



Gingival Health

in vivo study

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

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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

Sonicare FlexCare Platinum significantly reduced gingivitis, gingival bleeding and plaque following two and four weeks of product use.

Sonicare FlexCare Platinum group was significantly superior to MTB on all clinical metrics as follows:

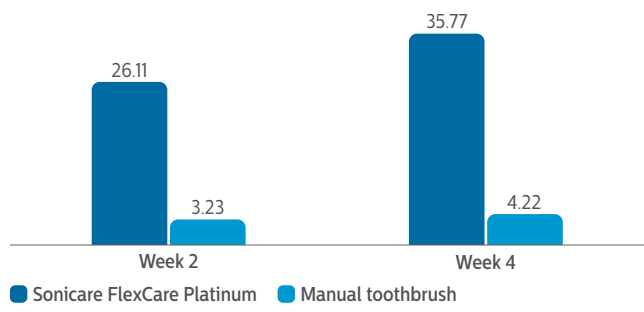
- For gingivitis reduction, FlexCare Platinum with InterCare standard brush head was superior to MTB at two and four weeks ($p < 0.0001$)
- For gingival bleeding reduction, FlexCare Platinum with InterCare standard brush head was superior to MTB at two and four weeks ($p < 0.0001$)
- For plaque reduction, FlexCare Platinum with InterCare standard brush head was superior to MTB at two and four weeks, overall and in all sub-regions ($p < 0.0001$)

There were no adverse events reported.

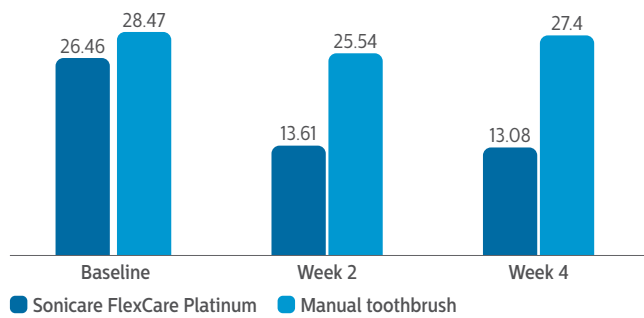
Conclusion

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
% of Gingivitis Reduction



Number of Sites with Gingival Bleeding
Mean Residual Protein Concentration ($\mu\text{g}/\text{ml}$)



**Percent Plaque Reduction from Baseline,
Overall and Posterior Interproximal**

