



## Gingival Health

in vivo study

# Comparison of gingivitis and plaque reduction over time by Philips Sonicare FlexCare Platinum with compact brush head and a manual toothbrush

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Data on file, 2012.

### Objective

To evaluate the ability of the Sonicare FlexCare Platinum toothbrush with InterCare compact brush head to reduce gingivitis, gingival bleeding and plaque versus a manual toothbrush following two and four weeks of product use.

### Methodology

One hundred fifty adults (104 females; 46 males) with mild to moderate gingivitis aged 18-65 years (mean age, 42.2 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  $\geq 1.8$  following three to six hours of plaque accumulation and a Gingival Bleeding Index of  $\geq 1$  on at least 20 sites. Eligible subjects were randomized to either Sonicare FlexCare Platinum with compact 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 group significantly reduced gingivitis, gingival bleeding and plaque following two and four weeks of product use.

Sonicare FlexCare Platinum with InterCare compact brush head was significantly superior to MTB on all clinical metrics as follows:

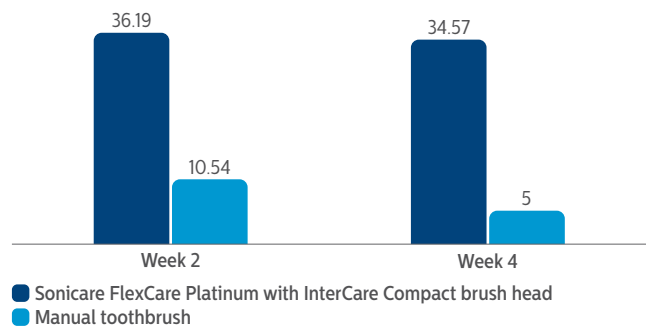
- For gingivitis reduction, FlexCare Platinum with InterCare compact brush head was superior to MTB at two and four weeks ( $p < 0.0001$ )
- For gingival bleeding reduction, FlexCare Platinum with InterCare compact brush head was superior to MTB at two and four weeks ( $p < 0.0001$ )
- For plaque reduction, FlexCare Platinum with InterCare compact 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.

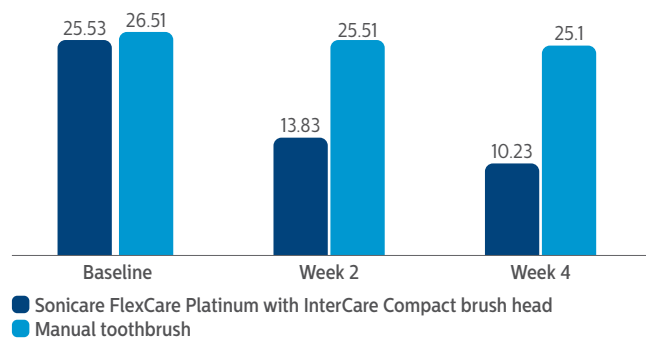
### Conclusion

Sonicare FlexCare Platinum with InterCare compact brush head 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. Both 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 ( $\mu\text{g/ml}$ )



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

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