

# Comparison of a Novel Sonic Toothbrush to Manual Brushing on Plaque Control and Gingival Inflammation: A Multicenter, Randomized, Controlled Clinical Trial



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The goal of this multicenter randomized controlled study was to evaluate the effectiveness of a newly developed ionic-sonic electric toothbrush in terms of plaque removal and reduction of gingival inflammation. A total of 78 subjects from three dental centers were invited to join the study. They were randomized to receive either a manual toothbrush (control group) or an ionic-sonic electric brush (test group). Full-mouth prophylaxis and oral hygiene instructions based on the stationary bristle technique were provided 1 week prior to the baseline visit. At baseline and at each follow-up appointment, Plaque Index (PI) and Gingival Index (GI) were recorded. In addition, probing depth (PD) and bleeding on probing were recorded at baseline and at the last appointment (week 5). At completion of the study, subjects in the test group were given a questionnaire regarding their satisfaction with the toothbrush. Sixty-four subjects completed the study (control: 28; test: 36). The mean age of the subjects was  $36.90 \pm 12.19$  years. No significant difference between the baseline and 5-week PD was found. Plaque removal efficacy and reduction in gingival inflammation were more significant for the test group at week 2. Both the control and test groups showed statistically significant improvement in PI and GI from baseline to week 5. The ionic-sonic toothbrush was more effective than manual toothbrush after a 1-week application. *Int J Periodontics Restorative Dent* 2021;41:99–104. doi: 10.11607/prd.5363

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Periodontitis is one of the most prevalent chronic diseases in the world, affecting more than 50% of Americans.<sup>1</sup> It is a chronic bacterial infection that elicits the host's immune response, resulting in the release of inflammatory mediators that can destroy structures that support the teeth. Dental plaque or biofilm is a community of many species of micro-organisms adherent to the tooth surface. Bacteria are found ubiquitously throughout the mouth, and sources report a range of 700 to 1,700 species of organisms.<sup>2</sup> To treat and prevent gingivitis and periodontal disease, microbial plaque biofilm control is essential. A classic study by Loe et al in 1965 clearly demonstrated the relationship in humans between plaque accumulation and the development of gingivitis when subjects stopped brushing.<sup>3</sup> Adherence to oral hygiene care by the patient is an important part in the maintenance of periodontal health.

Toothbrushes are the most widely used device to control supra-gingival plaque.<sup>4</sup> The new IONPA toothbrush (IONIC; Fig 1) is an innovative electric toothbrush that combines ion power with sonic vibration at 22,000 strokes per minute. The main advantage of ion power is that it can effectively break the bond between dental plaque and tooth surfaces due to a positive charge



Fig 1 IONPA toothbrush.

created by saliva.<sup>5</sup> The negatively charged ions released by the toothbrush could reverse the polarity and draw plaque molecules toward the brush bristles.

The purpose of the present study was to assess the effectiveness of this negative-ion-generating electric toothbrush compared to a manual toothbrush in terms of plaque removal and subsequent reductions in gingival inflammation.

## Materials and Methods

This prospective, short-term, multicentered, randomized, controlled clinical trial investigated the use of the ionic-sonic toothbrush to effectively remove plaque and reduce gingival inflammation. A total of 78 patients were enrolled from three centers, each recruiting 26 patients. The locations were North Carolina, USA; Lima, Peru; and Messina,

Italy. The patients were randomized into either the control group ( $n = 39$ , 13 from each center), receiving the manual toothbrush, or the test group ( $n = 39$ , 13 from each center) receiving the ionic-sonic toothbrush. All patients signed an informed consent form based on the Helsinki Declaration of 1975, as revised in 2013. The following inclusion criteria were applied: (1) between 20 and 70 years of age and requesting dental treatment; (2) willing to return for follow-up visits; and (3) being without a significant medical history and not presently taking medication that might complicate results. Subjects were excluded if they had significant untreated periodontal disease, caries, infections, or chronic inflammation in the oral cavity. Heavy smokers ( $> 10$  cigarettes per day) were also excluded.

Prior to the first study visit, subjects received full-mouth prophylaxis and oral hygiene instruc-

tion with the stationary bristle technique. One week later (baseline), subjects returned to the clinic and were randomized into either the test or control group. At this time, clinical pictures were taken, and pocket depth (PD), bleeding on probing (BOP), mobility, recession, furcation, keratinized tissue, Plaque Index (PI), and Gingival Index (GI) were clinically examined. The subjects were followed up each week for 5 consecutive weeks to record PI and GI. Oral hygiene instructions were reinforced at each visit. At the last visit, all clinical measurements taken at baseline, including PD and BOP, were taken again. At completion of the study, subjects in the test group were given a questionnaire with the following questions:

Q1: How did you feel after using the ionic toothbrush?

Q2: How do you rate the firmness of the toothbrush?

