

# Safety and efficacy of a novel toothbrush utilizing RF energy for the reduction of plaque, calculus and gingivitis

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**ABSTRACT: Purpose:** To evaluate the safety and efficacy of the ToothWave radiofrequency (RF) toothbrush in the reduction of plaque, calculus and gingival inflammation, as compared to a standard powered toothbrush accepted by the American Dental Association (ADA). **Methods:** This was a single-blind, double arm, prospective study. Subjects were randomized to one of two treatment groups, receiving either the RF powered toothbrush or a control powered toothbrush, and performing twice daily brushing for a test period of 6 weeks. Plaque (RMNPI), calculus (V-MI), gingival inflammation (MGI) and bleeding (GBI) were assessed at baseline, after 4 and 6 weeks. Comparisons were completed both within and between each treatment group. Statistical analyses were conducted using the Mann Whitney non-parametric model. **Results:** 85 subjects completed the study and had fully evaluable data. No significant differences between the groups were found in the baseline scores ( $P \geq 0.165$ ). Following 6 weeks, the RF test group demonstrated statistically significant reductions in plaque, gingivitis and calculus compared to the control powered toothbrush ( $P \leq 0.001$ ). Both toothbrushes were well-tolerated and no device-related adverse events were reported. The RF-utilizing powered toothbrush produced statistically significant reductions in dental plaque, calculus deposition, gingival inflammation and gingival bleeding as compared to a control powered toothbrush. (*Am J Dent* 2020;33:151-156).

**CLINICAL SIGNIFICANCE:** The RF powered toothbrush used twice daily resulted in an overall improvement in oral health.

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## Introduction

Gingivitis is an inflammation of the gums and a treatable initial stage of periodontal disease.<sup>1</sup> The direct cause of gingivitis is plaque, which is a soft, colorless film of bacteria that forms constantly on the teeth and gingiva. In cases where the plaque is not removed efficiently by daily brushing, it produces toxins that can irritate the gingival tissue, causing gingivitis. At this early stage in gingival disease, damage can be reversed by improving the oral hygiene, since the bone and connective tissue that hold the teeth in place are not yet affected. Left untreated, however, gingivitis can become periodontitis and cause permanent damage to the teeth and surrounding supporting oral tissues.<sup>1</sup>

One of the major causes of gingivitis is the accumulation of calculus (tartar), which is a form of hardened dental plaque, caused by precipitation of minerals from the saliva on the teeth. This rough and hardened substance provides an ideal surface for further plaque formation, which leads to calculus build-up and impairs gingival health. Calculus can form both along the gingival margin (supragingival) and within the narrow sulcus that exists between the teeth and the gingiva (subgingival).<sup>2</sup> The understanding that dental plaque and calculus are key etiological agents in the initiation and progression of gingival inflammation has been the basis of vast dental scientific and industrial research, aiming to find the optimal daily dental hygiene procedure.<sup>3-6</sup> Currently available scientific publications discuss the efficacy of various powered toothbrushes in reducing plaque, gingival inflammation, and gingival bleeding, following several weeks of twice-daily brushing at home.<sup>4,6</sup> However, none of the published research studies shows reduction of calculus by a standard powered toothbrush. It is widely accepted that once the calculus is formed, it is firmly attached to the tooth surface and is too hard to be removed with

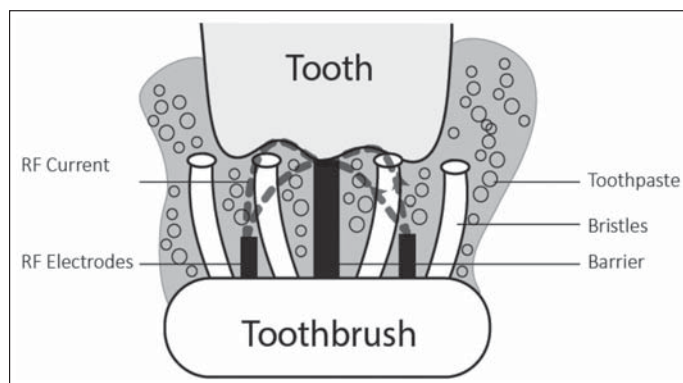


Fig. 1. Schematic representation of the RF current on the tooth surface.

a regular toothbrush; thus, in the conventional way, calculus build-up must be removed with ultrasonic tools or dental hand instruments (such as a dental scaler).<sup>2</sup>

