# Clinical evaluation of an ionic toothbrush in the removal of established plaque and reduction of gingivitis

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Abstract:

The clinical effectiveness of a manual ionic toothbrush in the removal of dental plaque and the reduction of gingivitis was evaluated. A double-blind study evaluated the effect of a small, imperceptible electric current on established dental plaque and gingivitis during toothbrushing. Sixty-four adults completed the study. Gingivitis and plaque scores were determined at baseline and after 3 and 6 months. The baseline indices of the two groups were well balanced. At each examination, the participants were instructed how to hold the toothbrush properly and reminded to change brush heads every 4 weeks. Statistically significant improvements in Löe Gingival Index scores were observed from baseline to 6 months between the control and test groups and within the test group. The Quigley-Hein Plaque Index scores also showed a significant improvement from baseline to 6 months between the control and test groups and within the test group.(Quintessence Int 1996; 27: 389-394)

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**Clinical relevance**

By using the ionic toothbrush conscientiously on a daily basis, the compliant patient can remove significantly more plaque than with other toothbrushes, reducing the risk of gingival inflammation and caries.

## Introduction

For many years, people have used various methods for cleaning their teeth. The most primitive method was the use of various types of wooden stick. The main reason for tooth cleaning in years past was the removal of food particles that caused oral discomfort, while oral hygiene today is specifically directed toward plaque control.[1] Today, toothbrushing is the most widely practiced method of oral hygiene and has a very high degree of social acceptability[2]. It has been shown that, in industrialized counties,

80% to 90% of the population brush their teeth one or two times a day.[3, 4] It has been further shown that the toothbrushing practiced by the majority of these people is unsatisfactory, if the goal is plaque control. An average daily brushing of approximately 2 minutes' duration will remove only half the accumulated plaque, leaving the other half to promote rapid regrowth.[5] This finding was supported by another study, in which it was shown that the average person, by brushing, removes only about 50% of the plaque present on his or her teeth.[6]

In an effort to increase the amount of plaque removed at each brushing, toothbrushes of different sizes and shapes and made of various materials have been developed. Brushes with soft bristles, multitufted heads, and end-rounded filaments have been introduced. In addition, many electric-powered toothbrushes have been developed. Generally, the manual and electric toothbrushes are equally effective in removal of bacterial plaque.[7] In spite of all this activity in improving toothbrush type and design, most people still remove only about 50% of the plaque present when they brush their teeth.[5] The development of a toothbrush that would allow the average person to remove more plaque from his or her teeth on a daily basis is highly desirable.

In an effort to achieve better plaque removal, a manual ionic action toothbrush was developed. The purpose of this study in humans was to evaluate the effectiveness of the hyG ionic toothbrush (Hukuba Dental) in removing dental plaque and reducing gingivitis.

## Principles of the Ionic Action Mechanism

A basic understanding of the ionic action mechanism is essential. The use of devices with ionic action in the oral cavity is not a new concept. The terms *iontophresis*, *electrophoretic*, and *electroionizing* have been used synonymously in dentistry for many years.[8-11] Ionic activity was a concept originally developed for the desensitization of natural teeth. Pratt[12] patented the idea in 1889.

The mechanism for the ionic action is due to a change in the polarity of the teeth. Teeth are normally negatively charged and plaque is positively charged. Opposite charges attract and bond to each other. Plaque, therefore, is attached to the tooth surface by ionic bonding.[13]

The hyG toothbrush has a 3-V lithium battery located under the metal band on the handle. The battery is similar to a watch battery and just as safe. The toothbrush bristles are negatively charged through the metal rod within the brush head. When the metal band on the toothbrush handle is held with moistened fingers, the positively charged ions are transferred to the teeth during brushing. The tooth polarity changes

from negative to positive. The positively charged tooth ions repel the positively charged plaque ions. The positively charged plaque ions are then attracted to the negatively charged bristles of the hyG toothbrush. This important ionic exchange, along with the normal mechanical action of the bristles on the tooth and gingival surfaces, may enhance plaque removal.

