Journal of the international Academy of Periodontology 2001 3/4: 95-103

A Split-Mouth Comparison of a Three-Dimensional-Action Electric Toothbrush and a High-Frequency Electric Toothbrush for Reducing Plaque and Gingivitis

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Abstract

Purpose: To compare the effectiveness in reducing plaque and gingivitis of an electric toothbrush with three-dimensional (oscillating/rotating/pulsating) brush head action, *Braun Oral-B 3D* Plaque *RemoverO,* and an electric toothbrush with high-frequency vibrating action, Sonicare PIusO. Materials and methods: This was a randomised, split-mouth study of 33 adult subjects who used both electric toothbrushes for a total of 9 weeks. After a 2-week acclimation period of brushing with each device on alternating days, subjects received a prophylaxis, then refrained from any oral hygiene on the mandibular teeth for 21 days to induce gingivitis. However, they continued to brush the maxillary teeth on alternating days with each electric toothbrush. Then, for a period of 4 weeks they brushed each side of the mouth with different toothbrushes, randomly assigned to right or left. Plaque and gingivitis were assessed initially, after the 21-day no-oral-hygiene period, and after 2, 3 and 4 weeks of brushing twice daily. **Results:** After 21 days without oral hygiene, mean mandibular plaque and gingivitis scores increased significantly for all subjects. Use of both electric toothbrushes during the treatment phase progressively reduced plaque and gingivitis scores at each successive examination. The *BraunO* toothbrush was significantly more effective than the Sonicareo toothbrush in reducing plaque at every examination and gingival bleeding after 4 weeks of brushing. It is concluded that the *BraunO* electric toothbrush with three-dimensional brush head action offers advantages over the SonicareO electric toothbrush with high-frequency vibrating action in terms of plaque control and potential improvement of gingival health following induction of experimental gingivitis.

Key words: Electric toothbrush, oral hygiene, plaque, gingivitis, clinical trial

Introduction

The first electric toothbrushes, which were introduced in the early 1960s, imitated the back-and-forth motion of manual brushing, but reviews of studies from this period (Ash, 1963; Greene, 1966) reported that the electric devices were no more effective than manual toothbrushes in removing dental plaque. Little progress was made with improving the effectiveness of this first generation of electric toothbrushes for many years, resulting in the same conclusion in 1986 by an international workshop on oral hygiene (Loe and Kleinman, 1986). However, starting in the 1980s many modifications were made to electric toothbrush design, resulting in a new generation of electric toothbrushes that fall into two general categories: those that use oscillating or rotating motions and those that move at a high frequency (Van der Weijden et al., 1998a). Evaluations of their efficacy in comparison with that of the manual toothbrush were conducted in a large number of short- and long-term clinical studies by many different researchers.

Although there are some reports that failed to show a benefit over a manual toothbrush, these studies demonstrate generally that this new generation of electric toothbrushes removes greater amounts of plaque with more improvement of the gingival condition than obtained with a manual brush (Saxer and Yankell, 1997;

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Walmsley,1997; Van der Weijden elal.,1998a; Heasman and McCraken, 1999). At an international workshop in 1996 it was concluded that electric toothbrushes provide additional benefit compared to manual brushes (Hancock, 1996).

An electric toothbrush with an oscillating/rotating action, the *Braun Oral-B Plaque Renzorer* (Models D5 and D7, Braun GmbH, Kronberg, Germany), was introduced in 1991 and has consistently been shown more effective than a manual toothbrush in controlling plaque and improving gingivitis (\Varren and Chater, 1996). This device, which has a small round brush head that moves at 2,800 oscillating rotations per minute, was modified in 1996 to provide a brush, the *Braun Oral-B* Ultra Plaque Remover (Model D9), with a new head design and an increased speed of 3,600 oscillating rotations per minute. However, this new design was comparable to the Model D7 brush in plaque removing efficacy when professionally brushed for different time intervals (Van der Weijden et al., 1996a). Recently, the design was modified further to include a pulsating brush head action providing three-dimensional movement to enhance access to occlusal fissures and interproximal areas (Driesen et al., 1998). This modification was proven more effective than a manual toothbrush in terms of plaque control and improvement of the gingival condition (Cronin et al., 1998; Van der NVeijden et al., 1998b). It was also shown to be more effective than the Model D9 brush in removing plaque (Ernst et al., 1998).

