

Comparison of the Hydrabrush® Powered Toothbrush with Two Commercially-Available Powered Toothbrushes

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Abstract

Introduction: An examiner-blinded, randomized, parallel, three-cell, controlled clinical trial was conducted to compare the efficacy of a new powered toothbrush (Hydrabrush®) to that of two presently marketed power brushes (Oral-B® and Sonicare®) in reducing stain, supragingival plaque, gingivitis and the signs of periodontitis while monitoring safety. **Methods:** One hundred ten subjects were randomly assigned to three groups (35 – Oral-B® group, 36 – Sonicare® group, and 39 – Hydrabrush® group). Subjects were instructed to use the assigned powered toothbrush according to the manufacturer's instructions for 2-minutes duration twice per day. Clinical examinations conducted at baseline and at weeks 4, 8, and 12 included the following parameters: 1) oral tissues; 2) staining; 3) plaque index; 4) gingivitis; 5) probing depth; 6) clinical attachment loss; and 7) bleeding on probing. **Results:** The results showed that the body intensity and extent of stain and the gingival intensity and extent of stain at 8 and 12 weeks, respectively, were significantly less in the Hydrabrush® group compared with the Sonicare® group. The modified gingival index (MGI) in all groups significantly decreased over the 12 weeks. However the groups did not differ from each other statistically. At 4, 8 and 12 weeks, the Hydrabrush® group had statistically significantly less plaque than the Sonicare® group. At 4 weeks, the Hydrabrush® group had statistically significantly lower mean probing depth than both the Oral-B® and Sonicare® groups. At 8 and 12 weeks, the Hydrabrush® group had statistically significantly lower mean probing depths than the Sonicare® group. With regard to mean percentage of sites with probing depth ≥ 4 mm, the Hydrabrush® group had statistically significantly fewer sites ≥ 4 mm at 4, 8 and 12 weeks. Differences among the groups in clinical attachment loss at 4, 8 and 12 weeks were representative of small imbalances at baseline. No differences were seen among the treatment groups with regard to gingival recession and bleeding on probing. **Conclusions:** With the exception of clinical attachment loss, all subject groups were balanced for all measured clinical parameters at baseline. Tooth stain became significantly less in the Hydrabrush® group compared with the Sonicare® group at 8 and 12 weeks. At all examinations, the Hydrabrush® group had statistically significantly less plaque than the Sonicare® group. At 4 weeks, the Hydrabrush® group had statistically significantly lower mean probing depth than both the Oral-B® and Sonicare® groups, and at 8 and 12 weeks, the Hydrabrush® group had statistically significantly lower mean probing depth than the Sonicare® group. With regard to mean percentage of sites with probing depth ≥ 4 mm, the Hydrabrush® group had statistically significantly fewer sites ≥ 4 mm when compared to the other two tested brushes at all examinations. No differences were seen among the treatment groups with regard to gingival recession and bleeding on probing and none of the tested brushes caused any adverse reactions.

Key words: Toothbrush, powered, Hydrabrush®, plaque, periodontal disease

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Introduction

Microbial plaque has been shown to be the primary etiological factor in the development of gingivitis (Löe *et al.*, 1965). Removal of plaque through oral hygiene measures has been shown to be effective in the prevention and treatment of plaque-induced inflammatory diseases of the periodontium (Axelsson *et al.*, 1991).

Tooth brushing, as part of an effective oral hygiene regimen, has long been performed by a majority of people using a manual toothbrush. The use of powered toothbrushes, which were introduced many years ago, has continued to gain favor with both clinicians and patients. Available powered toothbrushes have bristles that rotate, counter-rotate, oscillate/pulsate or vibrate at sonic or ultrasonic speeds. Rotating action brushes have a circular brush head with bristles of various lengths and shapes. Counter-rotating brushes have rectangular shaped heads with rows of tufts of varying lengths, some of which rotate and counter-rotate. Oscillating/pulsating brushes have circular shaped heads that oscillate and one also pulsates. Sonic/ultrasonic toothbrushes have bristles that vibrate at various frequencies to create acoustic energy. With regard to plaque removal, each of these designs has been shown to be at least equally effective, and in most cases superior to that of manual toothbrushes (Killooy *et al.*, 1989; Boyd *et al.*, 1989; Van der Weijden *et al.*, 1994; Johnson and McInnes, 1994).

Recently, a powered toothbrush with a novel design was submitted for clinical testing. The design consisted of a rectangular shaped head with rows of bristles pointing up and down and angled toward the facial and lingual surfaces. The action is a back and forth motion. The idea is to allow for brushing of all surfaces of maxillary and mandibular teeth simultaneously. Additionally, a reservoir holds an irrigant for use during brushing.

