



## Gingival Health

in vivo study

# Comparison of plaque removal and gingivitis reduction by Philips Sonicare 3 Series and a manual toothbrush

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### Objective

To compare gingivitis and plaque removal efficacy and safety of Philips Sonicare 3 Series and a manual toothbrush over time.

### Methodology

One-hundred thirty two healthy adults (mean age 43.0 years, 89 females/43 males) were randomized in this Ethics-committee approved parallel, Examiner-blinded clinical trial. Eligible subjects were non-smokers, aged 18-65 years who were routine manual toothbrush users. Enrolled participants had a minimum average plaque score of  $\geq 1.8$  (Lobene and Soparker Modified Quigley and Hein Plaque Index, (MPI)) following 3-6 hours plaque accumulation, and a minimum of 20 bleeding sites per Gingival Bleeding Index (GBI). Eligible subjects were evaluated to collect Baseline metrics including MPI, GBI and Modified Gingival Index (MGI). Subjects were then dispensed study products per random assignment, either Sonicare 3 Series power toothbrush with ProResults gum health brush head or an ADA reference manual toothbrush. Randomization was balanced by gender. Study subjects assigned to the Sonicare treatment group were instructed to brush at home twice daily for two minutes using the 'Clean' mode. Study subjects assigned the MTB were instructed to brush twice daily per their regular routine and technique. Subjects then returned to the clinic 14 and 28 days ( $\pm 1$  day) after Visit 1 with 3-6 hours plaque accumulation. They underwent an efficacy evaluation where plaque and gingivitis parameters were re-assessed by the Blinded study Examiner. Safety was assessed per subject report and intraoral examination. Subjects were then dismissed from the study.

### Results

One-hundred forty two subjects were screened for the study, 132 were randomized (89 females, 43 males) and 128 completed the study. Philips Sonicare 3 Series was statistically significantly superior to an ADA reference manual toothbrush in the following efficacy parameters:

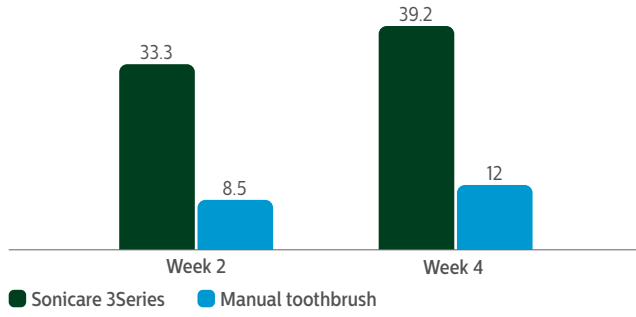
- Surface plaque (MPI) Overall at Weeks 2 and 4 (p-value  $<0.001$ , at each time point)
- Surface plaque (MPI) in Hard-to-Reach posterior interproximal areas at Weeks 2 and 4 (p-value  $<0.001$ , at each time point)
- Gingival Bleeding, (GBI) at Weeks 2 and 4 (p-value  $<0.001$ , at each time point)
- Gingival Inflammation (MGI) at Weeks 2 and 4 (p-value  $<0.001$ , at each time point)

There were a total of eight adverse events reported among eight subjects. The frequency of adverse events was balanced between treatment arms, with four events each reported in the two study treatment arms. There were no adverse events related to the use of the study product.

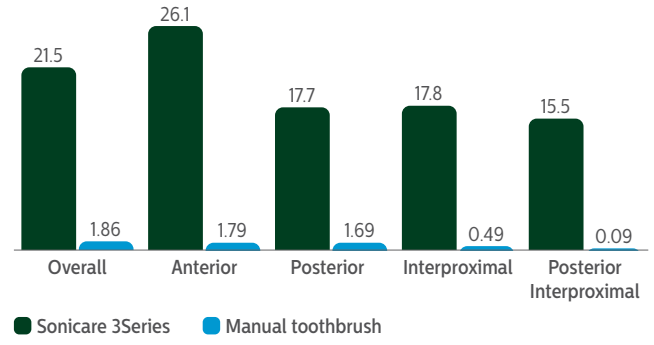
### Conclusion

Philips Sonicare 3 Series was found to be significantly superior to a manual toothbrush in reducing plaque, gingival inflammation and gingival bleeding following a period of two and four weeks of product use. Both products were safe for use.

% Gingivitis Reduction from Baseline



% of Plaque Reduction



% Reduction Gingival Bleeding Index from Baseline