A high-frequency electric toothbrush, Sonicare® (Optiva Corporation, Bellevue, WA), which was introduced in 1993, has a brush head that moves at 31,000 strokes per minute. It has been shown to be comparable to or more effective than a manual brush in removing plaque and reducing gingival inflammation in several studies (Johnson and McInnes, 1994; Tritten and Armitage, 1996; Zimmer et al., 1999).

Due to substantial variations in design and brush head actions, there are differences in the cleaning profiles of the various brands of electric toothbrushes that are currently available. Consequently, it is useful to compare the clinical efficacy of electric toothbrushes for plaque removal and gingival health. Previous clinical trials compared oscillating/rotating electric toothbrushes (*Braun* Models D7 or D9) and the high-frequency electric toothbrush (Sonicare® and showed equivalent effectiveness on plaque and gingivitis for the Model D7 brush (Grossman et al, 1995) and significantly better efficacy for the Model D9 brush (Isaacs et al., 1998). Because the electric toothbrush with three-dimensional (oscillating/rotating/pulsating) action was more effective than the Model D9 brush in laboratory and clinical studies (Driesen etal.,1998; Ernst etal.,1998), it was subsequently compared in a split-mouth clinical trial with the high-frequency brush for single-use. removal of plaque and showed significantly greater efficacy (Sharma et al., 1998).

The purpose of this study was to compare the clinical efficacy for reducing plaque and improving the gingival condition of an electric toothbrush with three-dimensional brush head action, *Braun Oral-B 3D* Plaque Remover® (3D), and an electric toothbrush with high-frequency vibrating action, Sonicare Plus® (SP). This investigation was conducted using an experimental gingivitis model, in which subjects abstained from oral hygiene for 21 days prior to the start of the treatment phase to develop gingivitis (Van der Weijden et al., 1998b), thus facilitating the comparison of the electric toothbrushes on the gingival condition. Additionally, due to the importance of subject attitudes toward electric toothbrushes with respect to acceptance and long-term compliance, this study included a questionnaire which assessed subject preferences and perceived efficacy of the two devices.

Materials and methods

Study population

Following written approval by the University ethics committee, 166 adult volunteers, who were recruited from the Center's database of previous study participants, presented for the initial screening visit. All subjects were apprised of study objectives, requirements, risks and benefits before signing a written consent form. Inclusion criteria included at least five teeth suitable for evaluation in each quadrant of the mandible, right hand predominance, no prior experience with electric toothbrushes, willingness to abstain from brushing the mandibular teeth for 21 days, and willingness to comply with study procedures and to refrain from using interdental cleaning aids, chewing gum and mouthrinse for the entire study. Exclusion criteria included the presence of partial dentures, orthodontic appliances, periodontitis (i.e. pocket depths =5mm), allergies to dental products, or serious medical conditions (including pregnancy). Other exclusion criteria were therapy within the past 28 days with any medication that might affect the clinical parameters and participation in any other clinical trial within the previous month. A total of 40 subjects who met all criteria were issued both test devices and began the acclimation phase. This sample size was based on an earlier study (Van der Weijden et al., 1998b) using the same design and clinical indices in which a significant difference at $P<0.05$ resulted from an 18% reduction in bleeding scores in a population of 35 subjects.

Study design

This investigation was an examiner-blind, split-mouth comparison of subjects who used two different elec-

