

Plaque reduction
In vivo study

Plaque reduction efficacy of the Philips Sonicare for Kids electric toothbrush vs. a manual toothbrush among children aged 3–12 years: Results of a 2-week randomized controlled trial

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Objectives

To compare the efficacy and safety of the Philips Sonicare for Kids toothbrush and a manual toothbrush in reducing dental plaque after 2 weeks of use in children aged 3–12 years.

Methodology

One hundred seventy-two children were enrolled in this 2-arm, 2-visit, examiner-blind, randomized, parallel design, IRB-approved clinical study. Children, aged 3–12 years, with a minimum of 16 scorable teeth of fully erupted primary and/or mixed permanent dentition, and an average plaque score of ≥ 1.8 per the Modified Plaque Index (MPI) after 3–6 hours of plaque accumulation, were recruited for the study. Eligible subjects were randomized to one of two treatment groups: Philips Sonicare for Kids (SFK) or a manual toothbrush (MTB). Subjects were instructed to brush twice per day with fluoridated toothpaste. Clinical and safety evaluations occurred at baseline and at week 2, during which surface plaque was assessed. Safety was assessed by subject report and oral examination. Compliance was tracked by subject diary review.

Results

A total of 172 subjects (N=89 female and N=83 male) completed the study with 85 in the SFK group and 87 in the MTB group.

Modified Plaque Index (MPI)

The clinical efficacy scores for dental plaque (MPI) are presented in Table 1 for the study population. At baseline there was no statistical difference in the MPI score between the SFK and MTB groups. After 2 weeks of home use, both the SFK and MTB groups showed within-group statistically significant reductions in plaque from baseline. Examining the between-group treatment difference, the SFK group exhibited a statistically significantly greater plaque reduction than the MTB group ($p < 0.0001$).

Safety

There were no safety concerns related to the study products. One subject in the MTB group had a mucosal ulcer that was mild in severity and not considered to be related to the toothbrush.

TABLE 1 Plaque efficacy score: Least squares mean (standard error)

Outcome		SFK ^a	MTB ^a	Treatment difference ^b	p-value ^{c,d}
Results -Overall		(N=85)	(N=87)		
Baseline	Observed score	3.74 (0.035)	3.74 (0.034)	0.00 (0.049)	0.9678x
Week 2	Observed score	2.74 (0.037)	3.53 (0.036)	-0.79 (0.052)	<0.0001x
	Reduction from baseline	0.99 (0.037) ^d	0.20 (0.036) ^d	0.79 (0.052)	<0.0001x
	Percent reduction from baseline	26.45% (1.004%) ^d	5.20% (0.992%) ^d	21.26% (1.411%)	<0.0001x

a: Treatment groups: SFK = Philips Sonicare for Kids, MTB = manual toothbrush.
b: Treatment difference = SFK outcome minus MTB outcome.

c: P-value for the treatment difference (ANOVA).
d: Statistically significant reduction from baseline.

Conclusions

The Philips Sonicare for Kids power toothbrush was statistically superior to a manual toothbrush in reducing surface plaque following 2 weeks of home use.

Both study products were safe to use.

Percent plaque reduction from baseline after 2 weeks