Contact of moist fingers with the metal band on the hyG toothbrush handle is essential to maximize ionic transfer of plaque molecules between the teeth and the toothbrush bristles. Laboratory studies have shown that the actual current circulation from the 3-V lithium battery is 1.5 V at the teeth when the brush is held with moistened fingers. The current is only 0.8 V when the brush is held with dry fingers.[14]

## Method and materials

Adult male and female subjects were selected from the faculty, staff, and general patients at Marquette University, School of Dentistry. All potential subjects were thoroughly screened, and those who participated were required to meet the following qualifications:

1. They completed a Confidential Health Questionnaire.
2. They signed an informed consent form that was approved by the Institutional Review Board at Marquette University.
3. They were dental plaque formers, as demonstrated by a clinical examination.
4. They were not taking any medication or using mouthwashes that could have an inhibitory effect on formation of dental plaque.
5. They had a minimum of 20 natural teeth.
6. They agreed to return for periodic examinations at 3 and 6 months following the recording of baseline data.

The intent of this study was to enroll 65 to 70 patients who met these criteria. Three examiners were trained by the principal investigator in the clinical indices to be used and were tested for intraexaminer and interexaminer reliability. A high level of reliability was achieved.

The Löe Gingival Index[15] was used to evaluate gingival inflammation. The gingival tissues were divided into two gingival scoring units, namely the labial/buccal and lingual/palatal surfaces. Criteria for scoring were as follows: 0 = normal gingiva; 1 = mild inflammation – slight change in color and slight edema, but no bleeding on probing; 2 = moderate inflammation – redness, edema, and some glazing, but no

bleeding on probing; and 3 = severe inflammation – marked redness, edema, and bleeding on probing.

The Quigley-Hein Plaque Index[16] was used to assess disclosed plaque on the labial/buccal and lingual/palatal tooth surfaces: 0 = no plaque; 1 = separate flecks of plaque at the cervical margin of the tooth; 2 = a thin continuous band of plaque (up to 1 mm) at the cervical margin of the tooth; 3 = a band of plaque wider than 1 mm but covering less than one third of the crown of the tooth; 4 = plaque covering at least one third but less than two thirds of the crown of the tooth; and 5 = plaque covering two thirds or more of the crown of the tooth.

Seventy-one subjects were selected for the study. Each received a complete-mouth gingival examination. After each tooth area was scored according to the Gingival Index, subjects were given a liquid disclosing solution and instructed to rinse for 15 seconds. Plaque scores were then determined and recorded.

The subjects were given a prepackaged and coded hyG ionic toothbrush (Fig 1). The toothbrushes were received evenly divided (36 of each) between those that had active batteries and those that had inactive batteries. Each packet had a code number that was recorded for the subject at the time of delivery. Neither the researchers nor the subjects knew whether their toothbrush contained an active or inactive battery.

Written instruction were given, and the subjects were shown how to hold the toothbrush properly so that their moist fingers touched the metal band during toothbrushing. Subjects were told to brush at least twice daily using their usual technique and dentifrice. They were further advised not to use any oral rinses that could affect plaque inhibition during the course of the study. Additonal toothbrush heads with soft multitufted 0.18 diameter nylon bristles were dispensed. Subjects were instructed to change brush heads every 4 weeks. They were then scheduled for an appointment for the next scoring session, approximately 3 months from the date of the initial examination.

At the 3-month examination, the gingival inflammation scores were determined and recorded. Each subject was given disclosing solution, and the plaque accumulations were scored and recorded. During the course of the examination, the subjects were observed to assure the safety of the toothbrush assigned to them. The safety assessment included examination of the tongue, hard palate, soft palate gingiva, oral mucosa, sublingual space area, tooth structure, dental restorations, and cervical root areas. They were questioned regarding any adverse reactions to their assigned toothbrush. Each subject was again instructed to hold the toothbrush properly and to change brush heads every 4 weeks. They were given an appointment for the final examination,

approximately 6 months from baseline.

Subjects returning for the 6-months, or final phase, of the study were again observed and questioned regarding the safety of their toothbrush. The gingival inflammation and plaque scores were determined and recorded. The subjects were informed that the study was completed.

All data were statistically analyzed with Statview 512 computer software (Brainpower). The statistical significance of the data for the Gingival Index and Plaque Index within a group was determined with the *t*-test.

