



Gingival Health

in vivo study

Comparison of Plaque and Gingivitis Reduction by Philips Sonicare DiamondClean Smart Toothbrush with Premium Gum Care Brush Head and a Manual Toothbrush

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Data on file (2016)

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Objective

To compare the effects of Philips Sonicare DiamondClean Smart toothbrush with Premium Gum Care brush head and an ADA reference manual toothbrush on plaque and gingivitis following two and six weeks of home use.

Methodology

One hundred eighty-eight adults (mean age 43.6 years; 137 female/51 male) completed this IRB-approved, single-center, three-arm, examiner-blind, parallel-design clinical trial. Eligible subjects were routine manual toothbrush users who were non-smokers, aged 18–65 with a minimum plaque score of ≥ 1.8 per Lobene and Soparker Modified Plaque Index (MPI) following 3–6 hours of plaque accumulation, and a Gingival Bleeding Index (GBI) of ≥ 1 on at least 20 sites. The primary objective of this study was to compare the effects of twice daily use of Philips Sonicare DiamondClean Smart with Premium Gum Care brush head in Gum Health mode, to an ADA reference manual toothbrush (MTB). There were 63 subjects who enrolled and completed in each of these two treatment groups. A third treatment group was included in the study to inform internal function development. As this was a secondary objective, the results are not reported here. All study products were used with a standard dentifrice. The use of any other oral hygiene procedure was prohibited during the study period. Modified Gingival Index (MGI), GBI and MPI efficacy metrics were assessed at Baseline, and following two and six weeks of home use of the study products. Subjects presented to clinic for all visits with 3–6 hours of plaque accumulation. Safety was assessed by intraoral exam and per subject report.

Results

Gingival Inflammation per Modified Gingival Index (MGI)

At Baseline, the MGI LS Mean (SE) outcome for the Sonicare group was 2.50 (0.04), and for MTB it was 2.44 (0.04).

Following two weeks of product use, LS Mean (SE) for the Sonicare group was 1.00 (0.05), and for MTB it was 2.05 (0.05), p-value < 0.0001 . Expressed as LS Mean percent reduction versus Baseline, this is 60.31% reduction for Sonicare, and 16.59% for MTB.

Following six weeks of product use, LS Mean (SE) for the Sonicare group was 1.02 (0.05), and for MTB it was 1.88 (0.05), p-value < 0.0001 . Expressed as LS Mean percent reduction versus Baseline, this is 59.59% reduction for Sonicare, and 24.18% for MTB.

Gingival Bleeding per Gingival Bleeding Index (GBI)

At Baseline, the GBI LS Mean (SE) outcome for the Sonicare group was 0.35 (0.02), and for MTB it was 0.36 (0.02).

Following two weeks of product use, LS Mean (SE) for the Sonicare group was 0.15 (0.01), and for MTB it was 0.32 (0.01), p-value < 0.0001 . Expressed as LS Mean percent reduction versus Baseline, this is 61.12% for Sonicare, and 7.97% for MTB.

Following six weeks of product use, LS Mean (SE) for the Sonicare group was 0.16 (0.02), and for MTB it was 0.41 (0.02), p-value < 0.0001 . Expressed as LS Mean percent reduction versus Baseline, this is 57.60% for Sonicare, and -10.77% for MTB.

Surface Plaque per Modified Plaque Index (MPI)

At Baseline, the MPI LS Mean (SE) outcome for the Sonicare group was 2.86 (0.05), and for MTB it was 2.88 (0.05).

Following two weeks of product use, LS Mean (SE) for the Sonicare group was 1.93 (0.04) and for MTB it was 2.73 (0.04), p-value < 0.0001 . Expressed as LS Mean percent reduction versus Baseline, this is 32.23% for Sonicare, and 4.07% for MTB.

Following six weeks of product use, LS Mean (SE) for the Sonicare group was 1.74 (0.05), and for MTB it was 2.68 (0.05), p-value < 0.0001 . Expressed as LS Mean percent reduction versus Baseline, this is 38.51% for Sonicare, and 5.70% for MTB.

Safety

There were two adverse events reported, one of which was reported as mild, the other as moderate. Both events were deemed possibly related to the study product.

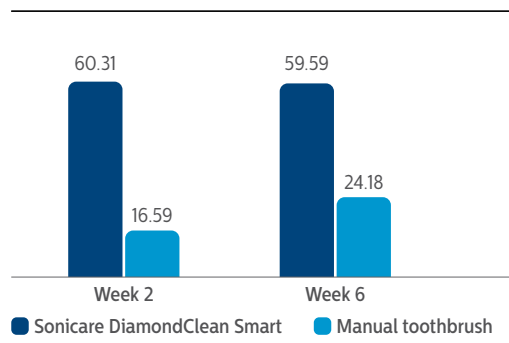
Conclusions

The use of Philips Sonicare DiamondClean Smart toothbrush with Premium Gum Care brush head used in Gum Health mode, was statistically significantly superior to an ADA reference manual toothbrush in reducing gingival inflammation, gingival bleeding and surface plaque following a 2- and 6-week period of home use.

Both products were safe for home use.

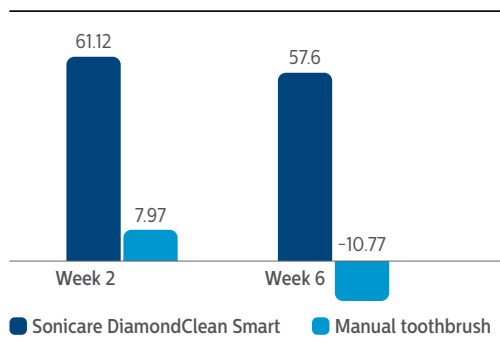
Least Squares Mean for Modified Gingival Index

Percent Reduction from Baseline to Week 2 and Week 6, Overall



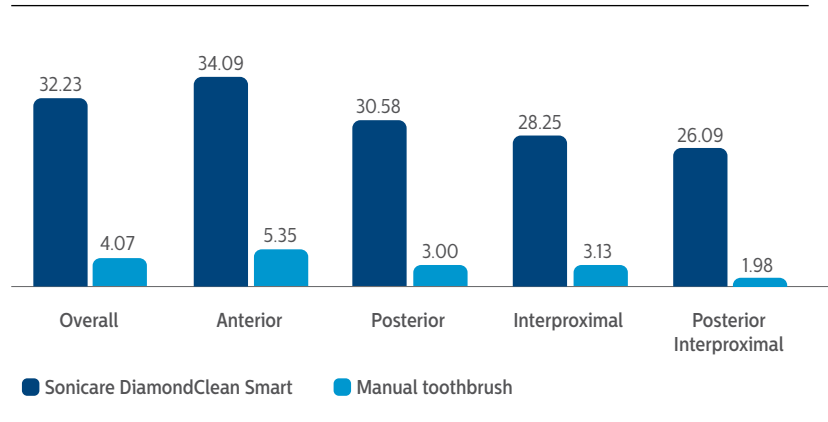
Least Squares Mean for Gingival Bleeding Index

Percent Reduction from Baseline to Week 2 and Week 6, Overall



Least Squares Mean for Modified Plaque Index

Percent Reduction from Baseline to Week 2, Overall and all Sub-Regions



Least Squares Mean for Modified Plaque Index

Percent Reduction from Baseline to Week 6, Overall and all Sub-Regions

