ORIGINAL ARTICLE

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Toothbrush efficacy for plaque removal

Abstract: Objectives: To determine the effectiveness of a novel sonic toothbrush in reducing plaque and in maintenance of gingival health when compared to a standard manual brush. *Methods:* This study was a block-randomized, examiner-blind, two-treatment, parallel group, single centre clinical investigation. A total of 84 subjects were enrolled and randomly assigned to receive either the Panasonic EW-DL90 or an American Dental Association-endorsed manual toothbrush. Subjects were instructed to follow a twice-daily brushing regimen without flossing. Plaque levels and gingival health were assessed at baseline and after 1 and 3 weeks of treatment using the Turesky Modification of the Quigley-Hein Plaque Index and the Papillary Bleeding Score. Results: Subjects assigned to the EW-DL90 group had significantly lower plaque levels after 1 and 3 weeks of treatment than those in the manual group (P = 0.003 and 0.0035, respectively). Both groups showed a reduction in plague levels at Week 3 relative to baseline. The EW-DL90 group had significantly lower gingival inflammation scores after 1 week of treatment (P = 0.0293), but there was no difference between groups after 3 weeks of treatment. Conclusion: The EW-DL90 toothbrush safely and effectively removes more plague than a standard manual toothbrush. Improvement in gingival inflammation was observed after 1 week of treatment. There was no difference in Papillary Bleeding Score between the two groups after 3 weeks of treatment. Clinical significance: The newly developed sonic brush (Panasonic EW-DL90) tested in this study was found to be more effective than a manual toothbrush at plague removal. The papillary bleeding scores were significantly lower in the sonic brush group after 1 week of product use. After 3 weeks of product use, both treatment groups had similar papillary bleeding scores almost returning to baseline values.

Key words: dental plaque; flossing; gingivitis; toothbrush

Introduction

It has been well documented that mechanical plaque removal is essential in the prevention of dental caries and diseases such as gingivitis and periodontitis (1). Recent evidence shows that approximately 47% of adults in the United States aged 30 years and older suffer from periodontitis, while 70% of individuals aged 65 and older also suffer from the disease (2). Although a manual toothbrush can be extremely effective in removing dental plaque when used correctly and for the appropriate amount of time, the majority of the population does not properly use these brushes (3). It is possible that the use of power toothbrushes could increase the overall oral health of patients who are unable or unwilling to properly use a manual toothbrush.



Previous studies comparing the plaque removal abilities of manual toothbrushes compared to power toothbrushes have produced varied results. Zimmer et al. found that a power toothbrush was significantly better at removing plaque than a manual brush (4), while Walsh et al. found no difference between the two (5). A study performed by Giuseppe et al. found that the power toothbrush was better at removing plaque from approximal surfaces but there was no difference on the marginal surfaces (6). A meta-analysis performed by Deery et al. found that in general, powered toothbrushes did not remove significantly more plaque than manual toothbrushes. However, brushes which utilized a rotation oscillation motion did remove significantly more plaque in both the short and long term, as well as significantly reduced gingivitis (7). Another meta-analysis conducted by Robinson et al. produced comparable results (8), suggesting that the effectiveness of power toothbrushes varies greatly from one model to another.

Recently, a new power toothbrush has been developed (Panasonic EW-DL90) which utilizes a sonic vibration movement to produce approximately 28 500 horizontal strokes per minute to remove plaque. The brush features a built-in timer, which pulses once every 30 s and twice after 2 min to help ensure that the user complies with the recommended brush time. The brush head uses both a multi-level and angled bristle arrangement, which have each been shown to be more effective than a conventional flat-trim bristle arrangement (9).

The primary aim of this study was to determine the plaque removal effect comparing a novel sonic toothbrush to a manual toothbrush over a 3-week timeline. The secondary aim was to assess gingival health in the two groups during the same time frame.

Methodology

Study population

A total of 104 subjects were recruited for this study from the New York University Bluestone Center for Clinical Research in New York City subject pool; 20 subjects who did not meet the inclusion/exclusion criteria were excluded. The final study population consisted of 84 healthy subjects who ranged in age from 19 to 62 and consisted of 34 males and 50 females; 35 were white, 25 were Asian, 11 were African American, two were Hispanic and 10 were other. Four subjects were excluded from the final analysis because they did not return for the final study visit.

To enrol in the study, subjects needed to meet the following inclusion criteria: aged 18 or older; have at least 20 natural teeth (not including 3rd molars), at least 16 uncrowned; be in good general and oral health; and at screening visit, have visible plaque accumulation represented by a continuous band of plaque (up to 1 mm) at the cervical margin on at least 30% of all facial tooth surfaces as measured by the Turesky Modification of the Quigley-Hein Plaque Index (score of 2 in this index). Subjects were excluded from the study if they had evidence of: powerbrush use within 3 months of study start; severe periodontal disease or active treatment for periodontitis; oral or gum surgery within 2 months of the study start; use of a pacemaker or other implanted device; fixed facial orthodontic appliances or use of antibiotics within 2 weeks of study start.