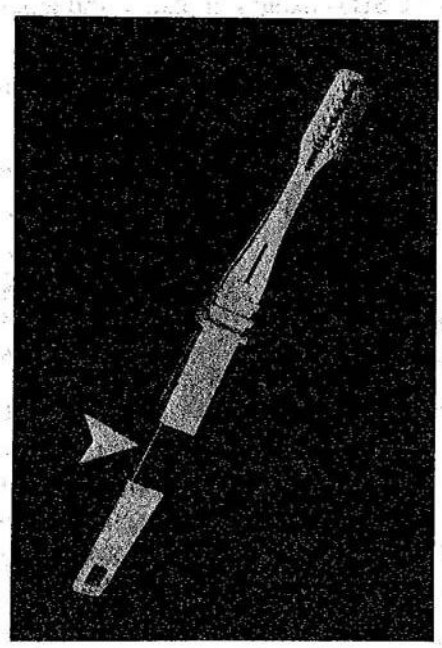

Fig 1 Electronic toothbrush evaluated. Metal pad *(arrow)*, or terminal, must have finger or palm contact.

*Table 1* Demographic data of subjects

| | Group A (test) | Group B (control) |
|---|---|---|
| No. | 34 | 30 |
| Female-male ratio | 30:4 | 25:5 |
| Average age (ys) | 32.47 | 33.20 |
| Age range (ys) | 18-60 | 19-67 |

## Results

At the completion of the clinical phase of the study, the codes denoting toothbrushes with or without an active battery were received from the sponsor. Based on the codes, subject data were divided into two groups for evaluation and statistical analysis. Group A included those subjects who received a toothbrush with an active battery. Group B included those who received a toothbrush with an inactive battery. Table 1 presents the demographic data of the subjects in the study. Of the 71 selected subjects, 64 completed the study. Seven subjects were eliminated from the study and their scores were not included in the final analysis. Of these, four did not use their assigned toothbrush exclusively during the test period, and three took physician-prescribed antibiotics.

*Table 2* Mean (± SD) changes in plaque and gingival indices with use of an ionic toothbrush

| | Group A (test) (n = 34) | Group B (control) (n = 30) | Significance |
|---|---|---|---|
| | *Plaque Index* | | |
| Baseline | 1.76 ± 0.50 | 2.00 ± 0.54 | NS |
| 3 Mo | 1.26 ± 0.46 | 1.38 ± 0.33 | NS |
| 6 Mo | 1.13 ± 0.44* | 1.63 ± 0.54 | $P = .001$ |
| Difference (3 Mo) | 0.50 ± 0.04 | 0.62 ± 0.21 | NS |
| Difference (6 Mo) | 0.63 ± 0.06 | 0.37 ± 0.00 | $P < .05$ |
| | *Gingival Index* | | |
| Baseline | 1.71 ± 0.56 | 1.68 ± 0.50 | NS |
| 3 Mo | 0.87 ± 0.34 | 0.91 ± 0.36 | NS |
| 6 Mo | 0.82 ± 0.40* | 1.18 ± 0.51 | $P = .001$ |
| Difference (3 Mo) | 0.84 ± 0.22 | 0.77 ± 0.14 | NS |
| Difference (6 Mo) | 0.89 ± 0.16* | 0.50 ± 0.62 | $P < .05$ |

* Statistically significant.
NS = not significant

The results of the study are presented in Table 2. The baseline indices of the two groups were well balanced. Mean Löe[15] baseline gingival scores of 1.68 to 1.71 were determined for the control and test groups, respectively. A statistically significant improvement was observed from baseline to 6 months between the control and test groups. There was also a statistically significant improvement within the test group from baseline to 6 months. The overall improvement in gingival health was 51.87% for the test group and 30.18% for the control group.

Mean Quigley-Hein[16] baseline plaque scores of 2.00 and 1.76 were found for the control and test groups, respectively. The scores indicated a statistically significant improvement from baseline to 6 months between the control and test groups. The test group had a 36.17% reduction in plaque, compared to only 18.56% for the control group. This means that the test group eliminated 48.69% more plaque than did the control group. There was also a statistically significant improvement within the test group from baseline to 6 months. Figure 2 and 3 illustrate the significant improvement observed during the course of the 6-month test.

## Discussion

This double-blind clinical study evaluated the effect of a small and imperceptible electrical current on established human dental plaque and gingivitis during toothbrushing. The hyG ionic action toothbrush used in the study has a 3-V lithium battery (Panasonic, Hitachi, or Sony) that supplied a positive electrical charge to the metal band on the handle and a negative charge to the bristles. The body, which is

electrically conductive, serves as a conduit for the electrical charge to the teeth.

