

6-Month Clinical Evaluation of Oral-B® iO Electric Toothbrush versus a Sonic Toothbrush for the Reduction of Gingivitis and Plaque

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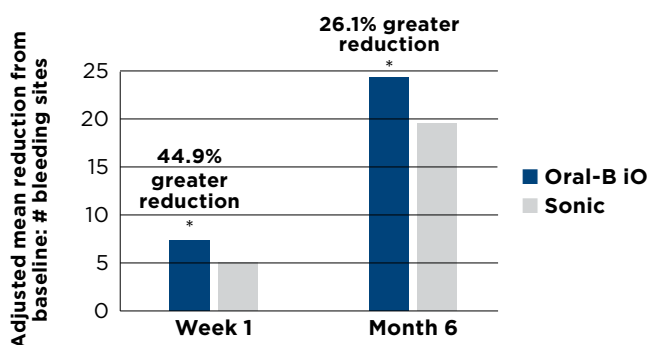
KEY GINGIVITIS RESULTS

Twice daily use of the novel Oral-B® iO oscillating-rotating smart-connected electric toothbrush for 6 months resulted in greater gingival health improvements versus Sonicare DiamondClean, including:

- 26.1% greater reduction in number of bleeding sites (See Figure 1)
- 32.6% greater gingivitis reduction (MGI)

These differences were statistically significant ($P < 0.001$).

Figure 1. Reduction in bleeding sites from Baseline at Week 1 and Month 6.

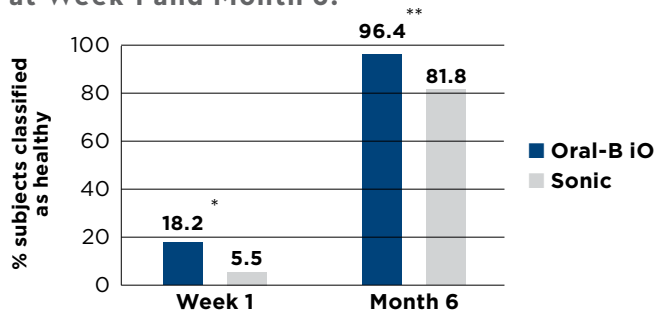


* $P < 0.001$; overall baseline number of bleeding sites = 31.03

TRANSITIONS TO GINGIVAL HEALTH

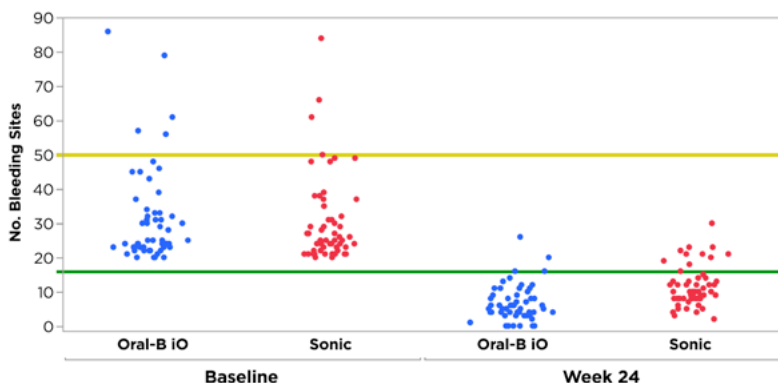
96.4% of subjects who had >10% bleeding sites at baseline and used the Oral-B® iO toothbrush were categorized as healthy (<10% bleeding sites), according to the World Workshop on Periodontology Gingivitis Case Definition,¹ at Month 6 compared to 81.8% of subjects using the sonic brush ($P = 0.029$). See Figures 2a & 2b. Subjects using the Oral-B® iO were also more likely to transition to a healthy gingivitis case status, with 3.9 times greater odds at Week 1, increasing to 5.9 times greater odds by Month 6, than those using the sonic brush.

Figure 2a. % of subjects classified as “healthy” (<10% bleeding sites) at Week 1 and Month 6.



* $P = 0.073$ ** $P = 0.029$

Figure 2b. Number of bleeding sites per subject at Baseline and Month 6.



LINGUAL SURFACE BENEFIT

While subjects brushing with the Oral-B® iO demonstrated superior whole-mouth gingival health outcomes versus the sonic brush irrespective of the gingival index used, this benefit was especially pronounced at the lingual surfaces. See Figure 3.

Figure 3. 6-month % differences in superiority for OralB® iO versus sonic showing a disproportionate benefit on lingual surfaces versus whole mouth for all GI indices.