With an aim to provide efficient reduction of dental plaque and calculus at home, and without changing the daily dental hygiene routine, a new power toothbrush was developed (ToothWave<sup>®</sup>). It is a novel toothbrush intended to remove effectively the impurities that are attached to the tooth surface, such as plaque and calculus, and thus to promote the reduction of bleeding and gingival inflammation. ToothWave utilizes low-power radiofrequency (RF) energy that streams between two electrodes and over a silicon barrier and reaches the tooth surface during brushing (Fig. 1). RF is an alternating electric current that oscillates at radio frequencies in the range of 3 kHz-300 GHz. It has been used in medicine for several decades for many different applications, from surgical to esthetic, providing various effects, depending on the specific parameters of the device in use.<sup>7</sup> Specifically, the ToothWave RF technology is proposed to bring charged molecules that originate

from the toothpaste, to the tooth surface, in order to destabilize the electrostatic bonds between the tooth and the impurities (calculus, stains, plaque) that are attached to it. In the current clinical study, the RF technology utilized by the ToothWave was evaluated for patient safety and efficacy in relation to dental plaque, calculus and gingival bleeding and inflammation compared to a standard powered toothbrush (control brush) that has been accepted by the American Dental Association (ADA).

## Materials and Methods

A randomized single-blind double arm prospective study was conducted, in order to evaluate the safety and efficiency of the RF-utilizing toothbrush (ToothWave), as compared to a control powered toothbrush (Smilesonic Pro Advanced Clean<sup>b</sup>). The control powered toothbrush was selected from a list of ADA-accepted toothbrushes, with features that were as similar as possible to the ToothWave. Both the Toothwave and the control toothbrush include an oval brush head, utilize a side-to-side vibration mode (as opposed to an oscillating round head), and a similar vibration speed. The protocol and consent form were approved (U.S. Institutional Review Board, U.S.IRB2019 SRI/03) before study initiation and verbal and written consent were obtained from all subjects.

**Participants** - Screened subjects received an oral soft tissue (OST) examination. Gingival status was evaluated using the Modified Gingival Index (MGI) and the Gingival Bleeding Index (GBI);<sup>8,9</sup> plaque examination was performed using the Rustogi Modified Navy Plaque Index (RMNPI),<sup>10</sup> and the calculus present on the lingual surfaces of the lower six anterior teeth was measured using the Volpe-Manhold Index (V-MI).<sup>11</sup>

Recruited subjects were 18-70 years of age, with baseline MGI scores of at least 1.80, baseline GBI scores equal to or greater than 1 on at least 20 sites, an overnight (12 to 18 hours abstinence from any oral hygiene) dental plaque (mean) scores greater than 0.6 according to the RMNPI Index,<sup>12</sup> and lingual calculus total scores greater than 7 mm on the lower anterior teeth according to V-MI. Exclusion criteria were composed of current or history of oral and/or oropharyngeal cancer, any active electrical implant anywhere in the body, pregnant or nursing, and any active condition or surgery in the oral cavity within 3 months prior to treatment. Subjects who did not practice daily oral hygiene were also excluded.

**Study procedures** - Eligible study participants were provided with regular, marketed Crest Cavity Protection Cool Mint Gel<sup>c</sup> toothpaste (0.243% sodium fluoride), and a toothbrush (either the ToothWave or the control powered toothbrush). Participants were randomized and assigned to the study group in accordance with a randomization schedule generated by an independent statistics agency prior to the start of the study, using validated software (SPSS,<sup>d</sup> version 25.0). Participants were stratified according to their age and ethnicity. Randomization numbers within each stratum were assigned in ascending numerical order according to appearance at the study site on the day participants were randomized.

The first brushing session was carried out under supervision at the study site. Participants brushed for 2 timed minutes in their usual manner with the standard fluoride toothpaste (Crest Cavity Protection Cool Mint Gel). Participants continued to use

their assigned study treatment twice-daily (morning and evening) for the next 6 weeks, recording each brushing in the diary provided. Participants returned to the study site every 2 weeks over the 6-week study period, bringing their study kit so that the toothpaste could be weighed to verify study compliance. Diaries were checked to assess compliance. The participants undertook a supervised brushing during the second visit as was conducted at the first visit, in order to make sure brushing was conducted according to the instructions.

