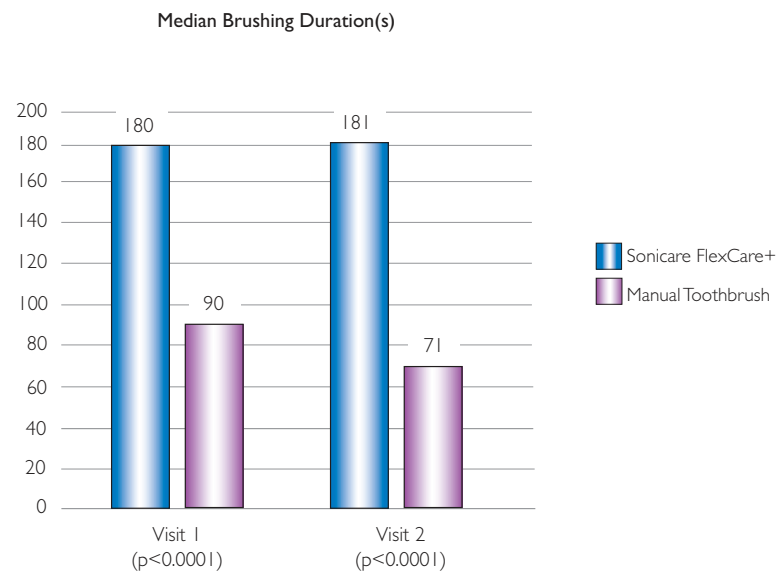
Compliance

in vivo study

Brushing duration of Philips Sonicare FlexCare+ versus a manual toothbrush

Milleman J, Putt M, Jenkins W, Jinling W, Strate J. Data on file, 2009

Objective	To compare the brushing duration with the Sonicare FlexCare+ versus a manual toothbrush after two weeks of home use.
Methodology	Fifty-six healthy subjects (24 females, 32 males) were enrolled in an IRB-approved randomized, parallel-design two-week study. At Visit 1, eligible subjects were randomized to either Sonicare FlexCare+ Gum Care mode or a manual toothbrush and were provided brushing instructions. They performed an on-site brushing session immediately thereafter, which was timed and video recorded from behind a one-way mirror for duration data collection. A home-use period of two weeks commenced with the assigned product in order for subjects to familiarize with the device. At Visit 2, the subjects were asked to brush with their assigned product. The recording procedure was repeated. Subjects were remunerated and dismissed. Statistical analysis was performed using the Wilcoxon signed rank test.
Results	Twenty-eight subjects were randomized to Philips Sonicare FlexCare+ and twenty-eight to a manual toothbrush. A longer median brushing duration was observed for Philips Sonicare FlexCare+ users at both time points. Sonicare FlexCare+ (180 seconds) compared to a manual toothbrush (90 seconds) at Visit 1 ($p < 0.0001$). Sonicare FlexCare+ (181 seconds) compared to a manual toothbrush (71 seconds) at Visit 2 ($p < 0.0001$).
Conclusion	Subjects brushing with Philips Sonicare FlexCare+ using Gum Care mode brushed significantly longer ($p < 0.0001$) than with a manual toothbrush following a familiarization period of two weeks.



Stain Removal

in vivo study

Evaluation of tooth shade change following stain induction and Sonicare FlexCare use

Master A, Jenkins W, Putt M, Milleman J, Wei J, Strate J. Evaluation of Tooth Shade Change Following Sonic Toothbrush Use. *J Dent Res* 88 (spec Iss A): 2581, 2009

Objective	To evaluate the efficacy of the Sonicare FlexCare to remove induced extrinsic tooth stains.
Methodology	Twenty healthy adults aged 19-53 years participated in a forced-stain model study to assess the ability of the Sonicare FlexCare to mechanically remove extrinsically induced stain. The stain inducing slurry consisted of 0.12% chlorhexidine, double-strength instant tea, instant coffee and grape juice concentrate used over a period of three weeks. Subjects were known stain formers and included coffee, tea, tobacco and red-wine users. Tooth shade was assessed on at least 3 buccal surfaces of the anterior dentition. The evaluation of tooth shade and color change was assessed using the X-Rite ShadeVision® device, a digital imaging analysis tool. Vitapan® Classical shades were derived on the system, as were changes in color parameters using the CIE color equation, $\Delta E = ((\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2)^{1/2}$. Following the period of stain induction, subjects were dispensed a Sonicare FlexCare for use over a 6-week period, with safety and efficacy intervals assessed at two, three, and six weeks post product use. A low abrasive dentifrice was used throughout the study.
Results	Sonicare FlexCare was proven to significantly reduce stain over a period of two, three and six weeks ($p < 0.0001$). Vitapan Classical shade improvements of at least two shades were seen at all time points. ΔE values greater than 3.5 were also observed at these intervals ($p < 0.0001$).
Conclusion	Sonicare FlexCare was shown to be effective in removing commonly observed extrinsic stain-forming pigments from tooth surfaces. An improvement of two Vitapan Classical shades was seen following two, three and six weeks product use.