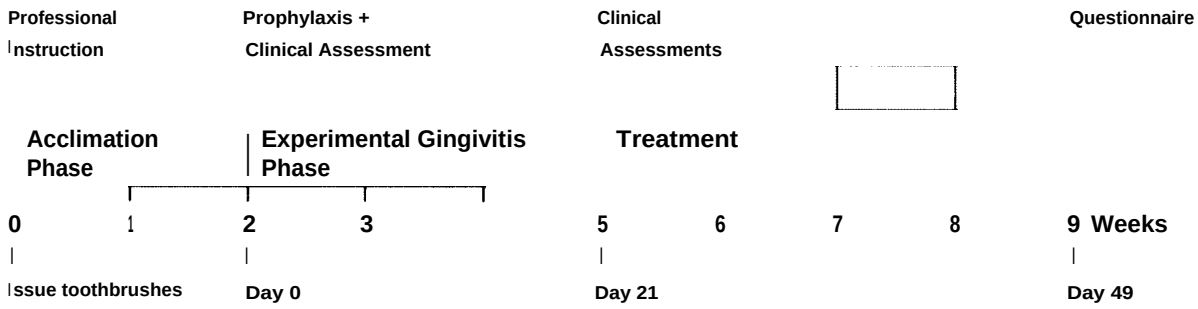

Figure 1. Study design

tric toothbrushes for a total of 9 weeks *(Figure 9).* The study began with a 2-week acclimation period in which subjects, after receiving verbal and written instructions, brushed with each device for 2 minutes on alternating days to become familiar with their use. Subjects then were assessed for plaque and gingivitis (i.e. Day 0), followed by a full-mouth scaling and polishing (Nupro® Medium Prophylaxis Paste, Ash Division, Dentsply International Inc., York, PA, USA) to provide equivalent oral conditions at the outset of the trial. Next, in order to promote plaque formation and induce experimental gingivitis, subjects were instructed to refrain from brushing their mandibular teeth for the next 21 days (i.e. experimental gingivitis phase). However, they were supplied with a regular sodium fluoride dentifrice (Crest® with Fluoristat, Procter & Gamble Company, Cincinnati, OH, USA) and continued to brush their maxillary teeth for 1 minute on alternating days with each electric toothbrush.

At Day 21 plaque and gingivitis in the mandible were reassessed. Those subjects with adequate bleeding scores, i.e. >0.30 according to the Angular Bleeding Index (Van der Weijden *et al.,* 1994), of the mandible were selected for the treatment phase. They were randomly assigned to one of two treatment (left/right) configurations using a split-mouth design with both test devices, then during the 4-week treatment phase, they brushed their teeth on each side of the mouth for 1 minute with either the 3D or SP electric toothbrushes. To prevent treatment side errors and to encourage compliance, the subject's treatment side assignment (left or right) was written in indelible ink on the handle of each toothbrush, and recorded on the take-home instructions.

Subjects were reassessed for all clinical indices following 2 (Day 35), 3 (Day 42) and 4 weeks (Day 49) of brushing. Oral soft tissue health was monitored throughout the study.

Test products

The two test devices were currently marketed electric toothbrushes *(Figure 2).* The *Braun/ Oral B 3D© Plaque Remover* (Braun GmbH, Kronberg, Germany) has a small, round brush head (13mm in diameter) with longer bristles (8.3mm) in an outer ring and shorter bristles (7.2mm) in two inner rings; all bristles are 0.15mm in diameter. The brush head has 3-dimensional movement that consists of an oscillating/rotating action of 63Hz with an angle of 56" combined with a pulsating action of 170Hz and total amplitude of -v0.15mm in the direction of the long axis of the bristle filaments. The Sorzicare Plus® (Optiva Corp., Bellevue, WA, USA) has a rectangular brush head (8.6 x 25mm) with three rows of scalloped bristles (0.16mm diameter) that moves with a side-to-side action at a frequency of 260112.

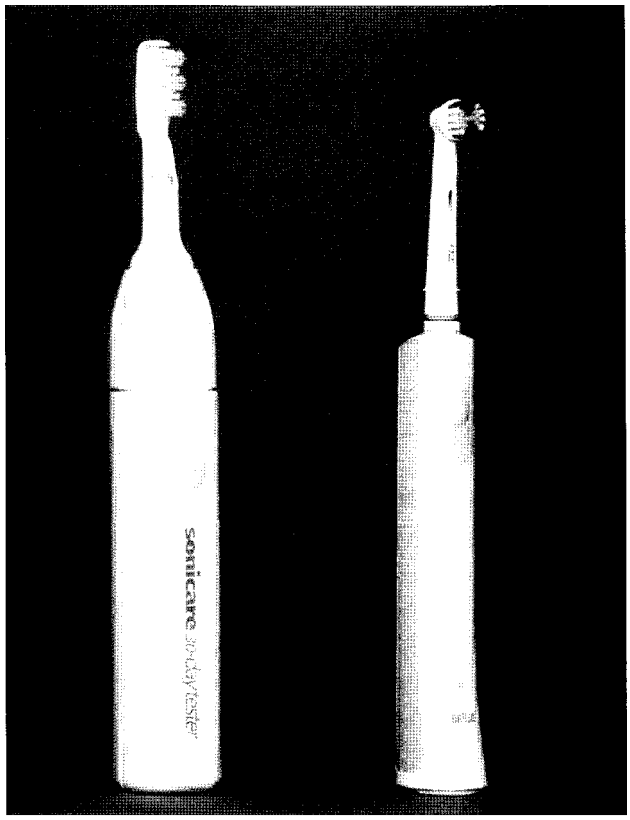

Figure 2. Test Devices: **Sonicare Plus®** *and* **Braun Oral-B 3D Plaque Remover*.**