**Assessments** - Clinical efficacy was evaluated at visits 3 and 4 (following 4 and 6 weeks of brushing, respectively). A full mouth gingival assessment was performed based on the Lobene et al<sup>3</sup> Modified Gingival Index. The gingiva was segmented into six sites per tooth (distobuccal, buccal, mesiobuccal and distolingual, lingual, mesiolingual surfaces), and the gingival inflammation was recorded at each tooth site on a scale of 0 to 4, where 0 denotes normal (absence of inflammation), 1 denotes mild inflammation (slight change in color, little change in texture) of any portion of the gingival unit, 2 denotes mild inflammation of the entire gingival unit, 3 denotes moderate inflammation (moderate glazing, redness, edema, and/or hypertrophy) of the gingival unit, and 4 denotes severe inflammation (marked redness and edema/hypertrophy, spontaneous bleeding, or ulceration) of the gingival unit.

A full mouth bleeding assessment was performed based on the Gingival Bleeding Index.<sup>9</sup> The gingiva was gently dried and lightly swept with a 0.5 diameter periodontal probe (to be used for each subject for all visits). The probe was engaged approximately 1 mm into the gingival crevice at a 60° angle to the tooth. A moderate pressure was used while sweeping from interproximal to interproximal along the sulcular epithelium. The gingiva was segmented into six sites per tooth (distobuccal, buccal, mesiobuccal and distolingual, lingual, mesiolingual surfaces). Bleeding or the absence of bleeding was assessed at each tooth site on a scale of 0 to 2, where 0 denoted no bleeding after 30 seconds, 1 denoted bleeding upon probing after 30 seconds, and 2 denoted immediate bleeding observed. Subjects with less than 20 bleeding sites at Visit 1 were dismissed from the study.

Plaque examinations were performed using the Rustogi Modified Navy Plaque Index (RMNPI).<sup>10</sup> Subjects swished with 5 ml of a disclosing solution for 10 seconds and expectorated, followed by 10 ml of water for 10 additional seconds. After disclosing, the plaque on each tooth was evaluated as present (1) or absent (0) at nine specific areas on both the facial and lingual surfaces. Mean plaque score for each subject was calculated using the total number of tooth sites with plaque present divided by the total number of tooth sites scored.

The supragingival calculus present on the lingual surfaces of six mandibular anterior teeth was calculated using the V-MI.<sup>11</sup> After drying the teeth with a stream of air and using a standard periodontal probe graduated in millimeters, the examiner placed the instrument on the most inferior border of the visible calculus, and measurements were obtained on the following three planes:

1. Bisecting the center of the lingual surface;
2. Diagonally through the mesial-incisal point angle of the tooth through the area of greatest calculus height; and
3. Diagonally through the distal point angle of the tooth through the area of the greatest calculus height.

Table 1. Baseline demographics and characteristics.

Characteristic	ToothWave N=45	Control N=41	Overall
<b>Sex, n (%)</b>			
Male	15 (33.3%)	13 (31.7%)	28 (32.6%)
Female	30 (66.7%)	28 (68.3%)	58 (67.4%)
<b>Race, n (%)</b>			
White/Caucasian/European/ Arabic heritage	36 (80%)	35 (85.4%)	71 (82.6%)
African American/ African heritage	6 (13.3%)	4 (9.8%)	10 (11.6%)
Asian Pacific Islander	2 (4.4%)	1 (2.4%)	2 (2.3%)
American /Alaskan Native	1 (2.2%)	1 (2.4%)	2 (2.3%)
<b>Age</b>			
Mean(SD)	44.9 (14.4)	46 (11.5)	45.4 (13.0)
Range	18-70	23-66	18-70

n (%) = number (percent) of participants; (SD) = standard deviation.