This novel brush, termed HydraBrush[®], is claimed to be “self-positioning” relative to the teeth and gingiva. According to the manufacturer, it has six brushes that are designed to correctly contact tooth and gingival surfaces. The user simply bites into the brushing head, and proper positioning is automatically achieved. The brushes reciprocate in short strokes in accordance with the recommended “Bass” brushing technique” (placing bristles 1/2 on teeth and 1/2 on the gums at approximately a 45 degree angle, and brushing with a short/quick back and forth action; Bass, 1954). The HydraBrush[®] oscillates at low speeds (600 cycles/minute) and claims to rely on accurate bristle positioning rather than ultrasonic speed to obtain effectiveness.

In addition to six brushes, the HydraBrush[®] has four water jets that irrigate during the brushing process. The manufacturer claims that the water jets are preset to an angle that directs the pressurized fluid precisely into the



a



b

Figure 1. The brushhead of the HydraBrush[®] illustrating the split head. a) A photograph of the HydraBrush[®] head illustrating the 3 brushes for the maxillary teeth and 3 brushes for the mandibular teeth, and b) positioned in a human mouth.

gingival sulcus and between teeth, again eliminating the element of human error. Thus, according to its maker, the HydraBrush[®], with its six brushes and four water jets all working simultaneously, generates an oral cleansing process that is very enjoyable, with effectiveness far beyond that of any other oral care product (Figure 1).

The prototype HydraBrush[®] used in this study is shown in Figure 2a. The final version of the HydraBrush[®] now available for retail sale is shown in Figure 2b.

The purpose of this clinical study was to compare, for safety and efficacy, the new HydraBrush[®] powered toothbrush to the Sonicare Plus[®] and the Braun Oral B 3D Excel[®] powered toothbrushes.

Materials and Methods

Subjects

Male and female adults, ages 18 to 65, who were in good general health, were available for the full duration



a



b

Figure 2. a) A photograph of the prototype Hydrabrush® tested in this study. b) Photograph of the final design of the Hydrabrush®.

of the study, were able to comply with the study requirements and who had a minimum of twenty natural, uncrowned teeth excluding third molars were selected for this study. To be included in the study, each subject was required to have a mean initial screening gingivitis score of at least 1.0 utilizing the modified gingival index (MGI, Lobene *et al.*, 1986) and a mean initial screening plaque index of at least 1.5 using the Turesky modification of the Quigley-Hein Index (Turesky *et al.*, 1970); both indices were determined as described below. In addition, all subjects were required to have a minimum of two periodontal pockets of not less than 4 mm depth with a minimum of 1 site with 2 mm or greater attachment loss determined as described below. This study was approved by the University of Tennessee Institutional Review Board and all subjects gave written informed consent.

Exclusion criteria included the presence of any orthodontic appliances or a severe malocclusion, soft or hard tissue tumors of the oral cavity, presence of extensive caries or severe calculus or acute periodontitis

characterized by the presence of pain, purulent exudate, or severe tooth mobility requiring immediate treatment intervention. Subjects who were pregnant or lactating, took a treatment course of antibiotics, steroidal or non-steroidal anti-inflammatory drugs less than four weeks prior to entry into the study (use of birth control pills was permitted), had a history of rheumatic fever, valvular heart disease or any condition requiring antibiotic premedication to prevent endocarditis, had diabetes, hemophilia or any other medical condition requiring medical support and/or drug therapy that may interfere with the parameters being investigated were also excluded. Subjects involved in any concurrent study, the nature of which might affect the parameters being investigated in this study, or who were using any medications that affect the flow of saliva or who received any previous oral or maxillofacial radiation that might affect salivation were excluded. Lastly, subjects could not smoke a pipe, consume more than two packs of cigarettes a day, or more than six cigars a day, or use smokeless tobacco.

Test materials

The sponsor supplied the powered toothbrushes and replacement brush heads. The investigator provided subject diaries and supplies necessary for conducting the study including the dentifrice (Crest® Regular, Procter and Gamble, Cincinnati, OH, USA).

Test powered toothbrushes included:

- 40 – Hydrabrush® with replacement heads (Oralbotic Research Inc, Escondido, CA, USA).
- 40 – Sonicare Plus™ with replacement heads (Philips Oral Healthcare, Snoqualmie, WA, USA).
- 40 – Braun Oral-B 3D Excel™, model D17525 with replacement heads (Oral-B, Gillette Company, Boston, MA, USA)

The two commercially available brushes were obtained through a private dental office. They were not obtained directly from manufacturers to preclude any pre-sorting or variations from commercially available units.

