



Stain removal

in vivo study

Comparison of Extrinsic Stain Reduction of Philips Sonicare DiamondClean Smart Toothbrush with Premium White Brush Head and a Manual Toothbrush

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Objective

To compare the effects of Philips Sonicare DiamondClean Smart toothbrush with Premium White brush head and an ADA reference manual toothbrush on the removal of extrinsic stain following a single product use, and after a home use period of three and six days.

Methodology

Two hundred sixty subjects (mean age, 44.0 years; 155 female/105 male) completed this IRB-approved, single-blind, randomized, parallel, multi-center, two-arm clinical trial. Eligible subjects were generally healthy volunteers aged 18–75 years, with a minimum total stain score of ≥ 8 (stain intensity \times area) per Macpherson Modified Lobene Stain Index (MMLSI) on the facial surface of at least 10 upper and lower anterior teeth. The objective of this study was to compare the stain removal effects of Philips Sonicare DiamondClean Smart with Premium White brush head and White+ mode, to an ADA reference manual toothbrush (MTB) following a single brushing, and then following a three- and six-day home use period. Subjects were instructed to observe a two-hour eating, drinking and smoking abstinence period prior to study visits. Those subjects who met the eligibility criteria were then randomized, received product instructions and were provided a standard leading whitening dentifrice to use with the assigned product. The use of any other oral hygiene and whitening products were prohibited during the study period. In addition to MMLSI, tooth shade change was assessed using VITA Bleached Guide 3D-Master (VBG). Safety was assessed via intraoral exam and by subject report per diary notecard.

Results

Macpherson Modified Lobene Stain Index

At Baseline, the LS Mean (SE) MMLSI score was 1.04 (0.06) for Sonicare, and 0.95 (0.06) for MTB, p -value = 0.3224.

Immediately following a single product use, the LS Mean (SE) score was 0.96 (0.002) for Sonicare, and 0.99 (0.002) for MTB, p -value < 0.0001 . Expressed as LS Mean percent reduction versus Baseline, this is 5.27% for Sonicare, and 0.10% for MTB.

Following a three-day period of home use, the LS Mean (SE) score was 0.86 (0.01) for Sonicare, and 0.98 (0.01) for MTB, p -value < 0.0001 . Expressed as LS Mean percent reduction versus Baseline, this is 17.13% for Sonicare, and 2.80% for MTB.

Following a six-day period of home use, the LS Mean (SE) score was 0.75 (0.01) for Sonicare, and 0.95 (0.01) for MTB, p -value < 0.0001 . Expressed as LS Mean percent reduction versus Baseline, this is 30.10% for Sonicare, and 5.68% for MTB.

VITA Bleached Guide 3-D Master

At Baseline, the LS Mean (SE) VBG score was 13.77 (0.41) for Sonicare, and 14.16 (0.41) for MTB, p -value = 0.5021.

Immediately following a single product use, the LS Mean (SE) score was 13.95 (0.01) for Sonicare, and 13.96 (0.01) for MTB, p -value 0.4974. Expressed as LS Mean percent reduction versus Baseline, this is 0.11% for Sonicare, and 0.07% for MTB.

Following a three-day period of home use, the LS Mean (SE) score was 13.35 (0.05) for Sonicare, and 13.62 (0.05) for MTB, p -value = 0.0004. Expressed as LS Mean percent reduction versus Baseline, this is 4.75% for Sonicare, and 2.53% for MTB.

Following a six-day period of home use, the LS Mean (SE) score was 12.71 (0.08) for Sonicare, and 13.23 (0.08) for MTB, p -value < 0.0001 . Expressed as LS Mean percent reduction versus Baseline, this is 9.42% for Sonicare and 5.30% for MTB.

Safety

There were two adverse events reported, both of which were mild, unrelated to study products and resolved by end of study.

Conclusions:

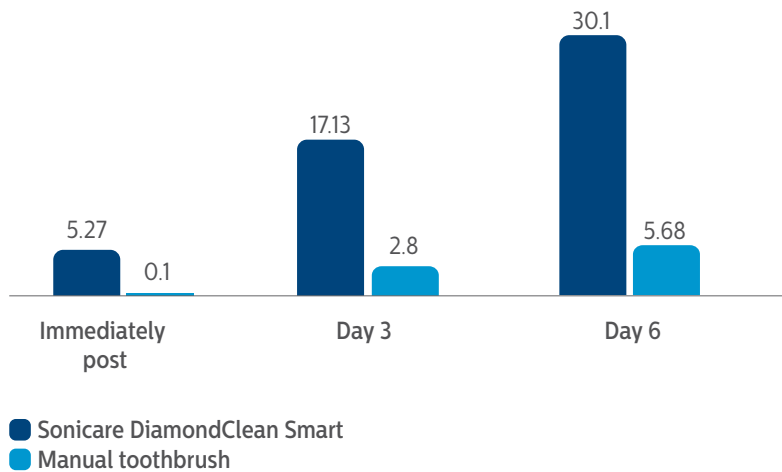
Philips Sonicare DiamondClean Smart toothbrush with Premium White brush head removes significantly more surface stain than a manual toothbrush, as measured by the Macpherson Modified Lobene Stain Index, immediately following, and after three and six days of home use.

Philips Sonicare DiamondClean Smart with Premium White brush head improves tooth shade significantly better than a manual toothbrush, as measured by VITA Bleached Guide 3-D Master, after three and six days of home use.

Both products were safe for home use.

Least Squares Mean, Macpherson Modified Lobene Stain Index

Percent Reduction from Baseline to Immediately Post, Day 3, Day 6



Least Squares Mean, Vita-Bleached Guide 3-D Master

Percent Reduction from Baseline to Immediately Post, Day 3, Day 6