Q3: Did you find the ionic toothbrush effective?

Q4: Did you feel that the surfaces of your teeth were smoother after using the ionic toothbrush?

## Statistical Analysis

Descriptive statistics were presented as mean  $\pm$  SD for each group. To compare measurements taken at baseline and each follow-up exam, *t* test for paired observation was used. To compare changes from baseline to follow-up visits between control and test groups, *t* test for unpaired observations was used. Significance was set at  $P \leq .05$  with a 95% level of confidence.

## Results

Of the original 78 subjects, 64 completed the study (control: 28; test: 36). The average age of the control-group participants (15% men and 85% women) was 38.25 years, and the average age of the test-group participants (27.3% men and 72.7% women) was 35.65 years. At baseline, the mean PDs for the control and test groups were  $2.98 \pm 0.38$  mm and  $2.99 \pm 0.53$  mm, respectively. PD was reevaluated at week 5 and showed no statistically significant changes (control:  $2.93 \pm 0.37$  mm; test:  $2.94 \pm 0.54$  mm). The BOPs at baseline were  $13\% \pm 0.05\%$  for the control group and  $15\% \pm 0.03\%$  for the test group. There were no statistical differences between the groups at baseline (Table 1).

### Gingival Inflammation

Gingival inflammation was evaluated with BOP at baseline and week 5, and GI was evaluated weekly from baseline to week 5. Both groups demonstrated reduction in BOP from baseline to week 5, down to  $10\% \pm 0.06\%$  ( $\Delta = 2\%$ ) for the control group and  $11\% \pm 0.08\%$  ( $\Delta = 4\%$ ) for the test group (Table 2).

For GI, both groups showed a steady reduction trend, with significant differences from baseline to week 5. The GI in the control group reduced from  $1.02 \pm 0.51$  to  $0.49 \pm 0.30$ , and GI reduced from  $1.24 \pm 0.75$  to  $0.64 \pm 0.34$  in the test group (Fig 2 and Table 3). While there was no statistical difference between the groups in terms of changes from

**Table 1 Baseline Data**

Variable	Control (n = 36)		Test (n = 36)		P
	Mean $\pm$ SD	Mean $\pm$ SD	Mean $\pm$ SD	Median	
Age, y	$38.25 \pm 11.05$	34.5	$35.68 \pm 13.01$	30.5	.507
PD, mm	$2.98 \pm 0.38$	3.03	$2.99 \pm 0.53$	2.92	.952
BOP, %	$13 \pm 0.05$	12	$15 \pm 0.03$	15%	.523
PI	$1.50 \pm 0.51$	1.625	$1.57 \pm 0.54$	1.43	.661
GI	$1.02 \pm 0.51$	1.09	$1.24 \pm 0.75$	1.15	.279

PD = pocket depth; BOP = bleeding on probing; PI = Plaque Index; GI = Gingival Index.

baseline to week 5, a significant difference was found between the groups in the changes from baseline to week 2.

### Plaque Index

Both brushing methods resulted in significant reduction in plaque accumulation from baseline to week 5. The control-group PI reduced from  $1.50 \pm 0.51$  to  $0.81 \pm 0.38$ , while the test-group PI reduced from  $1.57 \pm 0.54$  to  $0.82 \pm 0.52$ . The test group also had a significant reduction from baseline to week 2 (Fig 2 and Table 3).

### Questionnaire Answers

Most found the ionic toothbrushes met their standard for comfort and efficacy, with 86% of subjects feeling either good or excellent after usage. Most participants (97%) found the toothbrush to be at least somewhat effective, and 94% felt that the surfaces of their teeth were at least somewhat smoother. Interestingly, the results were slightly different

coming from three different countries, and participants from the Italian site had the highest overall satisfaction with the ionic toothbrush. Full results of the questionnaire can be found in Table 4.

## Discussion

Effective plaque removal and adherence to oral hygiene care by the patient are integral to the maintenance of oral health. However, the practice of brushing can be time-consuming, tedious, and difficult to achieve in populations with decreased manual dexterity.<sup>6</sup> Powered toothbrushes were developed to help patients perform better oral hygiene practice. Today, a patient shopping for a powered toothbrush will find a wide selection on the shelves of their local pharmacy; nonetheless, there is no insurance that one design will benefit the patient more than another.<sup>7</sup>

This randomized, controlled study evaluated the effectiveness of a newly developed ionic-sonic electric toothbrush in removing plaque and reducing gingival