Informed consent

The institutional review board (IRB) of the University of Tennessee Health Science Center approved the study protocol, informed consent form and any advertising and recruiting materials. The risks and benefits of participating in the study were explained to each potential subject prior to entering the study. A properly written and executed informed consent was obtained from each subject prior to entering the study.

Procedures

Examiners

Three examiners participated in a training and cali-

bration exercise prior to the start of the study. One examiner conducted the oral tissue, gingivitis and stain examinations and took photographs. A second examiner was responsible for all plaque and periodontitis measurements. A third examiner, calibrated with the other 2 examiners, served as a backup examiner when one of the other examiners could not fulfill their duties.

Screening and selection of subjects

Candidates reported to the clinical facility for screening by the examining dentists to identify those subjects who met the inclusion/exclusion characteristics. A medical-dental history was provided by each potential subject to determine if the candidate met the criteria for entry into the study.

Evaluation of the oral hard and soft tissues was conducted at this examination and all subsequent examinations. The lips, tongue, hard and soft palate, gingiva, mucobuccal folds, buccal mucosa, sublingual space and teeth were assessed and reported as normal or abnormal.

Photography

Two baseline photographs of the facial surfaces of both dental arches with the subject's teeth closed in an end-to-end relationship were taken using a single lot of Ektachrome 100 Professional Film (Kodak Inc, Rochester, NY, USA) in a single-lens reflex camera using a macro lens capable of 1:1 image size and a ring light. The subject's code number and appointment number were recorded on the film using a databack. All rolls of film were sent to Eastman Kodak Processing (Fairlawn, NJ, USA) for processing as a single batch.

Gingivitis evaluation

The initial screening examination included a gingivitis evaluation of the buccal and lingual marginal and papillary gingival units for the six representative teeth described by Ramfjord (1959; teeth #3, 9, 12, 19, 25 and 28 US system; 1-3, 2-1, 2-4, 3-6, 4-1, 4-4 FDI system). If any of these teeth were missing, the next distal tooth was scored. The scoring procedure used was the non-invasive modification of the Löe-Silness index (Löe and Silness, 1963), the modified gingival index (MGI) following Lobene *et al.* (1985).

Tooth stain evaluation

Tooth stain was evaluated on the facial surfaces of the six mandibular anterior teeth (#22-#27 US system; 3-3, 3-2, 3-1, 4-1, 4-2, 4-3 FDI system) following the method of Lobene, (1968).

Plaque evaluation

The initial screening examination also included a plaque evaluation of the Ramfjord teeth. The scoring criteria used were those of the modified Quigley-Hein (Turesky

modification) plaque index method (Quigley and Hein, 1962; Turesky *et al.*, 1970). The facial and lingual surface of each tooth were evaluated by the above criteria in each of the three vertical segments (disto-facial, mid-facial, mesio-facial, disto-lingual, mid-lingual, mesio-lingual) as described by Shaver and Schiff (1970).

Trace® (Young Dental Manufacturing, Earth City, MO, USA) plaque disclosant was utilized throughout the study to make the plaque visible. Subjects vigorously swished 10 drops in their mouths for 30 seconds followed by rinsing with water for 30 seconds to remove excess disclosant.

Periodontitis parameters

Probing depth (measured from the free gingival margin to the apical extent of the probeable sulcus/pocket) was determined to the nearest millimeter using a manual Hu-Friedy PQOW periodontal probe with Williams' markings (Hu-Friedy Inc., Chicago, IL, USA) using normal probing forces (20-30 gms). Each of the Ramfjord teeth or its substitute was assessed on 6 surfaces (mesiolingual, lingual, distolingual, distofacial, facial and mesiofacial).

Clinical attachment loss (measured from the cemento-enamel junction (CEJ) to the apical extent of the probeable sulcus/pocket) was determined to the nearest millimeter using a manual Hu-Friedy PQOW periodontal probe with Williams' markings. Each of the Ramfjord teeth was assessed on 6 surfaces (mesiolingual, lingual, distolingual, distofacial, facial and mesiofacial).

Recession (assessed from the cemento-enamel junction to the free gingival margin) was measured to the nearest millimeter using a manual Hu-Friedy PQOW periodontal probe with Williams' markings. Each of the Ramfjord teeth was assessed on the facial and lingual surface.

Bleeding on probing was recorded as positive or negative for each site following the measurement of probing depth and clinical attachment loss.