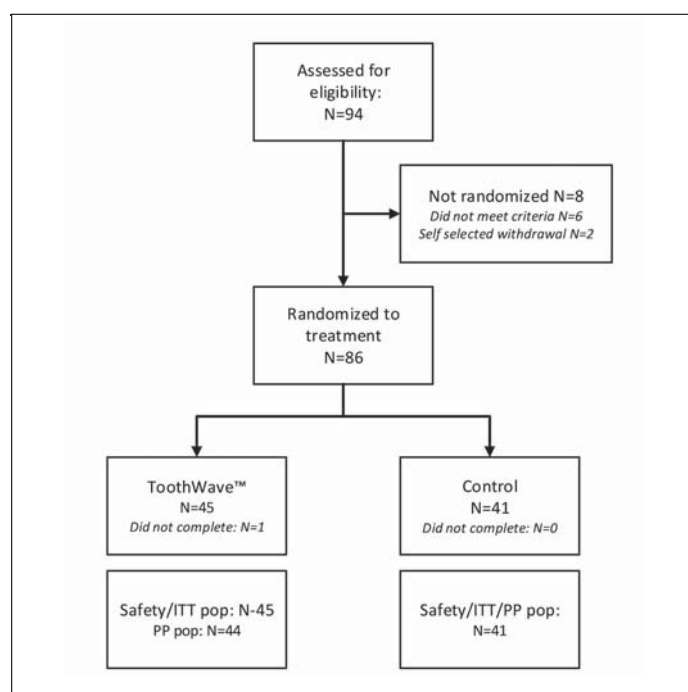


Fig. 2. Study flowchart.

The examiner assigned a score to each measurement plane, with measurements made in 0.5 mm increments starting at 0.5. A score of zero (0) denoted that there was no calculus present at a measurable site. The V-MI was calculated for each subject by summing the millimeter scores over all sites graded.

**Safety** - For safety, a thorough evaluation of the oral soft tissues was conducted at each visit, by way of a visual examination of the oral cavity, including the gingiva (free and attached), hard and soft palate, oropharynx/uvula, buccal mucosa, tongue, floor of the mouth, labial mucosa, mucobuccal/mucolabial folds, lips, and perioral area. A trained dental evaluator performed intra-oral examinations at each study visit. All adverse events (AEs) were recorded and monitored throughout the study. The AEs and any observed abnormalities noted during the OST examination were transcribed beginning at the screening visit until 5 days after the final use of study product. The investigator determined the causal relationship of each AE using their clinical experience and selected the appropriate severity des-

Table 2. Baseline efficacy measures.

Measure	Group	Mean (SD)	P-value*
GBI	Treatment (N=45) Control (N=41)	41.1 (15.8) 37.2 (13.7)	0.167
MGI	Treatment Control	2.6 (0.4) 2.5 (0.3)	0.222
Plaque	Treatment Control	0.86 (0.07) 0.83 (0.09)	0.165
V-MI	Treatment Control	16.2 (6.1) 16.1 (5.3)	0.846

\* Representing significance level, comparing the mean scores of Treatment and Control groups at baseline.

criptor as mild, moderate, or severe. Treatment-emergent AEs were reported for the safety population, which included all randomized participants who received study product.

**Data analysis** - A sufficient number of participants were to be screened in order to randomize at least 90 participants (approximately 45 to the Treatment, and 45 to the Control groups) to ensure 84 evaluable participants completed the entire study. The sample size in this study provided 80% power to detect a significant difference in the score improvements with type 1 error of 5%. Safety and efficacy analyses were carried out on a modified intent-to-treat (ITT) population, defined as all randomized participants who conducted at least one treatment.

Adverse event reports were summarized for each group. Summary statistics (e.g., count, mean & SD, Median, 25<sup>th</sup> and 75<sup>th</sup> percentile) of the demographic characteristics and the efficacy measurements were calculated for each group and study visit. Normality distribution of measures was evaluated using Shapiro Wilk test; as the majority of measures deviate from normal distribution, non-parametric approach was implemented.

To evaluate the improvement after 4 and 6 weeks as compared to baseline the difference was calculated as:

$$\text{Delta} = \text{Score(week i)} - \text{Score(Baseline)}$$

The mean baseline scores and the mean scores measured after 4 and 6 weeks were compared between the groups using the non-parametric Mann-Whitney test. The median, 25, and 75 percentiles of the delta values (reduction from baseline) were compared between the two groups as well using the Mann-Whitney test. Significance level was defined as  $\alpha = 0.05$ . Analyses were carried out using SPSS version 25.0.

## Results

A total of 94 subjects provided informed consent and were enrolled in this study, and 88 of these met the entrance criteria. Two subjects self-selected to withdraw during the first visit; 86 subjects were randomized at baseline to receive either the ToothWave or the control powered toothbrush. One subject in the Treatment group discontinued study participation prior to study end, with 85 subjects (90.4%) completing and deemed fully evaluable at the trial's conclusion (Fig. 2). As shown in Table 1, the mean age of the randomized study population was 45.4 years, with a range of 18 to 70 years; 58 (67.4%) of the subjects were female.