Product usage instructions

During the initial visit an instructor, who was trained to

deliver the manufacturers' instructions in a comparable manner and was experienced in the use of the test products, provided training on a one-to-one basis for both electric toothbrushes to ensure that all subjects followed the enclosed manufacturers' instructions. At this visit and two subsequent visits the instructor reviewed the requirements for each successive phase of the study and provided written instructions specific to that phase. During the second visit at the end of the acclimation phase, the instructor re-evaluated the brushing technique with both devices of each subject, and provided additional guidance if necessary. Throughout the study, subjects used the same commercial dentifrice (Crest©) in the amount that was normal in their oral hygiene regimen, and were instructed to replenish it on their toothbrush before brushing each quadrant. Diaries were distributed to provide a calendar for subjects to chronicle the times they brushed and to record medications, observations and comments. The instructor and personnel dispensing test products did not participate in clinical assessments to minimise potential bias. Examiners and recorders did not know which product was used on each side of the mouth, and they were not involved in providing instructions, which took place in a separate room. Subjects were not aware of the identity of the study sponsor.

Clinical assessments

Plaque, gingivitis, and gingival bleeding were scored on or adjacent to six areas (Lobene *et al.,* 1982) of all mandibular teeth (mesio-facial, mid-facial, disto-facial, mesio-lingual, mid-lingual, and disto-lingual), excluding third molars. Throughout the study the same clinical assessment at each examination was performed by the same examiner. Both examiners, who were experienced in using the respective indices, were evaluated in a separate calibration session and demonstrated significant intra-examiner repeatability (weighted kappa coefficient = 0.792 for MGI and 0.882 for MQH plaque). After staining with a commercial disclosant (Trace 28®, Lorvic Corporation, St. Louis, MO, USA) at full strength, dental plaque deposits were assessed using a weighted scale of 0 to 5 according to the index (MQH) of Quigley and Hein (1962) as modified by Turesky *et al.* (1970).

Visual symptoms of gingival inflammation were quantified using a 0 to 4 scale by means of the Modified Gingival Index (MGI) of Lobene *et al.* (1986). Bleeding on provocation was measured on a 0 to 2 scale after stroking the marginal gingiva at an angle of 60° to the longitudinal axis of the tooth using the Angular Bleeding Index (ABI) described by Van der Weijden *et al.* (1994), which is a refinement of the Gingival Bleeding Index (Ainamo and Bay, 1975; Saxton and Van der Ouderaa, 1989). Subjects were instructed to brush 2-3 hours prior to appointments to avoid the risk of increased bleeding due to toothbrushing (Abbas *et al.,* 1990). Safety was assessed by means of an oral soft and hard tissue examination which included the gingivae, lips, tongue, buccal and labial mucosa, hard and soft palate, mucobuccal and mucolabial folds, and sublingual and pharyngeal areas, as well as tooth crowns, exposed roots and cervical areas.

Questionnaire

At the end of the study, subjects were asked to complete a questionnaire concerning their preferences and attitudes about the characteristics and perceived efficacy of the two test devices.

Data analysis

The scores for each clinical index were computed to provide a mean score per mandibular quadrant at each clinical examination. Due to potential cross-over treatment effects, data from the central incisors were not included in the analyses. Statistical significance between toothbrush groups for plaque at each examination of the treatment phase was determined parametrically by a matched-pair t-test (2-tail). Due to gender effects on gingivitis, intergroup comparisons for gingival inflammation and bleeding during the trial phase were performed by means of a 2-way analysis of covariance with treatment and gender as factors using the corresponding baseline scores as covaraanes. Within-treatment comparisons were performed for plaque, gingivitis, and bleeding means using a one-sample t-test with respect to changes from the entry examination (Day 0) and from the baseline examination (Day 21) at 2, 3, and 4 weeks post-treatment (Days 35, 42 and 49). All comparisons were performed at a 0.05 level of significance using 2-sided tests.