The first 110 subjects who met the entry criteria were entered into the study. Approximately 225 subjects were screened to enroll the 110 qualified subjects. All subjects entered into the study were randomly placed into one of three groups based on a random number assignment sheet generated by a computer. Group A received the Oral-B® brush while groups B and C received the Sonicare® and Hydrabrush®, respectively. Only the study coordinator knew the group assignments and the brush that each group was using, as the examiners were blinded from that information. The study coordinator demonstrated the use of the assigned brush to each subject. All subjects were advised to brush for 2 minutes duration twice per day. *Figure 2a* is photograph of the prototype Hydrabrush® tested, while

Figure 2b is a picture of the final design of the now commercially available Hydrabrush®.

At-home use – instructions to subjects

Subjects were instructed to use their assigned brush twice daily (in the morning and before bedtime) at home, in accordance with the manufacturers directions and the instructions they received from the study coordinator. The subjects were requested to utilize only the dentifrice provided (Crest® Regular). The subjects were asked to record the times and dates of brush usage and any comments or unusual effects in the diary provided. They were asked to refrain from using any other oral hygiene products during the study. These included dental floss, interdental stimulators, toothpicks, other toothpastes, other toothbrushes, anti-plaque mouthrinses, anti-plaque chewing gum, oral cosmetic preparations (tooth whitening products) or water irrigation devices (such as Water PIK™). There were no restrictions with regard to smoking or diet habits. Subjects were informed that diaries must be returned at each examination.

Compliance

After each four weeks of at-home use, subjects were asked to return any unused dentifrice, their brushhead(s) and their diaries to the clinical facility and were issued one 175 gm (6.2-oz) tube of dentifrice, a new brush head and a new diary for use during the subsequent four weeks.

An estimation of compliance was determined by estimating the weight of each subject's returned dentifrice tube. No subject was found to be significantly out of compliance.

Four week examination

After four weeks, subjects returned to the clinical facility, bringing with them their assigned toothbrush and having refrained from any oral hygiene during the proceeding 2 hour period. The following evaluations were conducted in the order stated:

The lips, tongue, hard and soft palate, oro-pharynx, uvula, gingiva, mucobuccal folds, buccal mucosa, sublingual space, floor of the mouth and teeth were assessed and reported as normal or abnormal. Any reports of irritation, as well as any tissue changes observed during these examinations were recorded as well as the examiner's opinion regarding the relationship of the study toothbrushes to the adverse effect being reported.

Tooth stain was evaluated on the facial surfaces of the six anterior mandibular teeth as described for the screening examination. Two photographs of the facial surfaces of both dental arches with the subject's teeth closed in an end-to-end relationship were taken as previously described.

The examining dentists scored all subjects for gingi-

vititis, plaque, probing depth, clinical attachment loss and bleeding on probing using procedures identical to those applied at the screening examinations.

Eight and twelve week recall examinations

After eight and twelve weeks of at-home use of their assigned powered brush, subjects returned to the clinical facility having performed no oral hygiene for the previous 2 hours. Appointments were scheduled such that each subject completed the full four-week period (± 3 days) and was examined at the same time of day as the previous examinations (± 2 hours) as best the subject's schedule would allow. Subjects were reminded to bring with them any unused portion of their dentifrice, their brushhead and their diary. Evaluations were conducted as described for the 4-week examination.

Medications and dental treatment

Any dental treatment that the subject received during the study was required to be recorded in the subject's diary and reported to the investigators. Similarly, subjects who began taking prescribed or unprescribed medication during the study recorded such in their diary and reported this to the investigators.

Adverse reactions

The subjects were asked to immediately report any serious or unusual reaction to the investigators. The investigator examined the subject as soon as possible and, if necessary, treated the condition. All adverse reactions were documented. Subjects were also instructed to record any adverse reactions in their diary. No significant adverse reactions were noted throughout the duration (12 weeks) of the study that, in the opinion of the principal investigator, could be attributed to use of any of the powered brushes. Oral lesions observed included cheekbites, aphthous ulcers, herpetic lesions and geographic tongue.

Statistical analyses

Chi-square tests were used to examine the differences between groups in the Lobene (1968) stain indices, which were dichotomized as 0 versus ≥ 1 . For each parameter in which the baseline mean scores of the three groups were determined to be statistically equivalent, an analysis of variance (ANOVA) was used to evaluate differences between the groups at each evaluation period. If a significant difference existed between the two groups with regard to any parameter at baseline, an analysis of covariance using the baseline scores as a covariant was employed. For all analyses, a one-tailed test was used and statistical significance determined at $p \leq 0.05$. When all the data were available, repeated measures ANOVA were also performed on each parameter under investigation. All statistical analyses were

Table 1. Subject attrition – number of subjects enrolled in each group at each examination

Group	Baseline	4 weeks	8 weeks	12 weeks
A (Oral-B®)	35	35	33	33
B (Sonicare®)	36	35	33	33
C (Hydrabrush®)	39	31	30	29

performed using Statistical Package for the Social Sciences (SPSS), Version 11.0.1 (SPSS, Chicago, IL, USA).