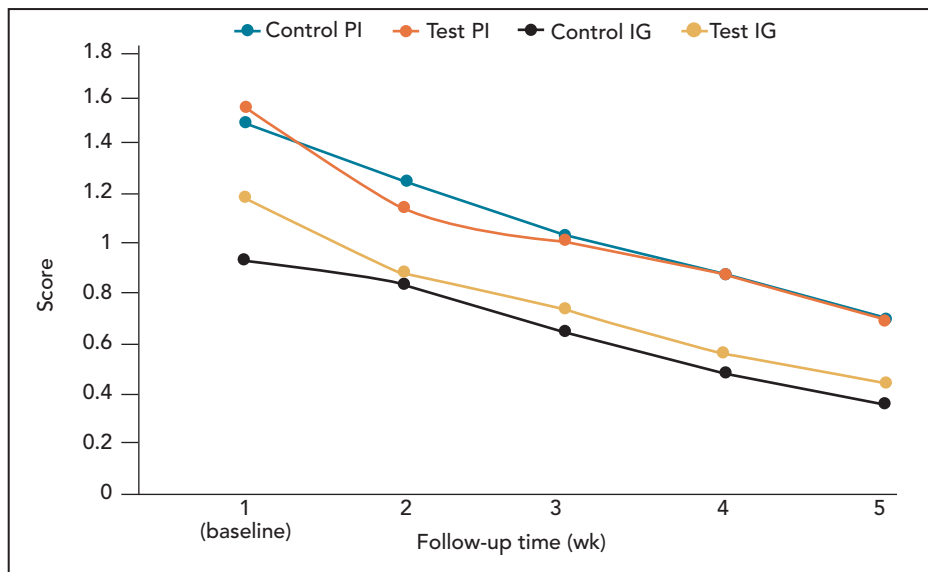


Fig 2 Plaque Index (PI) and Gingival Index (GI) changes over time.

Table 2 Changes in Bleeding on Probing from Baseline to Week 5

	Baseline	Week 5	Difference	P
Control	13% ± 0.05%	10% ± 0.06%	2% ± 0.07%	.557
Test	15% ± 0.03%	11% ± 0.08%	4% ± 0.07%	.373
P (control vs test)				.733

Values are presented as mean ± SD.

Table 3 PI and GI Changes from Baseline to Week 2 and Week 5

Variable	Baseline	Change between baseline and wk 2	P	Change between baseline and wk 5	P
<b>PI</b>					
Control	1.50 ± 0.51	0.20 ± 0.26	.225	0.68 ± 0.48	< .0001*
Test	1.57 ± 0.54	0.36 ± 0.38	.043*	0.75 ± 0.42	< .0001*
P (control vs test)			.119		.633
<b>GI</b>					
Control	1.02 ± 0.51	0.08 ± 0.11	.611	0.52 ± 0.31	.001*
Test	1.24 ± 0.75	0.26 ± 0.32	.230	0.61 ± 0.31	.001*
P (control vs test)			.024*		.133

PI = Plaque Index; GI = Gingival Index.

Values are presented as mean ± SD. These changes are all reductions (negative values).

\*Statistically significant.

**Table 4 Questionnaire Results: Overall and by Center**

	Overall	Italy	USA	Peru
<b>Question 1: How did you feel after using the ionic toothbrush?</b>				
Excellent	44%	100%	29%	23%
Good	42%	0%	57%	54%
Fair	14%	0%	14%	23%
Bad	0%	0%	0%	0%
<b>Question 2: How do you rate the firmness of the toothbrush?</b>				
Excellent	17%	67%	0%	0%
Good	25%	33%	29%	15%
Fair	36%	0%	57%	39%
Bad	22%	0%	14%	46%
<b>Question 3: Did you find the ionic toothbrush effective?</b>				
Yes	75%	100%	71%	61%
No	3%	0%	0%	8%
Somewhat	22%	0%	29%	31%
<b>Question 4: Did you feel that the surfaces of your teeth were smoother after using the ionic toothbrush?</b>				
Yes	69%	100%	57%	62%
No	6%	0%	14%	0%
Somewhat	25%	0%	29%	38%

inflammation. The result was consistent with other studies, demonstrating that the ionic-sonic powered toothbrush was more effective than a manual toothbrush in removing plaque and reducing gingival inflammation at 1 week of use.<sup>8,9</sup> This indicated that the ionic-sonic toothbrush was easy to use and had some positive effect subgingivally. Because the subjects in both groups were given oral hygiene instructions repeated weekly and the study population comprised younger individuals, it was not surprising that by week 5, both manual and powered toothbrushes were equally effective.

It was noted that regardless of age, the patients complimented

their experience with the ionic-sonic toothbrush and looked forward to being able to purchase replacement toothbrushes when the electric brushes become available. The significantly more positive results of the IONPA toothbrush demonstrated just 1 week after use suggest that it can be a useful tool for the elderly and people with different disabilities.

### Conclusions

This multicentered, randomized, controlled clinical trial compared manual brushing and brushing with a novel ionic-sonic toothbrush on the effect on plaque control and gin-

gival inflammation. It is obvious that the participants benefitted from the experience, and there were significant reductions in gingival inflammation as well as improved plaque removal.

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