Subjects were fully informed of study risks and procedures on the first visit, and a signed informed consent was obtained according to the policies of the New York University School of Medicine IRB.

Interventions

All participants were instructed to brush for 2 min twice a day using only their assigned toothbrush and dentifrice (Colgate Cavity Protection; Colgate-Palmolive Company, New York, NY, USA), and to refrain from using any other oral hygiene aids such as floss or mouth rinse for the duration of the study. Individuals assigned to the powerbrush group received a Panasonic EW-DL90 (Panasonic Corporation of North America, Secaucus, NJ, USA) toothbrush and manufacturer's instructions, and were told to brush as indicated using the high power setting. Individuals assigned to the manual group received an American Dental Association (ADA)-approved manual toothbrush (Pepsodent Complete Care toothbrush; Unilever, Englewood Cliffs, NJ, USA) and were instructed to brush in their customary manner. All subjects performed the first brushing under supervision at the study site.

Outcomes

The primary outcome measure was change in plaque levels after Week 1 and Week 3 of treatment. The secondary outcome measure was change in papillary bleeding scores (PBS) after Week 1 and Week 3 of treatment. Subjects were examined at baseline and after 1 and 3 weeks of product use. All subjects were instructed to brush with their assigned toothbrush twice-daily, and to brush 4–6 h prior to each study visit.

Measurements were taken by one of three calibrated study examiners who were blinded to treatment assignment. Study examiners were trained dentists and hygienists.

At each visit, oral soft tissues were thoroughly examined for evidence of abrasion or trauma which may have been associated with the toothbrushing. Compliance with the protocol was assessed using a subject-completed brushing diary.

Study assessments were performed on all teeth except 3rd molars. Plaque coverage was assessed using the Turesky Modification of the Quigley-Hein Plaque Index (10, 11) after the use of a disclosing solution (Young 2-Tone Disclosing Tablets, Young Dental). The facial and lingual sides of all teeth were given a plaque score of 0–5 for the mesial, middle and distal surfaces using the following classification: (0) no plaque, (1) separate flecks of plaque, (2) continuous band plaque up to 1 mm, (3) plaque covering >1 mm and <1/3 of tooth surface, (4) plaque covering >1/3 and <2/3 and (5) >2/3 of tooth covered with plaque. For scoring and statistical purposes, each

plaque score was assigned a percentage value which was representative of the per cent of plaque coverage. Plaque coverage percentages were assigned as follows: (0) 0%, (1) 10%, (2) 30%, (3) 50%, (4) 70% and (5) 100%.

The secondary outcome of the study was the presence of bleeding after 1 and 3 weeks of product use. To assess gingival bleeding, a Stim-U-Dent dental pick was inserted horizontal to the facial surface, depressing the interproximal papilla by up to 2 mm. After 15 s, each site was given a bleeding and redness score of 0–5 according to the Papillary Bleeding Index (PBI) (12) as follows: (0) healthy gingival, no bleeding upon insertion of Stim-U-Dent interproximally, (1) oedematous, reddened gingival; no bleeding upon insertion of Stim-U-Dent interproximally, (2) bleeding without flow along gingival margin upon insertion of Stim-U-Dent interproximally, (3) bleeding with flow along gingival margin upon insertion of Stim-U-Dent interproximally, (4) copious bleeding upon insertion of Stim-U-Dent interproximally, (5) severe inflammation, marked redness and oedema; tendency to spontaneous bleeding.

The sample size was chosen using a conservative pre-post correlation of 0.5 and starting with medium effect size (0.5), an adjusted effect size of 0.58 was attained. To compare the change in plaque between the groups at a single time point using an ANCOVA with adjustment for baseline plaque values, it was determined that 48 subjects per group (96 total) were required to achieve a power of 80% with a two-tailed type I error rate of 0.05. An internal pilot study design was employed, and an interim power analysis was conducted after 48 subjects had completed the study to assess whether the sample size could be decreased. Results of the interim analysis showed that a total of 80 subjects would be required and the study would need 40 subjects per group (80 total). As per standard clinical statistical practice, no other data were analysed for the internal pilot study.

Randomization

Subjects were randomized to receive either the manual or power toothbrush using a block randomization scheme. A statistician, who was not involved in the day to day conduct of the trial, performed the randomization. The randomization key was seen by only the lead study coordinator, who assigned randomization numbers to subjects in sequential order.

Blinding

Study investigators were blinded as to the treatment group of all subjects. Subjects were instructed not to disclose their group to investigators, and to bring their study toothbrush to the site in a non-transparent bag.

