



Gingival health

in vivo study

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

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Objective

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

Methodology

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

Results

Gingival Inflammation per Modified Gingival Index (MGI)

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

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

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

Gingival Bleeding per Gingival Bleeding Index (GBI)

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

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

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

Surface Plaque per Modified Plaque Index (MPI)

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

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

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

Safety

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

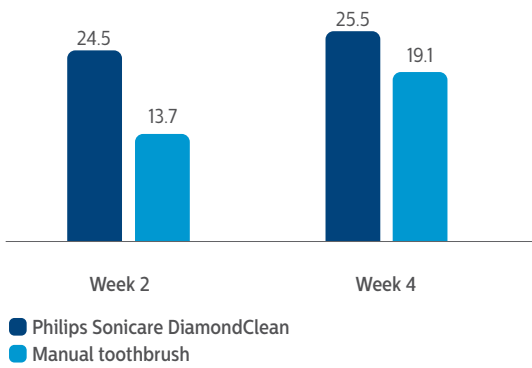
Conclusions:

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

Both products were safe for home use.

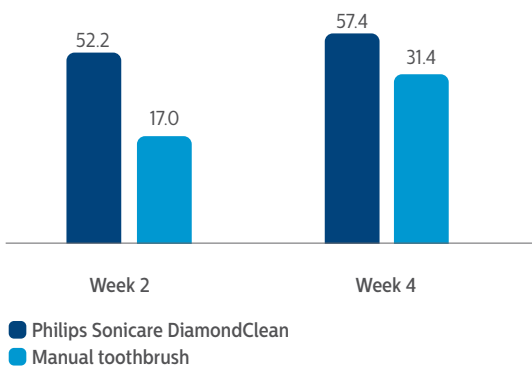
Least Squares Mean for Modified Gingival Index

Percent Reduction from Baseline to Week 2 and Week 6



Least Squares Mean for Gingival Bleeding Index

Percent Reduction from Baseline to Week 2 and Week 6



Least Squares Mean for Modified Plaque Index

Percent Reduction from Baseline to Week 2 and Week 6