Table 1 exemplifies the demographic baseline values, indicating that the study population was well-balanced with respect to all baseline demographic variables ( $P \geq 0.575$ ).

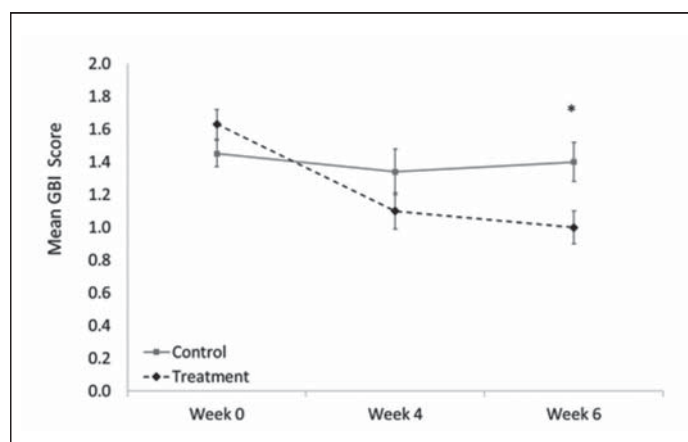


Fig. 3. GBI scores are significantly lower in the Treatment group as compared to the Control group following 6 weeks of brushing (\* $P=0.023$ ).

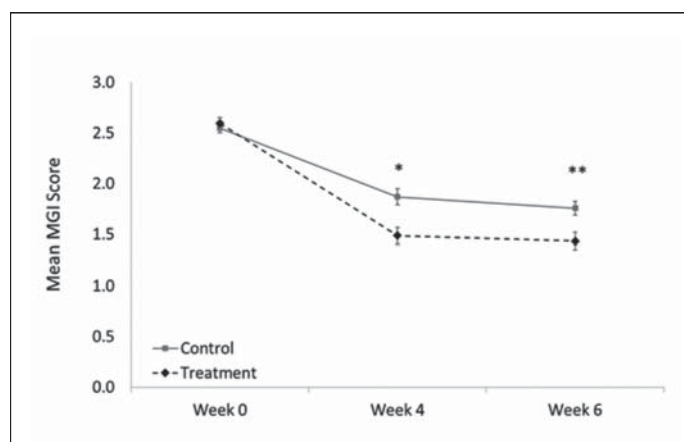


Fig. 4. MGI scores are significantly lower in the Treatment group as compared to the Control group following 4 and 6 weeks of brushing (\* $P=0.001$ , \*\* $P=0.003$ ).

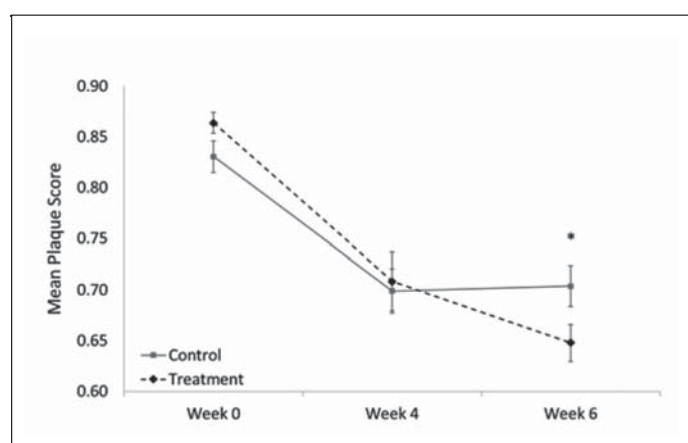


Fig. 5. Plaque scores in the Treatment group were significantly lower as compared to the Control group following 6 weeks of brushing (\* $P=0.051$ ).

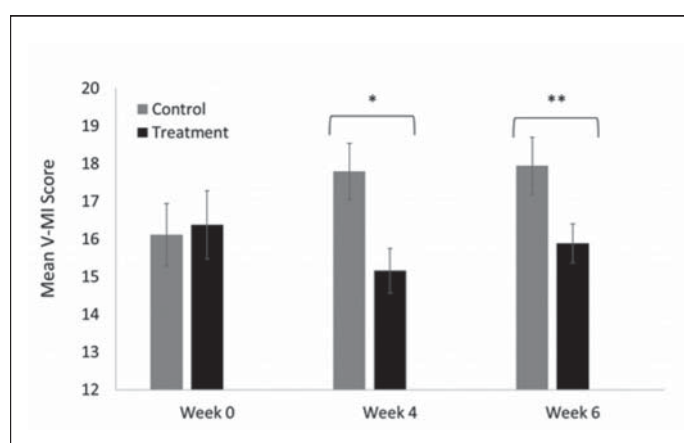


Fig. 6. The amount of calculus was reduced in the Treatment group and was increased in the Control group during the test phase of the study. (\* $P=0.009$ ; \*\* $P=0.05$ ).