Results

Attrition

Two subjects in the Oral-B® group, 3 subjects in the Sonicare® group and 10 subjects in the Hydrabrush® group did not complete the study. The major loss occurred between baseline and 4 weeks in the Hydrabrush® group, where 8 subjects dropped out. Six of these subjects disclosed that they either found the brush too complicated to use, too large to travel with, or too intimidating (Table 1).

Stain

At baseline, Chi-square analysis indicated no significant differences among the groups in stain intensity or extent scores. However, by 8 weeks the Hydrabrush® group had no subjects with intensity or extent stain scores on the tooth body of 1 or greater, while the Oral-B® group had 12.1% of subjects with both an intensity and extent stain score ≥ 1 and the Sonicare® group had 24.2% of subjects with both an intensity and extent stain score ≥ 1 (Chi-square, $p = 0.015$). Similarly, at 12 weeks the Hydrabrush® had 3.4% of subjects with intensity and extent stain scores on the gingival area of the tooth of 1 or greater, while the Oral-B® group had 6.1% of subjects with both an intensity and extent stain score ≥ 1 and the Sonicare® group had 21.2% of subjects with both intensity and extent stain scores ≥ 1 (Chi-square, $p = 0.044$; Figure 3).

Gingival index scores

The subjects' mean MGI significantly decreased over the 12 weeks of the study ($p < 0.0001$) without regard to treatment group. However, the treatment groups did not statistically differ from each other ($p = 0.917$; Figure 4).

Plaque index

The mean plaque index (PI), as measured on a 0–5 scale (Turesky, 1970), and the percentage of sites with a score ≥ 3 were calculated for each group at each examination. At baseline, the groups did not differ significantly in mean PI or percentage of sites ≥ 3 . However, the repeated measures analyses clearly establish that the treatment groups differed significantly over

time for plaque mean ($p = 0.004$) and almost reached significance ($p = 0.076$) for the mean percent of sites ≥ 3 . Post-hoc testing established that the mean plaque index and mean percent surfaces ≥ 3 were significantly less in the Hydrabrush® group versus the Sonicare® group at 4, 8 and 12 weeks (Table 2). The Oral-B® group differed significantly from the Sonicare® group in mean percent surfaces ≥ 3 at 4 and 12 weeks ($p < 0.05$; Table 2).

Probing depth

Probing depth was expressed as mean depth in millimeters and percentage of sites ≥ 4 mm. At baseline, the groups did not differ significantly in mean probing depth or percentage of sites ≥ 4 mm. At 4 weeks, the Hydrabrush® group had statistically significantly lower mean probing depths than both the Oral-B® and Sonicare® groups. At 8 and 12 weeks, the Hydrabrush® group had statistically significantly lower mean probing depth than the Sonicare® group. With regard to mean percentage of sites with probing depth ≥ 4 mm, the Hydrabrush® group had statistically significantly fewer sites ≥ 4 mm at 4, 8 and 12 weeks than the Sonicare® group (7.6% vs. 14.7% at 4 weeks, 5.7% vs. 14.3% at 8 weeks, and 6.7% vs. 13.7% at 12 weeks, Hydrabrush® vs. Sonicare® groups, respectively; $p < 0.05$ for each; Table 3).

Clinical attachment loss

Clinical attachment loss was measured from the CEJ to the nearest millimeter and expressed as both mean attachment loss for each group and percentage of sites with clinical attachment loss ≥ 2 mm. By random chance, the Hydrabrush® group had significantly less mean attachment loss than the Oral-B® group and Sonicare® group at baseline (0.38 ± 0.22 mm vs. 0.64 ± 0.64 mm vs. 0.75 ± 0.72 mm, respectively, $p = 0.037$). Without regard to treatment group, the subjects' mean clinical attachment loss significantly decreased over the 12 weeks of the study ($p < 0.0001$). However, the treatment groups did not statistically differ from each other ($p = 0.728$). Additionally, the percentage of surfaces with clinical attachment loss ≥ 2 mm decreased significantly over the 12 weeks of the study ($p = 0.0008$), but the decrease could not be attributed to the superiority of any of the tested powered toothbrushes ($p = 0.760$; data not shown).