Results

Of the 40 subjects who entered the study, 33 subjects completed all examinations during the 4-week treatment phase after achieving adequate levels of gingivitis following the 21-day experimental gingivitis phase. Five subjects were disqualified at baseline as a result of insufficient bleeding scores. Two individuals withdrew for reasons unrelated to the study, one due to emergency surgery during the experimental gingivitis phase and another due to concomitant medication for a concurrent illness during the first week of the treatment phase. The final subject population consisted of 11 males and 22 females between 22 and 58 years of age (mean = 34.2 years), and all were in good general health. With respect to device allocation for the split-mouth design, 17 subjects used the 3D toothbrush on the left side and 16 used the SP toothbrush on the left side. Based on diary entries for toothbrush use, compliance with the regimen of two unsupervised treat-

Table 1. Comparisons between examinations for plaque and gingivitis scores from each group

Test device	Statistical parameter	Study day Day 0	Day 21	Day 35	Day 42	Day 49
		Modified Quigley-Hein Plaque Index (MQH)				
3D	Mean ± SE'	2.42 ± 0.07	3.60±0.09	2.12±0.10	2.04±0.09	1.71 ±0.10
	Sig' vs. Day 0	–	0.0001 *	0.004*	0.0001 *	0.0001
	Sig[4] vs. Day 21	–	–	0.0001 *	0.0001 *	0.0001
SP	Mean ± SE'	2.34+0.07	3.58+0.09	2.28±0.09	2.27±0.09	2.07±0.09
	Sig' vs. Day 0	–	0.0001	0.449	0.418	0.007*
	Sig' vs. Day 21	–	–	0.0001 *	0.0001 *	0.0001
		Modified Gingival Index (MGI)				
3D	Mean ± SE'	1.50 ± 0.07	2.23 ± 0.06	1.70±0.07	1.55±0.07	1.31 ±0.07
	Sig[4] vs. Day 0	–	0.0001	0.001 *	0.441	0.001
	Sig[4] vs. Day 21	–	–	0.0001 *	0.0001 *	0.0001
SP	Mean ± SE'	1.50 ± 0.07	2.21 ± 0.04	1.76+0.08	1.57+0.08	1.33 ± 0.08
	Sign vs. Day 0	–	0.0001	0.0001 *	0.168	0.001
	Sig' vs. Day 21	–	–	0.0001 *	0.0001 *	0.0001
		Angular Bleeding Index (ABI)				
3D	Mean ± SE'	0.14+0.02	0.70+0.04	0.22±0.03	0.22±0.03	0.13±0.03
	Sig` vs. Day 0	–	0.0001	0.001 *	0.004*	0.538
	Sig[4] vs. Day 21	–	–	0.0001 *	0.0001 *	0.0001
SP	Mean ± SE'	0.13 +0.02	0.67+0.04	0.23±0.03	0.22±0.03	0.18±0.02
	Sig' vs. Day 0	–	0.0001	0.0001 *	0.010*	0.020*
	Sig' vs. Day 21	–	–	0.0001 *	0.0001 *	0.0001

[1] Scoring index mean ± standard error of the mean (N = 33).
[4] Significance level between examinations.
* Statistically significant difference between examinations.

ments per day was nearly 100% for all participants during all three phases of the study.

Experimental gingivitis phase

As shown in *Table 1,* **the plaque, gingival inflammation and bleeding indices all increased significantly from Day 0 to Day 21 when all oral hygiene measures for the mandible were discontinued. At the end of the experimental gingivitis phase (Day 21), there were no significant differences between the two electric toothbrushes with respect to any of these indices. In both groups plaque increased from approximatelv 2.4 to 3.6, gingival inflammation from 1.5 to 2.2, and gingival bleeding from 0.14 to 0.69.**

Treatment phase

Plaque levels decreased significantly from Day 21 for both toothbrushes after the first 2 weeks of treatment (Day 35) and continued to decrease until the final examination (Day 49) after 4 weeks *(Table 1).* **At the 2-week assessment both toothbrushes had reduced the plaque index below the pre-gingivitis phase level (Day 0) attained during the 2-week device acclimation phase. The reduction for the 3D was significant and continued for both subsequent assessments, but the reduction for the SP did not attain significance until the final visit (Day 49).**