Table 3. Calculated difference from baseline after 6 weeks of twice daily brushings.

Measure	Group	N	Baseline mean	6 weeks mean (SD)	Delta mean (SD)	P value*
GBI	Treatment	44	41.6 (15.7)	26.5 (17.8)	-12.8 (16.8)	< 0.001
	Control	41	37.2 (13.7)	36.2 (20.4)	-2.34 (19.2)	
MGI	Treatment	44	2.6 (0.4)	1.43 (0.6)	-1.11 (0.4)	< 0.001
	Control	41	2.5 (0.3)	1.76 (0.4)	-0.68 (0.4)	
Plaque	Treatment	44	0.86 (0.06)	0.65 (0.1)	-0.17 (0.1)	0.001
	Control	41	0.83 (0.09)	0.70 (0.1)	-0.13 (0.1)	
V-MI§	Treatment	44	16.4 (6)	15.66 (3.7)	-1.22 (3.5)	0.001
	Control	41	16.1 (5.3)	17.96 (4.8)	1.68 (2.6)	

\* Representing significance level, comparing the delta scores (reduction from baseline) between Treatment and Control groups, following 6 weeks of brushing.

§ Calculus index decreased in the Treatment group, and increased in the Control group during 6 weeks of brushing.

**Efficacy** - The Treatment and Control groups' average baseline scores are shown in Table 2. The test groups did not differ significantly in the efficacy measurements mean scores ( $P \geq 0.165$ ).

Figure 3 shows the GBI scores of the Control and Treatment groups over time, indicating a statistically significant reduction in the Treatment group following 6 weeks of brushing ( $P < 0.001$ ), and no significant change in the Control group ( $P = 0.147$ ). Figure 4 exemplifies the changes in gingival inflammation (MGI) over time, indicating a significantly lower MGI score in the Treatment group as compared to the Control following 6 weeks of brushing ( $P = 0.003$ ). A lower plaque

score (RMNPI) was also detected in the Treatment group as compared to the Control following 6 weeks of brushing, as seen in Fig. 5 ( $P = 0.051$ ). Figure 6 indicates the changes in V-MI scores over time, showing a decrease in the Treatment group following 6 weeks of brushing and increase in the Control group. The V-MI scores were found to be significantly lower in the Treatment group as compared to the Control, following 4 and 6 weeks of brushing.

Table 3 summarizes the mean delta values (difference from baseline) of all efficacy measures, following 6 weeks of brushing. Negative delta values represent an improvement in the measured score, having scores that are decreased with time;



a greater negative value represents a greater improvement. An improvement in GBI, MGI, and Rustogi plaque was realized in both groups, as indicated by the negative delta values. The improvements reported in the Treatment group were found to be statistically significantly greater than those calculated for the Control group following 6 weeks of brushing ( $P \leq 0.001$ ). A negative delta value was obtained in the V-MI score of the Treatment group, indicating a calculus reduction in week 6 as compared to baseline. Moreover, a positive delta value was measured for the V-MI of the Control group in week 6 as compared to baseline. The calculus comparison between the test brush and control toothbrush found a statistically significant difference ( $P = 0.001$ ) after 6 weeks of use.

**Safety** - Both toothbrushes were well-tolerated and no device-related adverse events or any side effects were reported during the study. There were no medical device incidents, and no participants with AEs that led to discontinuation of treatment or withdrawal from the study.

## Discussion

Plaque is a gel-like material forming on the tooth pellicle (a thin biofilm, coating the teeth, gums and tongue) and is composed of bacteria, polysaccharides and glycoproteins. Within 2 to 14 days of plaque formation, the plaque deposits will bond with minerals in the saliva to form a calcified deposit called calculus, more commonly known as tartar.<sup>9</sup> Stains and calculus that are attached to the tooth surface can rarely be removed by regular brushing, either with a manual or powered toothbrush. However, in the current study, the ToothWave showed a significant reduction in plaque and calculus, as well as in gingival inflammation and bleeding. The improvement seen in the efficacy measures was found to be significantly greater in the Treatment group as compared to the Control; and specifically, the significant calculus reduction in the Treatment group compared to the gradual calculus accumulation in the Control group occurring over the 6-week test phase of this study.