Before



After 2 weeks of use

Plaque Removal

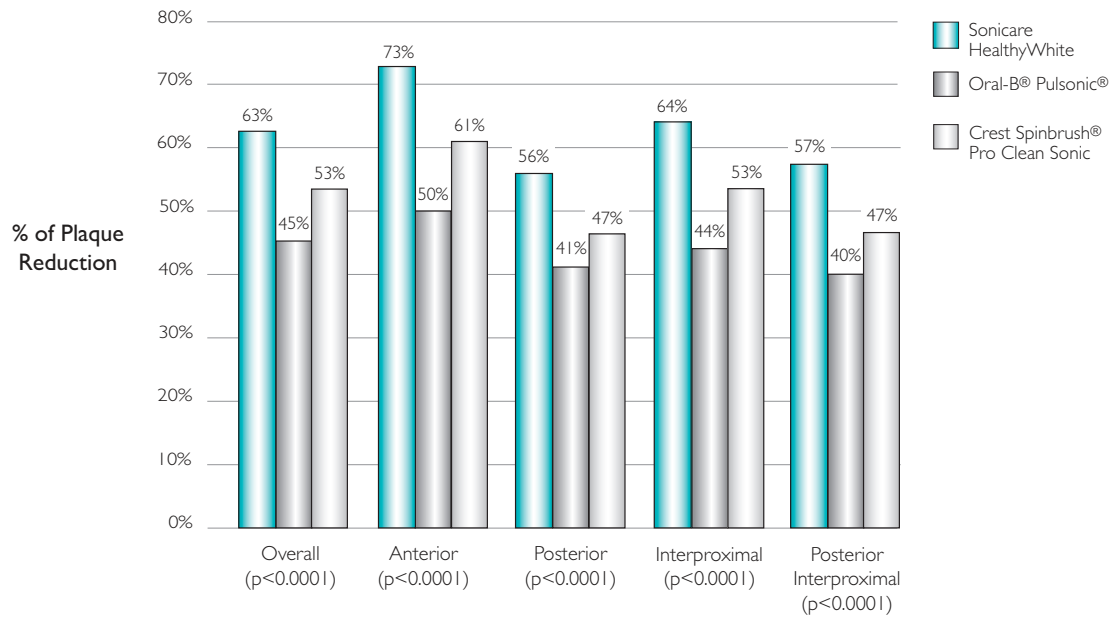
in vivo study

Comparison of plaque removal by Sonicare HealthyWhite, Oral-B® Pulsonic® and Crest Spinbrush® Pro Clean Sonic toothbrushes

Schaeken M, Jenkins W, Wei J, Strate J. Data on file, 2009

Objective	To compare the plaque removal ability of the Sonicare HealthyWhite to the Oral-B Pulsonic and Crest Spinbrush Pro Clean Sonic toothbrushes after a two-minute brushing.
Methodology	Fifty-four healthy adults aged 19-55 years participated in a single-blind, randomized, crossover-design study assessing the plaque removal efficacy and safety of three power toothbrushes. Each toothbrush was used for three days for familiarization followed by four days of manual toothbrush use (for wash out) at home (twice daily for two minutes). At the end of each period, subjects presented with 24 (+/- 3) hours of plaque accumulation and then had an assessment of plaque using the Turesky-Modified Quigley-Hein Plaque Index before and after a two-minute supervised brushing with the assigned toothbrush. Safety was assessed in oral soft tissue examinations prior to all assessments of plaque.
Results	Sonicare HealthyWhite removed significantly more plaque than Oral-B Pulsonic and Crest Spinbrush Pro Clean Sonic from the dentition overall ($p<0.0001$) as well as in all sub-regions of the mouth ($p<0.0001$), i.e., the posterior teeth ($p<0.0001$) and the interproximal spaces ($p<0.0001$). All brushes were safe to use.
Conclusion	Sonicare HealthyWhite was found to remove significantly more plaque than Oral-B Pulsonic and Crest Spinbrush Pro Clean Sonic when assessed over the entire dentition (overall) as well as in hard-to-reach areas.