Statistical methods

Initially, all demographical and experimental variables were described using appropriate statistics and graphs. Statistical analysis for plaque efficacy was based on the percentage plaque coverage computed at baseline (Week 1), Treatment Visit 1 (Week 2) and Treatment Visit 2 (Week 4). For each visit, the percentage plaque coverage on all surfaces measured was averaged to attain a representative plaque score for that subject. Differences between the brushing groups were assessed using the non-parametric Mann-Whitney-Wilcoxon test. This model asymptotically approaches the t-test with respect to power. Differences in baseline plaque and gingival scores were assumed to occur at random. A separate statistical model was used to test each hypothesis at each visit. All statistical tests were two-tailed and carried out at the 5% significance level unless otherwise stated. No adjustments to the P-values were made for multiple testing. All analyses were conducted in SAS version 9.3. Additional statistical techniques were utilized to more fully understand the data. P-values for additional tests were adjusted using Bonferroni or Bonferroni-like techniques to correct for the resulting increase in Type I error. Statistical analysis of the gingival scores (as measured by the PBI) proceeded along the same lines as above.

Results

Participant flow

A total of 104 subjects were screened for the study and 20 were excluded from the study. Of the excluded subjects, 19 did not meet the eligibility criteria (11 did not have enough plaque at screening, seven did not have enough teeth, one was taking antibiotics) and one was participating in another study which did not allow for simultaneous participation in a second study. Of the 84 subjects enrolled in the study, 80 subjects were included in the final analysis. Each treatment group consisted of 40 subjects. The four subjects who were not included in the final analysis were lost to follow-up and did not complete the final visit of the study (Fig. 1).

Baseline data

The two groups were comparable in regard to age, gender, ethnicity and smoking history (Table 1). At baseline, the two groups showed no significant difference in plaque scores or bleeding index (P = 0.6132 and P = 0.6747, respectively).

Outcomes and estimation

Both the Panasonic EW-DL90 and the manual toothbrush decreased subjects' plaque levels at Week 3 relative to baseline. After 1 week of treatment, mean rank plaque scores in the powerbrush group were significantly lower than in the manual group (K-W $\chi 2 = 8.80$, P = 0.003) (Table 2). Likewise, mean rank papillary bleeding scores in the powerbrush group were significantly lower than those in the manual group (K-W $\chi^2 = 4.75$, P = 0.03) (Table 3). Plaque scores in the powerbrush group remained significantly lower than those in the manual group after 3 weeks of treatment (K-W $\chi 2 = 8.53$, P = 0.003) (Table 2). After 3 weeks of treatment, the mean



Table 1. Baseline demographics of randomized su	bjects
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Characteristic	Manual brush n = 42	Powerbrush n = 42	Total n = 84
Age			
Mean (SD)	29.0 (7.2)	30.2 (10.8)	29.6 (9.1)
Range	19–50	19–62	19–62
Gender (N,%)			
Male	18 (42.9%)	16 (38.1%)	34 (40.5%)
Female	24 (57.1%)	26 (61.9%)	50 (59.5%)
Race (N,%)			
White	13 (31.0%)	22 (52.4%)	35 (41.7%)
Black or African American	8 (19.0%)	3 (7.1%)	11 (13.1%)
Hispanic or Latino	1 (2.4%)	2 (4.8%)	3 (3.6%)
Asian	13 (31.0%)	12 (28.6%)	25 (29.8%)
Other	7 (16.7%)	3 (7.1%)	10 (11.9%)
Smoking history (N,%)			
Never smoked	36 (85.7%)	32 (76.2%)	68 (81.0%)
Past smoker	5 (11.9%)	9 (21.4%)	14 (16.7%)
Current smoker	1 (2.4%)	1 (2.4%)	2 (2.4%)

difference in per cent plaque coverage from baseline to Week 3 in the manual group was 7.66, representing a 21% decrease in plaque; the mean difference in plaque coverage from baseline to Week 3 in the Panasonic group was 12.6, representing a 36% decrease in plaque (Table 4). There was no significant difference in bleeding scores between the groups at this time point (K-W $\chi 2 = 0.44$, P = 0.7122) (Table 3).

Fig. 1. Flow chart of study participants.

Table 2.	Mean ran	k plaque	scores of	manual	and	powerbrush	ł
groups a	at all study	/ time po	ints				

	Manual brush Mean rai	Powerbrush nk score	P-value	Kruskall– Wallis χ ²
Baseline, $n = 42/\text{group}$ 1 week of treatment, n = 42/group 3 weeks of treatment, n = 40/group	43.86 50.39 48.09	41.14 34.61 32.91	n.s. 0.003 0.0035	0.2600 8.7951 8.5294

Adverse events

One incident of tooth sensitivity was reported by a subject assigned to the powerbrush group after 1 week of product use. The subject was asked to use the low power setting for 1 week, and to return to the high setting if symptoms had subsided. The subject was able to complete the full 3 weeks of treatment, and symptoms were completely resolved after 3 weeks of treatment. Overall, both brushes were well tolerated.

