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Efficacy of plaque removal of the Sonicare Elite versus the Sonicare Advance from hard-toreach sites

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Abstract

Objective: To compare the Sonicare Elite with the Sonicare Advance in terms of the reduction in supragingival plaque in the posterior, hard-to-reach areas of the mouth. Method: This was a single-cohort, 6-week, two-treatment, single-blind, cross-over clinical trial that recruited 45 subjects. Plaque scores were recorded throughout the study using a modification of the Quigley and Hein plaque index (PI). All subjects had a minimum pre-brushing PI of 1.8 at screening following 24 h abstention from tooth cleaning. Subjects then used a Sonicare Advance powered toothbrush at home for 4 weeks for familiarisation purposes. At the next visit (2), subjects were given either the Sonicare Elite or the Sonicare Advance powered toothbrush for a further 2 weeks of home use. Twenty-four hours prior to visit 3, subjects abstained again from tooth cleaning. At visit 3, the PI was recorded pre- and post-tooth brushing and then all remaining "mature" plaque was removed professionally with a dental prophylaxis. After a further period of 24 h (to accumulate new plaque) without tooth brushing the subjects returned for visit 4 at which PIs were again recorded pre- and post-tooth brushing. The subjects were then given the second toothbrush in the cross-over sequence and attended for visits 5 and 6 at which the protocol for visits 3 and 4 was repeated.

Results: The Sonicare Elite powered toothbrush was more effective than the Sonicare Advance model in removing both mature and newly formed plaque. The magnitude of the differences between the toothbrushes for all posterior sites, interproximal and smooth surfaces, respectively, was 0.35 U (p < 0.001), 0.39 U (p < 0.001) and 0.32 U (p < 0.001) of the modified Quigley and Hein PI. There was no evidence of a significant period effect comparing data from visits 5 and 6 against those from visits 3 and 4. There was, however, a significant visit effect with full-mouth (p < 0.01), interproximal (p < 0.001) and smooth surface (p < 0.01) post-brushing plaque scores being significantly lower at visits 4 and 6 than at visits 3 and 5.

Conclusion: The data support the observation that the Sonicare Elite toothbrush is more effective than the Sonicare Advance model in removing both newly formed and mature plaque from all posterior, interproximal and smooth tooth surfaces.

G. I. McCracken¹, P. M. Preshaw¹, L. Heasman¹, F. Stacey¹, N. Steen² and P. A. Heasman¹

¹School of Dental Sciences, University of Newcastle upon Tyne; ²Centre for Health Services Research, University of Newcastle upon Tyne, UK

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In a previous article reviewing the design of clinical trials and powered toothbrushes, we suggested that the testing of brushes should be structured and a new prototype should be tested against the marketed model that it is intended to supersede, thus where possible, eliminating as much bias from the design and reporting of the study as possible (Heasman & McCracken 1999). We have since reported clinical trial designs that enabled successful testing of one and two prototype brushes in short-term studies of up to 12 weeks (McCracken et al. 2000, 2002). Nevertheless, there remains significant variation in the design of powered toothbrush trials and the problem has been further highlighted in a systematic review (of powered versus manual brushes), which concluded that observation of methodological guidelines and greater standardisation of design would benefit both future trials and meta-analyses (Heanue et al. 2003).

Our previous studies have focused entirely on the relative plaque removing efficacies of the oscillating-rotating design of powered toothbrush prototypes and we are yet to investigate the potential improved efficacy of other designs of brush such as those that use a "sideto-side" action. The Sonicare Elite (Philips Oral Healthcare Ltd, Snoqualmie, WA, USA) powered toothbrush was designed to enable better access, and therefore tooth cleaning, than the Sonicare Advance (Philips Oral Healthcare Ltd) in hard-to-reach areas of the mouth.

The primary aim of this study, therefore, was to:

• Compare the Sonicare Elite with the Sonicare Advance in terms of the reduction in supragingival plaque in the posterior, hard-to-reach areas of the mouth.