Plaque comparisons between the two electric toothbrushes at each visit *(Table 2)* **revealed that the 3D produced significantly, lower MQH plaque means than the SP at all assessments, with the difference progressively increasing from 7°/u after 2 weeks to 18% after 4 weeks.** *Table 3* **summarises for the entire study (all 5 visits) the shift in MQH plaque score categories for each device. For the first two examinations (Days 0 and 21), the frequency distributions were nearly identical between the two groups. However, for the trial phase examinations, although there was a shift toward lower scores for both devices, for teeth brushed with the 3D there was a consistently greater increase in the number of sites without plaque (`0' scores) and a consistently larger decrease in the number of sites with `3' and `4' scores when compared with teeth brushed with the SP at each clinical assessment (Days 35, 42 and 49).**

Gingival inflammation for both toothbrushes progressively decreased from the levels at the end (Day 21) of the experimental gingivitis phase over the course of the 4-week treatment phase, and as observed for plaque, all decrements were statistically significant *(Table 1).* **By the final assessment (Day 49) both toothbrushes had significantly reduced the Modified Gingival Index below the pre-gingivitis phase (Day 0) level attained during the 2-week device acclimation phase. When results for the two toothbrushes were compared, there was a consistent trend towards lower scores in favour of the 3D toothbrush at each visit** *(Table 2),* **but these differences did not achieve statistical significance.**

Table 2. Comprehensive summary of plaque and gingivitis data

Study day	Examination	Mean ± SE' *Braun@ 3D*	Mean ± SE' SonicareO	Difference`	Significance
		Modified Quigley-Hein Plaque Index (MQH)			
0	Entry	2.42 ± 0.07	2.34+ 0.07	-	0.447
21	Baseline	3.60 ± 0.09	3.58 ± 0.09	-	0.863
35	2 Weeks	2.12 ± 0.10	2.28 ± 0.09	7%	0.034*
42	3 Weeks	2.04+0.09	2.27 ± 0.09	10%	0.002*
49	4 Weeks	1 .71 ± 0.10	2.07+0.09	18%	0.0001
		Modified Gingival Index (MGI)			
0	Entry	1.50 ± 0.07	1.50 ± 0.07	-	0.970
21	Baseline	2.23 ± 0.06	2.21 ± 0.04	-	0.814
35	2 Weeks	1.74 ± 0.07	1.83 ± 0.07	5%	0.317
42	3 Weeks	1.58+0.07	1.63 +0.07	3%	0.580
49	4 Weeks	1.36 ± 0.06	1.40+0.06	3%	0.614
		Angular Bleeding Index (ABI)			
0	Entry	0.14 ± 0.02	0.13 ± 0.02	-	0.618
21	Baseline	0.70 ± 0.04	0.67 ± 0.04	-	0.594
35	2 Weeks	0.23 ± 0.03	0.24 ± 0.03	5%	0.768
42	3 Weeks	0.22 ± 0.03	0.22 ± 0.03	0%	0.958
49	4 Weeks	0.12 ± 0.02	0.18 ± 0.02	34%	0.050*

' Scoring index mean ± standard error of the mean (N = 33).
Percentage difference between treatment groups.
Significance level between treatment groups.
* Statistically significant difference between treatment groups.

Table 3. Frequency distributions of plaque scores for all visits

MQH score	*Braun 3DO* Day 0	Day 21	Day 35	Day 42	Day 49	Sonicare Plus@ Day 0	Day 21	Day 35	Day 42	Day 49
0	54 (4.7%)	0 (0.0%)	133 (11.6%)	154 (13.5%)	271 (23.7%)	70 (6.1%)	0 (0.0%)	109 (9.5%)	111 (9.7%)	153 (13.3%)
1	101 (8.8%)	1 (0.1%)	157 (13.7%)	157 (13.7%)	164 (14.3%)	106 (9.2%)	1 (0.1%)	117 (10.2%)	120 (10.4%)	144 (12.5%)
2	397 (34.8%)	136 (11.9%)	382 (33.4%)	395 (34.6%)	392 (34.4%)	430 (37.4%)	152 (13.2%)	369 (32.1%)	374 (32.6%)	380 (33.1%)
	512 (44.8%)	486 (42.5%)	409 (35.9%)	389 (34.0%)	284 (24.8%)	462 (40.3%)	479 (41.7%)	469 (40.8%)	459 (39.9%)	415 (36.1%)
4	70 (6.1%)	226 (19.8%)	38 (3.3%)	34 (3.0%)	23 (2.0%)	68 (5.9%)	222 (19.3%)	65 (5.7%)	63 (5.5%)	48 (4.2%)
	9 (0.8%)	294 (25.7%)	24 (2.0%)	14 (1.2%)	9 (0.8%)	13 (1.1%)	295 (25.7%)	20 (1.8%)	22 (1.9%)	9 (0.8%)
Total sites	1143 (100.0%)	1143 (100.0%)	1143 (100.0%)	1143 (100.0%)	1143 (100.0%)	1149 (100.0%)	1149 (100.0%)	1149 (100.0%)	1149 (100.0%)	1149 (100.0%)