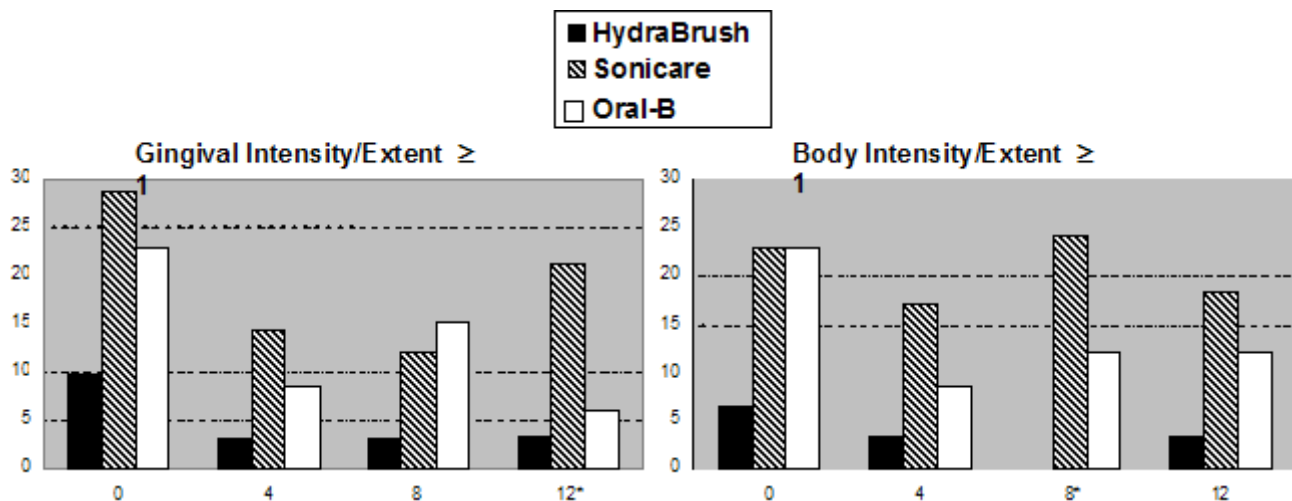


Figure 3. Percentage of sites with a stain score of 1 or greater. * = Chi-square $p < 0.05$ (less stain in HydraBrush® group than Oral-B® and Sonicare® groups)

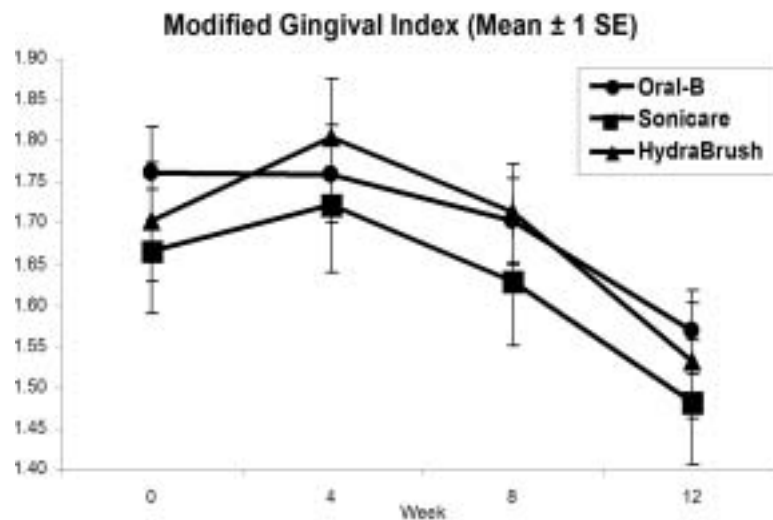


Figure 4. The mean modified gingival index for each group at each examination. A = Oral-B®, B = Sonicare®, C = HydraBrush®. Repeated measures ANOVA; effect of time, $p < 0.0001$, effect of treatment ($p = 0.917$).

Table 2. Plaque Index – Mean Plaque Index $\pm$ 1 standard error for each group at each examination

Group	Baseline	4 weeks	8 weeks	12 weeks
A (Oral-B®)	2.91 $\pm$ 0.09	2.55 $\pm$ 0.11	2.92 $\pm$ 0.09	2.95 $\pm$ 0.10
B (Sonicare®)	2.88 $\pm$ 0.10	2.88 $\pm$ 0.10*	3.20 $\pm$ 0.10*	3.26 $\pm$ 0.09†
C (Hydrabrush®)	2.86 $\pm$ 0.10	2.47 $\pm$ 0.10*	2.67 $\pm$ 0.10*	2.86 $\pm$ 0.09†

*Statistical differences between groups at 4 and 8 weeks, $p < 0.05$

† Statistical differences between groups at 12 weeks, $p = 0.012$

Table 3. Mean probing depth in mm $\pm$ 1 standard error for each group at each examination