The secondary aims were to:

- Extend and develop our previous trial design model to investigate whether there are differences between the brushes with respect to the removal of new and mature plaque and
- Determine whether there are any differences between the brushes with respect to safety.

Materials and Methods

This was a single-cohort, 6-week, twotreatment, single-blind, cross-over clinical trial to compare the plaque removing efficacy of two powered toothbrushes. Ethical approval was obtained from the Local Research Ethics Committee of Newcastle upon Tyne.

Subjects

Forty-five subjects were recruited for the study. Inclusion criteria stipulated that subjects should be 18–65 years of age, have a minimum of 18 natural teeth, be in excellent general health and



Fig. 1. The Sonicare Elite [left] and Advance toothbrushes.

have an overnight, pre-brushing plaque score of at least 1.8 recorded at the screening visit. The exclusion criteria have been published previously (Mc-Cracken et al. 2002).

All subjects provided written, informed consent to participation at the screening visit and the trial was undertaken in accordance with guidelines for good clinical practice.

Power and sample size

Power calculations were performed using data from both internal and published studies. With n = 45, there was 75% power of the *t*-test to detect a difference of 5% (or greater) plaque reduction between the two groups, assuming a standard deviation of 8–12, at the 0.05 level of significance. The difference of 5% had been observed repeatedly in internal and pilot studies.

Randomisation

The subjects were randomised to a treatment sequence Advance then Elite or Elite then Advance within blocks of eight, or approximately the number of subjects evaluated on 1 day of the trial, using a computer-generated randomisation schedule.

Calibration of the examiner

Prior to the study, the examiner (P.A.H.) was calibrated for accuracy and repeat-

ability using the Turesky modification of the Quigley and Hein plaque index (PI) (Turesky et al. 1970) on a population of five subjects identical to those selected for the study. Calibration training preceded the calibration exercise proper. The intra-examiner κ statistic was 0.72 with 81% perfect agreement scores measured on 480 posterior sites. In the main study, the examiner was blinded at all times to the treatment provided.

Powered toothbrushes

Two designs of the Sonicare toothbrush were evaluated and compared with respect to plaque removal efficacy (Fig. 1). At the time of testing, both the Sonicare Advance and the Sonicare Elite powered toothbrushes were marketed brushes. With respect to the Advance, the Elite brush is lighter, allowing increased manoeuvrability and has a more streamlined, narrower brush head with a view to achieving higher levels of plaque reduction from the hard-to-reach sites on posterior teeth.

Plaque scoring

Plaque was scored after disclosing at six sites/tooth (mesiobuccal, midbuccal, distobuccal, mesiolingual, midlingual and distolingual) using the Turesky et al. (1970) modification of the Quigley and Hein (1962) plaque index. Plaque was scored on all molars and premolars present with the exception of the third permanent molars. All measurements were recorded by a single, experienced examiner (P.A.H.).

Study design

The clinical trial was carried out over six subject visits. These were preceded by a study information meeting at which the information document was presented and the subjects had an opportunity to ask questions about the study. Specific ethical issues such as the requirement to abstain from tooth cleaning prior to study visits were addressed.

Visit 1 – screening

Subjects were instructed not to brush their teeth or use oral hygiene aids for 24 h prior to this visit. When a subject met the inclusion criteria, the test teeth were disclosed and the plaque score was recorded. The minimum entry plaque score of 1.8 was confirmed. Those subjects who qualified and agreed to take part were given a Sonicare Advance powered toothbrush to use at home for 4 weeks as part of a familiarisation period to become accustomed to the unit.

Visit 2 (4 weeks after screening)

Professional cleaning of the teeth was performed with an ultrasonic scaler to remove visible calculus and a prophylactic brush to remove plaque. The toothbrush used during the familiarisation period was collected. The subject was assigned to the treatment brush according to the randomisation chart. The manufacturer's instructions for the toothbrushes were given to the subjects and these were read under supervision so that any queries could be answered directly. The subjects were instructed to brush for 2 min on two occasions each day. The subjects were reminded not to brush their teeth for 24 h prior to visit 3.