Percent Plaque Reduction, Sonicare HealthyWhite vs. Oral-B Pulsonic and Crest Spinbrush Pro Clean Sonic



Sanitization

*in vitro study**

In vitro evaluation of the Sonicare FlexCare integrated UV sanitizer

Hix J, Elliott N, de Jager M. Data on file, 2007

Objective	To evaluate in vitro the ability of the Sonicare FlexCare integrated UV sanitizer to reduce viability of microorganisms on the FlexCare ProResults brush heads.
Methodology	Several in vitro studies were executed examining various microorganisms and brush heads. In each study, clinical conditions were mimicked carefully: brush heads were artificially contaminated with a selected microorganism in a two minute "brushing" cycle, then rinsed with tap water and sanitized using the 10-minute cycle of exposure to the germicidal ultraviolet light of the UV sanitizer. Non-treated brushes served as a control. Commonly observed microorganisms were tested, including Escherichia coli, Streptococcus mutans, and Herpes Simplex Virus type 1 (HSV1). Investigated brush heads included the Sonicare FlexCare regular-sized and small ProResults brush heads.
Results	Following this procedure, it was demonstrated that the UV sanitizer could reduce up to 99% of E. coli, S. mutans and HSV 1 for both FlexCare ProResults brush heads.
Conclusion	The Sonicare FlexCare integrated UV sanitizer effectively kills up to 99% of select microorganisms on selected toothbrush heads.

**Results will vary with actual use*

Sanitization

*in vitro study**

In vitro evaluation of the Sonicare UV sanitizer for various power toothbrush heads

Hix J, Elliott N, De Jager M. Data on file, 2007

Objective	To evaluate in vitro the ability of the Sonicare UV sanitizer to reduce viability of microorganisms on several types of brush heads of power toothbrushes.
Methodology	Several in vitro studies were executed examining various microorganisms and brush heads. In each study, clinical conditions were mimicked carefully: brush heads were artificially contaminated with a selected microorganism in a two minute "brushing" cycle, then rinsed with tap water and sanitized using the 10-minute cycle of exposure to the germicidal ultraviolet light of the UV Sanitizer. Non-treated brushes served as a control. Commonly observed microorganisms were tested, including Escherichia coli, Streptococcus mutans and Herpes Simplex Virus type 1 (HSV 1). Investigated brush heads included the Sonicare Elite standard brush head, the Sonicare FlexCare regular-sized and small ProResults brush heads, the Oral-B Professional Care FlexiSoft® and FlossAction brush heads, and the National® Doltz EW910 and EW920 brush heads. ^{1,2}
Results	Following this procedure, it was demonstrated that the UV Sanitizer could reduce up to 99% of E. coli, S. mutans and HSV 1 for the brush heads tested in this study.
Conclusion	The Sonicare UV Sanitizer effectively kills up to 99% of select microorganisms on selected toothbrush heads.

**Results will vary with actual use*

Meta-analysis

Updated meta-analysis on the clinical efficacy of side-to-side powered toothbrushes vs. manual toothbrushes

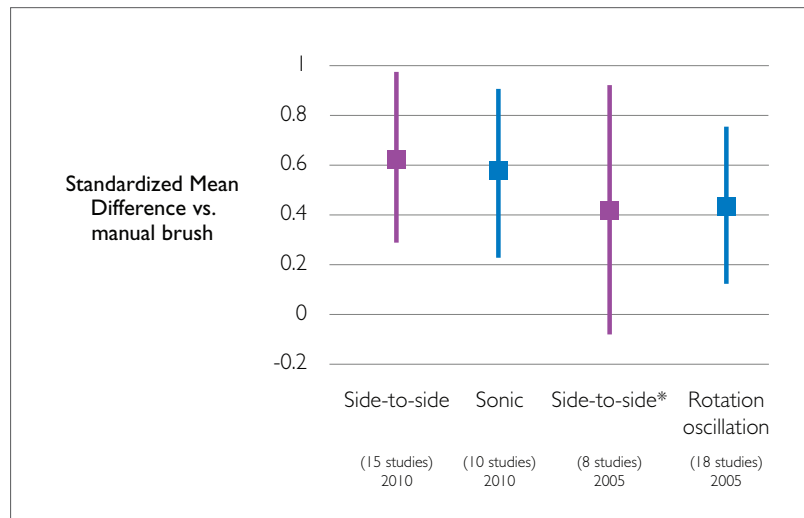
de Jager M, Schmitt P, Jain V, Master A, Wei J, Strate J. *J Dent Res* 89 (Spec Iss B): 3694, 2010