Discussion

This study was a randomized, controlled, examiner-blinded clinical trial where efficacy of a power toothbrush (the ability to remove plaque) was evaluated for 3 weeks. Because dental

Table 3. Gl scores of manual and powerbrush groups at all study time points

	Manual brush	Power brush	<i>P</i> -value	Kruskall –Wallis χ ²
	Mean rank ging	gival blee	ding score	
Baseline 1 week treatment 3 weeks treatment	40.89 48.27 41.46	43.13 36.73 39.54	n.s. 0.0293 n.s.	0.1800 4.7472 0.1397

Table 4. Mean plaque coverage (in percentages) of manual and powerbrush groups at all study time points

	Manual brush	Panasonic	
	Mean plaque coverage (%)		
Baseline, $n = 42/\text{group}$ 1 week of treatment, $n = 42/\text{group}$ 3 weeks of treatment, $n = 40/\text{group}$ Decrease in mean plaque coverage from baseline to 3 weeks treatment (%)	36.68 30.99 29.02 21%	34.99 22.85 22.39 36%	

flossing plays an important role in interproximal plaque control, this clinical trial was specifically designed to assess the efficacy of brushing alone, in the absence of additional coadjutant cleaning tools such as flossing.

The results demonstrate that the Panasonic EW-DL90 power toothbrush removes significantly more supragingival plaque after 1 and 3 weeks of use than a manual toothbrush. Improvements in gingival health were observed in all subjects after 1 week of treatment; however, the PBS score was significantly lower in the powerbrush group than in the manual toothbrush group. It is of interest that after 3 weeks of treatment, the difference in PBS between the two groups had almost disappeared. This may be partially explained by the fact that all subjects were instructed to refrain from using dental floss or any other interdental cleaning device for the duration of the study, regardless of their usual home care routine. Although this study did not measure any additional parameter of gingival health, previous studies have demonstrated that an evolution from a non-pathogenic interproximal microbial flora to a pathogenic flora is assumed to occur in the absence of dental flossing, supported by clinical evidence that dental floss reduces gingival bleeding dramatically when used regularly in conjunction with tooth brushing (13). It is possible that although plaque removal was observed after 3 weeks of treatment, the absence of flossing had a negative impact on preserving long-term gingival health at the interproximal sites. In summary, this clinical trial showed that the new Panasonic powerbrush EW-DL90 consistently demonstrated greater plaque reduction efficacy than a manual toothbrush after 1 and 3 weeks of treatment. The results would suggest that the addition of flossing to a powerbrushing regimen may be able to further improve plaque removal interproximally and provide superior long-term gingival health stability.

Overall evidence

Results of studies comparing the plaque removal efficacy of power toothbrushes versus manual toothbrushes are varied. Results of this study are in agreement with a few other studies which also compared the plaque removal efficacy of a sonic vibration power toothbrush with a standard manual toothbrush (4, 14). However, a meta-analysis of studies comparing powered and manual toothbrushes found no consistent significant difference in plaque removal between the two groups (8). A difference was noted between rotating oscillating toothbrushes and manual toothbrushes, although the authors were unable to determine clinical significance of this difference. Although grouping and analysing toothbrushes according to their mode of action provided a more powerful meta-analysis, the authors mention it is possible that subtle differences in toothbrush design could produce significant differences which would not have shown up in their study.

Results of the present study suggest that there is no difference in the papillary bleeding scores between subjects using a manual toothbrush and subjects using a power toothbrush after 3 weeks of use. These results differ from those of other studies, which have found significant differences in gingival health between individuals using power toothbrushes and individuals using manual toothbrushes (4, 15). Of note, however, is the fact that these previous studies enrolled subjects with mild to moderate gingivitis, while the present study enrolled only gingivally healthy subjects. It is possible that a power toothbrush is better at improving gingival health than a manual brush, but they are equally noneffective at maintaining long-term gingival health in the absence of flossing. We recommend further studies testing the long-term efficacy of power toothbrushes in a population who is prohibited from using interdental cleaning devices.

In conclusion, the Panasonic EW-DL90 toothbrush was shown to consistently remove significantly more plaque than a standard, ADA-endorsed manual toothbrush. There was no difference between the two toothbrushes with regard to papillary bleeding scores after 3 weeks of use, suggesting that the regular use of dental floss or other interdental cleaning devices is essential for the long-term maintenance of gingival health, regardless of toothbrush choice.

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Disclosure

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