As shown in Table 1, the gingival bleeding data also exhibited significant improvements in the gingival condition for both electric toothbrush groups after the first 2 weeks (Day 35) and continued further at 4 weeks (Day 49). At the 4-week assessment the 3D toothbrush had reduced the bleeding index to the level observed following the pre-gingivitis phase (Day 0), but the SP toothbrush did not attain this benchmark and its bleeding scores remained significantly higher at all visits. Comparisons between the two toothbrushes at each visit, provided in 7able 2, showed nearly identical ABI means after 2 and 3 weeks of treatment; however, 3D yielded a significantly lower mean score than SP after 4 weeks of treatment.

Safety

Oral soft and hard tissues were monitored throughout the study. No clinically significant device-related adverse events were reported by subjects, and no evidence of significant soft tissue pathology was observed by the examiner. In addition, no changes in previously existing hard tissue conditions (e.g. abrasion sites) were noted,

and no new or evolving pathologies were observed by the examiner.

Response to questionnaire

Analysis of questionnaires completed by subjects at the last visit showed that 50% preferred the 3D, 41% the SP toothbrush, and 9% expressed no preference. Attributes of the 3D that subjects most preferred were the size of the brush head and handle, ease and pleasantness of use, and ability to clean hard to reach surfaces as well as to clean fast and thoroughly yet gently. The features *of* the SP that subjects most preferred were its timer and the level of vibrations during use. Characteristics that elicited similar responses for the two toothbrushes were the noise level, bristle configuration, removing plaque, cleaning below the gum line, and cleaning between the teeth. Eleven subjects reported that they experienced tooth staining, and of these 18% thought that the 3D toothbrush was more effective at removing these stains, compared with 9% who favoured the SP toothbrush and 73% who indicated no preference.

Discussion

This clinical study was designed to compare the effect on plaque and gingival health of two electric toothbrushes with different mechanical methods of brushing action. In order to achieve maximum performance from electric toothbrushes, it is necessary to provide professional instruction and training in their use. However, these procedures lead to healthier gingivae for the participants. Therefore, since this study included professional instruction and a device acclimation phase, an experimental gingivitis phase was used to establish an appropriate level of gingivitis after the training period (Van der Weijden *et al.,* 1998b). Using this design, after 3 weeks without brushing the mandibular teeth, an adequate level of gingivitis developed, then its resolution by means of the assigned toothbrushes subsequently was assessed. Because of the experimental gingivitis phase, there was no need for a minimum level *of* inflammation at baseline, and thus no gingivitis inclusion criterion was established for Day 0. The level of gingival bleeding (mean ABI of 0.70) at the end of the experimental gingivitis phase was comparable to that reported previously by Putt *et al.* (1993) under similar conditions. This study demonstrated that this moderate level of gingivitis could be resolved over a period of 4 weeks after resuming toothbrushing.

The results of this controlled, split-mouth trial indicate that an electric toothbrush with three-dimensional oscillating/rotating/pulsating head action (3D) and an electric toothbrush with high-frequency vibrating action (SP) effectively removed plaque and resolved 'experimental' gingivitis. However, there is evidence from this study that the 3D toothbrush is more effective than the SP Overall, there were significantly lower plaque scores on teeth brushed with the 3D compared with the SP at every visit of the treatment phase. These results are consistent with those of Sharma *et al.* (1998) who reported significantly greater removal of 48-hour plaque deposits using the 3D brush. Although not as definitive as the plaque data, there also were advantages in favour of the 3D for gingivitis, culminating in a significant difference in bleeding after 4 weeks. The lack of significant inter-group differences in bleeding after 2 and 3 weeks cannot be explained with certainty, but may be related to the delay in gingival improvement normally observed following plaque removal. In this trial both toothbrushes removed significant amounts of plaque during the treatment phase, and the difference between groups increased progressively at each examination, so it is possible that the difference in bleeding was delayed until 4 weeks. A comparison using a study design with a longer treatment period may be necessary to elucidate this divergence. While this is the first clinical trial comparing the effectiveness against gingivitis of the 3D and SP electric toothbrushes, a comparative study with a predecessor *(Braun D9)* using a 6-week cross-over design showed that its oscillating/rotating action was slightly more effective in reducing gingivitis than a brush with high-frequency vibrating action (Isaacs *et al.,* 1998).