Group	Baseline	4 weeks	8 weeks	12 weeks
A (Oral-B®)	2.57 $\pm$ 0.05	2.56 $\pm$ 0.05*	2.47 $\pm$ 0.04	2.44 $\pm$ 0.04
B (Sonicare®)	2.61 $\pm$ 0.07	2.59 $\pm$ 0.07*	2.55 $\pm$ 0.07†	2.55 $\pm$ 0.06†
C (Hydrabrush®)	2.48 $\pm$ 0.04	2.35 $\pm$ 0.04*	2.33 $\pm$ 0.03†	2.31 $\pm$ 0.04†

*Statistical differences between groups A/C and B/C at 4 weeks, $p < 0.05$

† Statistical differences between groups B/C at 8 and 12 weeks, $p < 0.05$

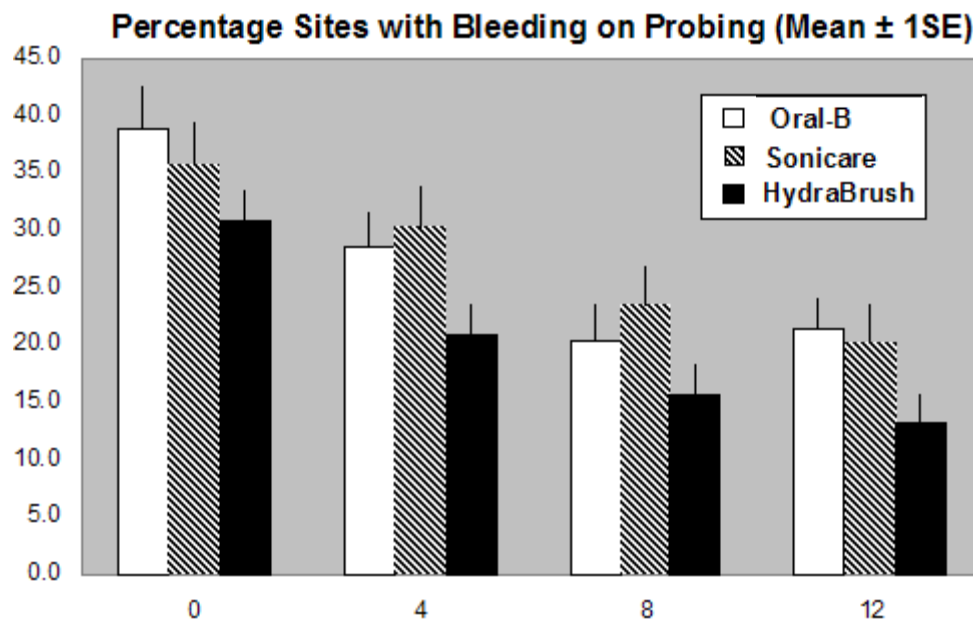


Figure 5. The mean percentage bleeding on probing for each group at each examination. A = Oral-B®, B = Sonicare®, C = Hydrabrush®. Repeated measures ANOVA; effect of time, $p < 0.0001$, effect of treatment ($p = 0.590$).

Bleeding on probing

Bleeding on probing was scored as positive or negative for each site at each examination. Although bleeding on probing decreased significantly in all groups over the duration of the study ($p = 0.0001$), no differences were observed that could be associated with the tested treatments ($p = 0.590$; Figure 5).

Recession

Recession was assessed from the cemento-enamel junction to the free gingival margin on the facial and lingual surfaces of the 6 Ramfjord teeth. None of the treatments differed from the others with regard to gingival recession (data not shown, $p = 0.276$). Inspection of the data indicated that none of the tested brushes was associated with increasing gingival recession (data not shown).

Discussion

This clinical trial compared a novel toothbrush design with two powered toothbrushes in widespread use. Although biopsies were not taken (Engel *et al.*, 1993), no visible damage to the teeth or oral soft tissues was noted during the 12 week study. All three toothbrushes tested were found to be safe. These findings support the results of Saxer and Yankell (1997) in their report on the impact of improved brushes on dental disease.