The results of this study provide evidence for the unique technological feature of the ToothWave, which utilizes RF energy that streams onto the tooth surface during brushing. There are several references in the literature to “electronic toothbrushes”, which are also referred to as “ionic toothbrushes.” These toothbrushes produce a low-level direct electrical current that streams from the brush head into the oral cavity, using a power source (battery or solar) and a metal rod conductor.<sup>14-22</sup> The scientific data available on these electronic toothbrushes is highly inconsistent. Although in vitro studies indicate their potential effect on removal of bacterial biofilms, mixed results were reported on reduction of microbial activity.<sup>18,19</sup> Moreover, while some clinical studies indicate that a significant benefit on plaque<sup>17,22</sup> or gingival inflammation<sup>20</sup> was observed, most of the clinical evidence concluded that the performance of an electronic toothbrush does not differ from that of a conventional one,<sup>14-16,21</sup> and no beneficial effect on calculus was reported in any of the studies.

The improvement in efficacy may be explained by technological differences between the ToothWave and the electronic toothbrushes described in the literature. The electronic toothbrush utilizes a direct electrical current (DC), which runs from the brush into the oral cavity through the body

and arm back to the brush handle.<sup>16</sup> Instead, the Toothwave utilizes RF energy, which is an alternating electrical current (AC) that streams back and forth between two electrodes, providing a localized effect that is limited to the surface of the teeth. The high frequency of the alternating current that is set by the RF parameters allows it to safely increase the electrical power as compared to DC current, and thus achieve more significant results.<sup>24</sup> The difference in the effect size of the ToothWave, when compared to the electronic toothbrushes, results from the type of current that is utilized (alternating vs direct) and its intensity. Moreover, the RF current tends to flow along the surfaces of electrical conductors, what is known as the “skin effect”,<sup>25</sup> and thus directs the current towards the surface of the teeth. The electro-mechanical silicon barrier, which is located between the ToothWave electrodes additionally contributes to the ToothWave’s increased efficacy. Furthermore, when compared to a standard powered toothbrush, the electric current is theorized to reach hard-to-reach areas (i.e. between the teeth) as these areas and surfaces would otherwise be chronically missed using traditional mechanical means (i.e. bristles).

Despite their technological differences, both the ToothWave and the electronic toothbrushes share the same mechanism of action, which is based on the principle of polarity that every element in nature has a positive or negative charge.<sup>22</sup> Specifically, plaque and calculus compositions include charged organic and inorganic compounds which are inter-linked strongly via electrostatic bonds, while dental plaque is considered as the precursor of calculus.<sup>26</sup> The electronic toothbrushes induce an electric charge, which is postulated to damage electrostatic bonding of plaque proteins to tooth surfaces; thus, enhancing plaque removal.<sup>17</sup> Similarly, since the RF alternating current streams close to the tooth, it brings the charged molecules that are present in the toothpaste close to the tooth surface and changes the chemical environment around it. Once charged, molecules accumulate near the tooth surface and the chemical balance is shifted towards the removal of compounds that are electrostatically attached, replacing them by other, non-staining charged substances, which might have greater affinity to the surface area (for instance fluoride).

We hypothesize that by changing the local charges around the tooth, the alternating electrical current is able to disturb the electro-chemical balance on the tooth surface and remove substances (i.e., calculus, stains) that are otherwise attached strongly to the enamel layer. We assume that the electrically charged toothpaste ingredients take part in the process that occurs on the surface of the teeth. Toothpastes are water-based complex mixtures of abrasives and surfactants, humectants, binders, and other active ingredients. All available toothpastes contain charged molecular compounds that once the RF is activated, act as electrolytes in the medium, carry the charges along the tooth surface, and achieve the desired effect.

In conclusion, the ToothWave novel toothbrush demonstrated statistically significant reductions in dental plaque, calculus, gingival bleeding and inflammation compared to a conventional power toothbrush. The oral health improvements from this human clinical study provide positive evidence to support the RF mechanism as a beneficial feature that is uniquely utilized by the ToothWave power toothbrush.

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