The plaque and gingival bleeding data for the 3D toothbrush at each visit paralleled the results of an earlier study in which the 3D was compared with a manual toothbrush using the same experimental design (Van der Weilden *et al.,* 1998b). In both studies by the 2-week assessment (Day 35), the 3D toothbrush had reduced the plaque index below the Day 0 level attained during the 2-week device acclimation phase prior to the experimental gingivitis phase. Similarly, in both studies the bleeding index also was lower than the Day 0 level by the 4-week assessment (Day 49). These results coincide with the traditional experimental gingivitis model in which, during the absence of oral hygiene for 3 weeks, gingivitis increased to significantly greater levels, then returned to initial levels when plaque removal procedures were restored. These findings also illustrate the excellent reproducibility of the methodology in spite of different examiners, locations, and subject populations.

The fact that the gingivitis indices (MGT and ABI) readily differentiated between levels of gingivitis at various time points indicates that both were sufficiently sensitive scoring methods for detecting small differences in levels of gingivitis between treatment groups. Although there is not a definitive explanation for the lack of correlation between inflammation (MGT) data and the significant finding observed for bleeding (ABI)

data at the final examination, it may be related to the different immunological processes underlying the clinical signs of redness/oedema and bleeding or possibly to sensitivity of visual versus bleeding indices. The current understanding of the pathogenesis of gingivitis suggests that visual signs of inflammation and bleeding represent different clinical manifestations of the same fundamental disease process associated with host response to microbial challenge (Van Dyke elal., 1999).

It has been established that the new generation of electric toothbrushes is more effective than manual toothbrushes and enhances long-term compliance (StAInacke et al., 1995; Warren and Chater, 1996; Walmsley, 1997; Van der Weijden etal.,1998a; Heasman and VIcCraken, 1999), but not all electric toothbrushes are equally well accepted. Although it is important to demonstrate the effectiveness of one toothbrush over another under controlled clinical conditions, such an improvement attains practical relevance only if it motivates patients under normal usage conditions to maintain good, long-term compliance. Thus, a critical aspect of toothbrush design is patient acceptance and preference. The findings from the questionnaire regarding preferences and attitudes about the test devices indicate that the subjects valued many characteristics of the two toothbrushes, but there were several noteworthy differences. Overall, there was a preference for the 3D toothbrush, which was associated with the size of its brush head and handle, enabling it to reach and thoroughly and rapidly clean all areas of the mouth while contributing to ease of use. These findings corroborate a previous study (Sharma et al., 1998) in which subjects preferred the 3D versus the SP, as well as earlier studies (Grossman etal.,1995;Van der Weijden et al., 1996b; Isaacs et al., 1998) that have consistently found patient preference for oscillating/rotating toothbrushes *(Braun* D7 and D9) over a high-frequency vibrating toothbrush. While these observations are obviously subjective, it is possible that patient preferences may contribute to better long-term compliance with the 3D toothbrush.

It is concluded that both the *Braun Oral-B 3D Plaque Remover®* with three-dimensional brush head action and the *S'onicare* Plus® with high-frequency vibrating action were effective during a 4-week period in removing plaque and resolving experimentally-induced gingivitis. Also, there was no evidence associating toothbrush use with any oral soft or hard tissue abnormalities during this trial, providing further support for the conclusions of Saxer and Yankell (1997) regarding the safety of electric toothbrushes. However, a 4-week comparison of the two toothbrushes showed that the 3D was significantly better at removing plaque and superior with respect to its potential for improving the gingival condition, following induction of experimental gingivitis. In addition, an assessment of subject attitudes about using the two devices indicated a preference for the 3D toothbrush.

Acknowledgements

The authors thank Diana S. Kuchler, Senior Project Coordinator, Health Science Research Center, for her invaluable contributions to this study, and thank Braun GmbH, Kronberg, Germany for financial support of the study.

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