Introduction	In 2005, The Cochrane Collaboration for evidence-based healthcare reviewed “manual versus powered toothbrushing for oral health” concluding “brushes with a rotation oscillation action removed plaque and gingivitis more effectively than manual brushes in the short term.” In addition, the 2005 study concluded that “no other powered designs were as consistently superior to manual toothbrushes,” including side-to-side powered toothbrushes. Since the review, additional clinical studies evaluating the efficacy of side-to-side brushes were published warranting an updated meta-analysis.
Objectives	To compare the clinical efficacy of manual and side-to-side powered toothbrushes in reducing plaque and gingivitis in everyday use by conducting an updated meta-analysis using the Cochrane methodology with additional qualifying studies published in 2004 through 2007.
Methods	Following Cochrane's methodology, a literature search in PubMed, <i>The Cochrane Library</i> and IADR abstracts was performed to find parallel or cross-over; randomized controlled trials comparing plaque or gingivitis reduction. Studies needed to include at least one manual and one powered toothbrush and be conducted with subjects without disability affecting toothbrushing. Qualifying studies were added to Cochrane's data set and the meta-analysis was updated to calculate the Standardized Mean Difference and corresponding 95% Confidence Interval, which allows comparison of plaque and gingivitis reduction of side-to-side versus manual toothbrushes across multiple studies.
Results	Seven qualifying studies with sufficient data were added to the eight short-term studies already in the Cochrane Review. These fifteen studies together involved over 1,300 subjects and included a variety of side-to-side brushes, e.g., various Philips Sonicare models, Oral-B Pulsonic, Oral-B Sonic Complete and Ultreo. The meta-analysis revealed that side-to-side brushes had statistically significantly greater plaque and gingivitis reduction versus manual brushes. A subgroup analysis of ten high-frequency, high-amplitude “sonic” side-to-side studies, with almost 900 subjects, yielded comparable results.

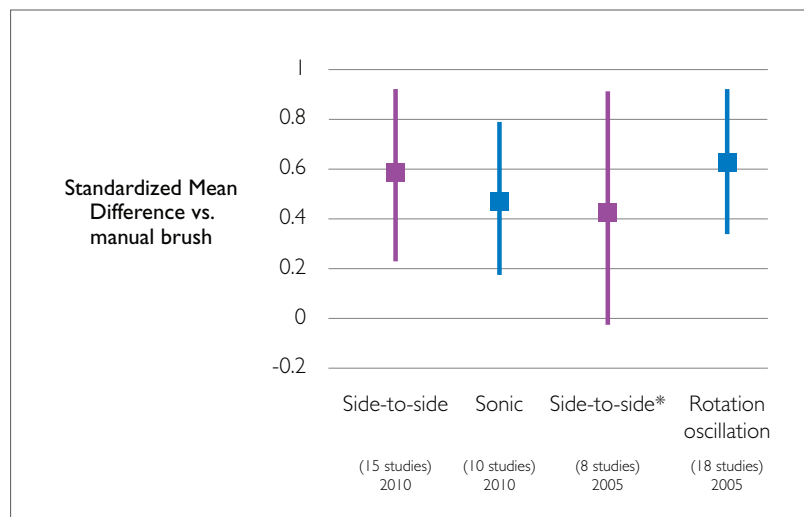
Conclusion

The updated meta-analysis on short-term clinical studies representing everyday use showed that side-to-side and sonic side-to-side powered toothbrushes resulted in significantly greater plaque and gingivitis reduction than manual toothbrushes. Thus, given this updated analysis, an evidence-based approach to optimizing home oral care includes the introduction of side-to-side and sonic brushes into the daily oral hygiene regime.

Plaque Removal Benefit Over Manual



Gingivitis Reduction Benefit Over Manual



*Difference with manual toothbrush not significant

Figures show Standardized Mean Differences with corresponding 95% Confidence Intervals for powered versus manual toothbrushes for the 2010 updated analysis and 2005 Cochrane Review.



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