Assessment	Whole Mouth	Lingual
MGI	32.6%	43.0%
GBI	23.7%	41.7%
Bleeding Sites	26.1%	43.9%

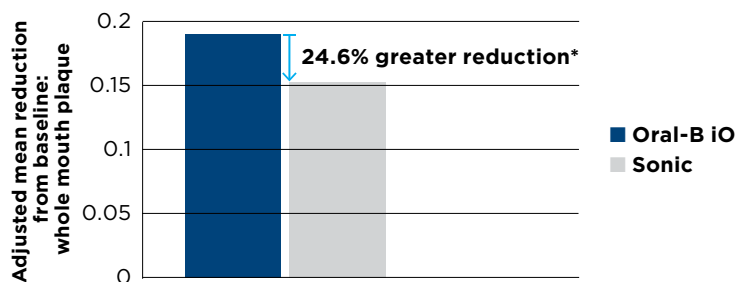
KEY PLAQUE RESULTS

Starting from Day 1 and continuing through Month 6, Oral-B® iO provided statistically significantly greater plaque reductions than Sonicare DiamondClean for whole mouth, interproximal and gingival margin plaque areas ($P \leq 0.008$).

Compared to the sonic brush, at Month 6 Oral-B® iO removed:

- 24.6% more whole mouth plaque (See Figure 4)
- 25.8% more interproximal plaque
- 61.9% more plaque along the gumline

Figure 4. Reduction in whole mouth plaque from Baseline to Month 6.



* $P < 0.001$; overall baseline whole mouth plaque score = 0.634.

OBJECTIVE

To evaluate the efficacy of the Oral-B® iO oscillating-rotating electric rechargeable toothbrush with micro-vibrations to the Sonicare DiamondClean sonic toothbrush for reduction of gingivitis and plaque.

STUDY DESIGN

- This was a 6-month, single-center, examiner-blind, 2-treatment, parallel group, randomized controlled trial conducted at All Sun Research Center in Ontario, Canada.
- 110 subjects with evidence of gingivitis and plaque were enrolled and randomized to one of two treatments, balancing for baseline gingivitis and plaque scores, number of bleeding sites and tobacco use:
 - Oral-B® iO oscillating-rotating smart-connected electric rechargeable toothbrush with micro-vibrations and Ultimate Clean brush head (M8/OC15, Procter & Gamble)
 - Sonicare DiamondClean sonic smart-connected toothbrush with Premium Plaque Control brush head (HX9903/11, Philips)
- Subjects brushed with their assigned toothbrush and a standard sodium fluoride dentifrice (Crest® Cavity Protection) twice daily for 6 months. Subjects were assisted to download and install the App and instructed to use it according to each manufacturer's instructions.
- Plaque and gingivitis were assessed at Baseline, Week 1 and Month 6 using the Modified Gingival Index and Gingival Bleeding Index. Plaque measurements were taken at Baseline (pre- and post-brushing), Week 1, and Month 6 visits (both pre-brushing only) using the Rustogi Modification of the Navy Plaque Index. Oral Soft Tissue examinations were also conducted at Baseline, Week 1 and Month 6.
- All 110 subjects finished the study. Subjects had a mean age of 46.2 years; 69% were females.

CLINICAL RELEVANCE

The OralB® iO electric rechargeable toothbrush represents the next generation in oscillating-rotating technology, combining oscillating-rotating motion with gentle micro-vibrations. In this randomized controlled clinical trial, OralB® iO showed statistically significantly greater gingivitis and plaque reductions than an advanced model sonic toothbrush, when both were used in smart-connected mode over 6 months. This resulted in more OralB® iO users transitioning to a “generally healthy” gingivitis case status (<10% bleeding sites, based on the World Workshop on Periodontology Gingivitis Case Definition¹) versus the sonic brush users. Moreover, subjects using the OralB® iO were more likely to transition to a “generally healthy” gingivitis case status as early as Week 1 (3.9 times greater odds), increasing to 5.9 times greater odds of transitioning to health by Month 6 than those using the sonic brush.

These results demonstrate that OralB® iO's superior plaque and gingivitis reductions from a previous 8-week study versus Sonicare DiamondClean,² which did not include smart connectivity, have been maintained over a significantly longer 6-month study period suggesting OralB® iO's smart connectivity contributes to sustained oral health benefits over time. These findings are also consistent with those from published meta-analyses showing superior gingival health benefits for oscillating-rotating toothbrushes versus various sonic control brushes.³⁻⁵ Notably, the disproportionate gingival health benefits demonstrated for the OralB® iO brush for lingual surfaces suggest that the round-shaped brush head is more suited for cleaning lingual areas which are often neglected.

1. Trombelli L et al., *J Clin Periodontol.* 2018;45 (Suppl 20): S44-S67.

2. Adam R et al., *Int Dent J.* 2020 Apr;70 Suppl 1:S16-S21

3. Grender J et al., *Am J Dent.* 2020 Feb;33(1):3-11.

4. Clark-Perry D et al., *J Am Dent Assoc.* 2020 Apr;151(4):265-275.e6.

5. Ccahuana-Vasquez RA et al., *J Clin Dent.* 2018 Mar;29(1):27-32.