Both the Oral-B® and Hydrabrush® reduced the plaque levels at four weeks. A return to baseline values was noted for the Hydrabrush® by the end of the study. However, the plaque index for the Oral-B® and Sonicare® groups had actually rebounded to higher

levels than baseline values by the end of the study period. The differences between the Oral-B® and the Hydrabrush® at twelve weeks were minimal; while the differences between the Hydrabrush® and the Sonicare® reached statistical significance. A possible explanation for the initial reduction in plaque levels with a subsequent rebound to baseline levels, or higher, may be the novelty effect. This phenomenon has been noted in clinical trials for many years and was mentioned by Ash (1964) in a very early review of toothbrush studies. Patients are motivated by the “newness” of a particular device. But after a period of time their hygiene levels fall and the plaque scores rebound toward baseline levels. Despite the rebound of the plaque indices for all the brushes, the gingival index showed a statistically significant decrease for all groups. Typically, as the plaque levels decrease, the levels of gingival inflammation are reduced (Stoltze and Bay, 1994; Tritten and Armitage, 1996; Haffajee *et al.*, 2001). However, this is not always the case. Ainamo *et al.* (1991) found a reduction in gingivitis without a reduction in plaque scores and Spindel *et al.* (1985), in their study on the effects of three different dentifrices, found reductions in plaque accumulation without a commensurate reduction in gingivitis. In the present study, in spite of the rebound of the plaque scores, the gingival inflammation was significantly reduced and remained that way throughout the study. Possibly, if the study had gone on longer, we may have seen a rebound of the gingivitis levels to accompany the increase in the plaque levels. A recent systematic review of the literature concluded that the most effective powered toothbrush for a reduction in plaque and gingivitis was the rotation-oscillation

powered toothbrush (Niederman, 2003). In this clinical trial we found the Hydrabrush® with 45 degree pre-angled bristles and back and forth action to be as effective in plaque removal as the rotation-oscillation type brush (Oral-B®) and superior to the brush with the sonic type bristle action (Sonicare®).

Although no computer or digitized images were used in this study to measure the intensity of the stain (McInnes *et al.*, 1994), the Hydrabrush® was found to be superior to the Oral-B® and the Sonicare® in stain removal. All subjects were asked to use the assigned brush for two minutes twice per day. The simultaneous cleaning of the maxillary and mandibular arches may provide an added benefit over single surface cleaning. Since the other brush designs only allow for cleaning of either the facial or lingual surfaces during an equivalent time period, the bristles of the other brushes would not be in contact with the tooth surfaces for as long as those of the HydraBrush®. This may explain why the Hydrabrush® had no intensity and stain score ≥ 1 by 8 weeks and only 3.4% of subjects with a score ≥ 1 at 12 weeks. Both the Oral-B® and the Sonicare® had a significantly higher percentage of scores ≥ 1 at both 8 and 12 weeks. Given the high demand by the public for esthetically pleasing smiles, effective stain removal is an important function of an oral hygiene instrument.

The design of the study did not include the determination of patient preference of the tested brushes. That would require a crossover study design. However, the greatest subject attrition did occur in the Hydrabrush® group. This possibly may be reflective of the fact that some patients were uncomfortable with the complexities of using the Hydrabrush® or they were intimidated by its size and appearance. However, the Hydrabrush® issued to the study group consisted of a prototype design and was far more cumbersome to use than the final design available today for purchase commercially. Also, the majority of subject attrition occurred between baseline and four weeks. After that period, the attrition rate was identical to that for the other brushes. This may indicate that after a period of acclimation to the use of the Hydrabrush® patients were as comfortable as with the other powered brushes.

While the Hydrabrush® appeared to be statistically superior in stain removal, plaque removal and probing depth reduction, it is not clear that the magnitude of these differences was clinically meaningful. Demonstration of clinically meaningful improvements would require assessments of the effect of the Hydrabrush® on long-term (> 1 year) plaque control and inflammation.

Conclusions

1. With one exception, in a wide variety of clinical indicators, the groups did not differ significantly (p

$= 0.05$) at baseline. That is, randomization was successful and produced equivalent groups at baseline.

2. The body intensity and extent of stain and the gingival intensity and extent of stain at 8 and 12 weeks, respectively, was significantly less in the Hydrabrush® group compared with the Sonicare® group.
3. At 4, 8 and 12 weeks, the Hydrabrush® group had statistically significantly less plaque than the Sonicare® group.
4. At 4 weeks, the Hydrabrush® group had statistically significantly lower mean probing depths than both the Oral-B® and Sonicare® groups. At 8 and 12 weeks, the Hydrabrush® group had statistically significantly lower mean probing depths than the Sonicare® group. With regard to mean percentage of sites with probing depth ≥ 4 mm, the Hydrabrush® group had statistically significantly fewer sites ≥ 4 mm at 4, 8 and 12 weeks.
5. Differences among the groups in clinical attachment loss at 4, 8 and 12 weeks represent small imbalances at baseline.
6. No differences were seen among the treatment groups with regard to gingival recession and bleeding on probing.
7. Neither the Hydrabrush® nor the other tested brushes caused any adverse reactions that could be attributed to the brush.
8. Neither the Hydrabrush® nor the other tested brushes caused any increase in gingival recession.

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