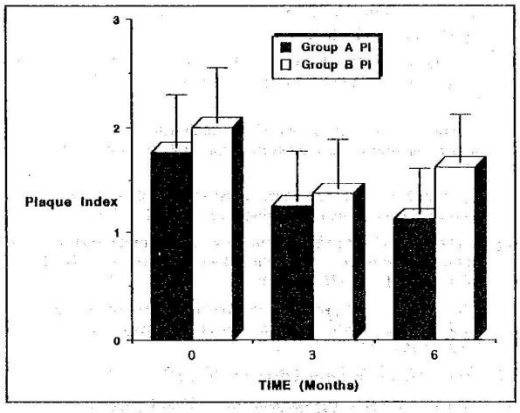


Fig 2 Changes in Plaque Index over time. Group A: Toothbrush with active battery. Group B: Toothbrush with inactive battery.

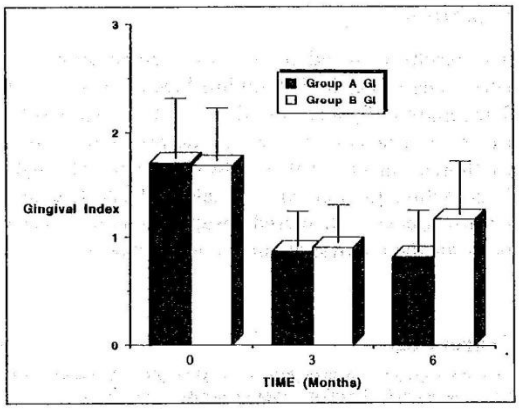


Fig 3 Changes in Gingival Index over time. Group A: Toothbrush with active battery. Group B: Toothbrush with inactive battery.

When the toothbrush is held in the moist hand and the bristles of the toothbrush head contact the target teeth or gingiva in the presence of saliva, an imperceptible electrical circuit is energized. The saliva becomes the electrolyte in which ions commerce their selective motion.[17] This electron flow temporarily reserves the polarity of the contacted teeth to a positive charge. It allows a break in the ionic bonding between the teeth and the plaque. The plaque is then attracted to the negatively charged bristles of the toothbrush, which may enhance removal of the plaque.[18]

The results of the study revealed a statistically significant beneficial effect in lower plaque and gingivitis scores after 6 months. These findings contradict those of a study by Van der Weijden et al,[19] who found no beneficial effect. Their study was similar, although it ran for only 5 months instead of 6 months. Their current source was two 1.5-V batteries. An important difference may be their toothbrush design. The toothbrush tested in the present study was designed for manual use, while the toothbrush used in the Van der Weijden study[19] was designed to deliver both an electric current and make a vibrating motion. The bulky design of their toothbrush handle would seem to make manual use difficult. The toothbrush was tested with the vibrating action switched off, which gives credence to the theory that manipulation was difficult. In addition, they used only a half-mouth scoring design, and we used a complete-mouth scoring design.

No effort was made to change the subjects' brushing habits, although they were instructed to hold the toothbrush properly. They were also told to use only their assigned toothbrush for the duration of the study. At the 3-month examination, the proper use of the toothbrush and the importance of maintaining the twice-a-day level of

brushing were again emphasized. Specifically, patients were told that the brush handle should be moist and that the thumb or fingers must contact the metal band (see Fig 1).

In the present study, statistically significant changes in the plaque and gingivitis scores were not observed at 3 months; however, the mean scores were lower in the test group. This indicates that the subject could expect significant improvement over time. It is probable that statistical significance was not evident at 3 months because of the Hawthorne effect.[20] That is, subjects tend to show immediate improvement in both control and test groups because of high interest and motivation. With time, interest wanes, and subjects tend to return to their usual brushing practices. This undoubtedly occurred between the 3- and 6-month visits. Improvement in plaque and gingival scores recorded at 3 months may in part be attributable to the high level of compliance of both groups early in the study. However, by the end of 6 months, all subjects are likely to revert back to their former brushing habits. Thus at 6 months, the benefits of the ionic action were evident at a statistically significant level.

This possibility is supported by the rebound in plaque and gingival scores that was observed in the control group but not in the test group. This would indicate that the ionic action of the hyG toothbrush is effective and helped subjects with average oral hygiene practices accomplish better overall plaque removal.

## Conclusions

The results obtained in the study demonstrate the effectiveness of an ionic toothbrush with a 3-V battery. The removal of plaque and reduction of gingivitis can be enhanced by the use of the hyG ionic action toothbrush in personal oral hygiene care. The hyG ionic action toothbrush is a safe and effective oral cleansing device when used unsupervised on a regular basis for the removal of human dental plaque.

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