

A 12-Week Clinical Comparison of the Safety and Efficacy of Two Power Toothbrushes in the Reduction of Plaque and Gingivitis



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KEY CLINICAL RESULTS

Plaque

- Oral-B® Triumph® had 30% and 33% lower post-brushing plaque scores at 6 and 12 weeks, respectively, compared to Sonicare® FlexCare ($p<0.001$).
- Across the 12-week usage period, Triumph had a 14.6% higher plaque reduction vs. baseline than FlexCare ($p<0.001$).

Gingivitis

- Triumph had significantly lower gingivitis scores compared to FlexCare at Weeks 6 and 12 ($p<0.001$).

Bleeding

- Triumph had 29.4% lower bleeding scores compared to FlexCare after 12 weeks of use ($p=0.010$).

OBJECTIVE

To evaluate and compare the safety and efficacy of two toothbrushes in the reduction of gingivitis and plaque over a 12-week period.

MATERIALS AND METHODS

- This was a single-center, examiner-blind, 12-week, 2-treatment, open label, parallel group, randomized study. 177 subjects with evidence of gingivitis were enrolled.
- Plaque and gingivitis measurements were taken at three (3) timepoints: Baseline, Week 6 and Week 12. Plaque measurements were also taken pre- and post-brushing at each visit. Treatments were evaluated using the Rustogi Modification of the Navy Plaque Index (RMNPI), the Modified Gingival Index (MGI) and the Gingival Bleeding Index (BGI).
- At baseline, qualified subjects were stratified and randomly assigned to one of the two treatment groups based on baseline pre-brushing plaque and gingivitis scores, gender and smoking:
 - Oral-B Triumph with oscillating-rotating technology (Procter & Gamble) or
 - Sonicare FlexCare, with sonic technology (Philips)
- Subjects then received oral hygiene instructions and product usage instructions. They brushed according to the manufacturer's toothbrush instructions with their assigned toothbrush. Following brushing the examiner carried out a post-brushing plaque exam.
- Subjects were instructed to brush with their assigned toothbrush and dentifrice for two minutes twice daily at home according to the written and verbal usage instructions given to them during product distribution. Subjects were reminded to refrain from brushing their teeth for 12 hours and refrain from eating, chewing gum, drinking, smoking for four (4) hours prior to their next visit.
- Subjects returned for gingivitis and pre- and post-brushing plaque measures at six (6) and twelve (12) weeks following the Baseline visit.

STUDY POPULATION

- 175 subjects were randomized to treatment. 173 subjects were evaluable for Week 6 analyses and 171 for Week 12 analyses.
- Treatment groups were balanced for age ($p=0.883$) and gender ($p=0.276$), but not for ethnicity ($p=0.029$) mainly due to the difference in Asian Indians in the Triumph group ($n=13$; 35.1%) relative to the FlexCare group ($n=24$; 64.6%).

RESULTS

- **Post-brushing plaque** – At Weeks 6 and 12 respectively, Triumph had 30% and 33% lower plaque scores compared to FlexCare ($p<0.001$). See Table 1.
- **Pre-brushing plaque** – At Week 12, there was no significant treatment difference between the two brushes ($p=0.279$). At Week 6, Triumph brush users were found to have statistically significantly higher pre-brushing plaque scores than FlexCare ($p=0.047$). See Table 1.
- **Plaque Reduction (pre-brushing minus post-brushing) across Visits (repeated measures)** – Triumph had 14.6% better plaque removal across the three visits ($p<0.001$). Oral-B Triumph also had a statistically



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significantly higher plaque reduction at each Visit (Baseline, Week 6 and Week 12) than Sonicare FlexCare ($p < 0.001$). See Table 2.

- **Modified Gingival Index** – Triumph had significantly lower gingivitis scores compared to FlexCare ($p < 0.001$) at Week 6 (4.1%) and Week 12 (8.2%). See Table 3. Both brushes delivered a statistically significant reduction from baseline in MGI after 6 and 12 weeks of use (Triumph 0.17 and FlexCare 0.10 unit reductions at 6 weeks and Triumph 0.36 and FlexCare 0.22 unit reductions at 12 weeks; all $p < 0.001$).
- **Gingival Bleeding Index** – At Week 12, Triumph had significantly lower bleeding scores (29.4%) compared to FlexCare ($p = 0.010$). At Week 6, there were no significant difference in GBI scores for Triumph vs. FlexCare ($p = 0.185$). See Table 3. Both brushes delivered a statistically significant reduction in GBI after 6 weeks (Triumph 0.02 and FlexCare 0.01 unit reduction; $p \leq 0.028$) and 12 weeks (Triumph 0.04 and FlexCare 0.02 unit reduction; $p < 0.001$) of use relative to the Baseline visit.
- **Safety** – There were no adverse events reported.

Table 1. Plaque Results

	Oral-B Triumph	Sonicare FlexCare	Treatment Comparison p -value
Baseline (Mean, SD)	0.621 (0.04)	0.614 (0.04)	0.300
Post-Brushing Plaque			
Week 6 (Adj mean, SE)	0.119 (0.01)	0.170 (0.01)	<0.001
Week 12 (Adj mean, SE)	0.108 (0.00)	0.162 (0.01)	0.003
Pre-Brushing Plaque			
Week 6 (Adj mean, SE)	0.611 (0.00)	0.602 (0.00)	0.047
Week 12 (Adj mean, SE)	0.596 (0.00)	0.590 (0.00)	0.279

Table 2. Pre- Minus Post-Brushing Mean, Repeated Measures

Visit	Oral-B Triumph	Sonicare FlexCare	Treatment Comparison p -value
Baseline Mean Reduction	0.507 (0.01)	0.435 (0.01)	<0.001
Week 6 Mean Reduction	0.492 (0.01)	0.433 (0.01)	<0.001
Week 12 Mean Reduction	0.488 (0.01)	0.428 (0.01)	<0.001
Across all 3 Visits	0.495 (0.00)	0.432 (0.00)	<0.001

Table 3. Gingivitis Results

Visit	Oral-B Triumph	Sonicare FlexCare	Treatment Comparison p -value
Mean Gingival Index			
Baseline (Mean, SD)	2.04 (0.07)	2.05 (0.07)	0.361
Week 6 (Adj mean, SE)	1.87 (0.01)	1.95 (0.01)	<0.001
Week 12 (Adj mean, SE)	1.68 (0.01)	1.83 (0.01)	<0.001
Gingival Bleeding Index			
Baseline (Mean, SD)	0.080 (0.09)	0.091 (0.11)	0.505
Week 6 (Adj mean, SE)	0.064 (0.01)	0.074 (0.01)	0.185
Week 12 (Adj mean, SE)	0.048 (0.01)	0.068 (0.01)	0.010

For Tables 1 and 2:

Baseline: N=87 Triumph, N=88 FlexCare.

Week 6: N=85 Triumph, N=88 FlexCare.

Week 12: N=84 Triumph, N=87 FlexCare.

SD = Standard Deviation; Adj Mean = Adjusted mean; SE = Standard Error.