Visit 3 (2 weeks after visit 2)

The objective of this visit was to evaluate the plaque removal efficacy of the toothbrushes on "mature" plaque. The test teeth were disclosed and a pre-brushing plaque score was recorded. The subject then used the test toothbrush for 2 min (30 s/quadrant) in the presence of a clinician. After brushing and rinsing, the soft tissues were inspected for abrasion lesions and then disclosing solution was reapplied before the post-brushing plaque score was recorded. The examiner then polished the coronal surfaces of the teeth and used dental floss interproximally to bring the plaque score to zero. Subjects were reminded not to brush their teeth for the next 24 h and also to return the next day for visit 4.

Visit 4 (24 h after visit 3)

The objective of this visit was to evaluate the plaque removal efficacy of the toothbrushes on "new plaque" that had grown since visit 3, 24 h earlier. The toothbrush was the same as that used for visit 3 with the plaque again being scored pre- and post-toothbrushing. The subject was then assigned to the second sequence of the study according to the randomisation chart. Again, they were reminded to abstain from oral hygiene measures for the 24 h period prior to the next visit (5).

Visits 5 and 6

These visits corresponded to the second, cross-over arm of the trial. Visit 5 was 2 weeks after visit 4, and visit 6 was 24 h later. The clinical protocol was, therefore, identical to that followed in visits 3 and 4.

Data collection

All data were collected on electronic data entry forms. Scanned data were reviewed and verified for completeness and accuracy.

Statistical analysis

The primary outcome variable for toothbrush efficacy was the pre- to postbrushing reduction in PI, and pre-brushing plaque scores for each visit were included as covariates. Scores were computed as means (SDs) and the pre- to post-brushing changes were evaluated as means of the differences between scores for each subject at each visit. The overall strategy was to analyse data from 3, 4, 5 and 6 simultaneously and to adopt a mixed effects model with two random factors: subjects and visits. Analysis of variance accounting for the cross-over nature of the trial was used to test the difference between treatment groups at the 0.05 level of significance. Between-group differences were estimated with 95% confidence levels. A period effect was fitted to identify changes over time between visits 3 and 4, and 5 and 6. A visit type effect was fitted to identify differences between visits 3 and 5, and visits 4 and 6. A brush effect was fitted to identify a difference between the two brush types. All analyses were undertaken using SPSS software.

Results

The number of subjects who attended the visits were: screening (visit 1), 45; visit 2, 45; visit 3, 40; visit 4, 39; visit 5, 40 and visit 6, 38.

The pre- and post-brushing fullmouth plaque scores by brush and visit type are presented diagrammatically in Fig. 2. Data corresponding to the main effects analysis of pre- to post-brushing plaque scores for period, visit and toothbrush effects are presented in Table 1.



Fig. 2. Pre- and post-brushing all posterior sites plaque scores for the removal of "mature" plaque (visits 3 and 5) and "new" plaque (visits 4 and 6) using the Sonicare Elite and Sonicare Advance toothbrushes (N denotes the number of subjects at each visit). The statistically significant differences between the brushes and visits are shown separately in Table 1.

Table 1. The main effects analysis of the differences between the Sonicare Elite and the Sonicare Advance powered toothbrushes for the pre- to post-brushing plaque scores for period, visit and toothbrush effects

Sites	Period effect		Visit effect		Brush effect	
	difference	CI	difference	CI	difference	CI
all posterior sites interproximal smooth	-0.03 -0.12 -0.05	$\begin{array}{r} -\ 0.09, 0.02 \\ -\ 0.19, \ -\ 0.05 \\ -\ 0.10, 0.01 \end{array}$	- 0.09** - 0.15*** - 0.13**	$\begin{array}{r} -0.15, -0.03 \\ -0.22, -0.07 \\ -0.21, -0.05 \end{array}$	- 0.35*** - 0.39*** - 0.32***	-0.39, -0.31 -0.45, -0.33 -0.39, -0.26

The visit effect was such that plaque removal was significantly greater at visits 4 and 6 compared with 3 and 5, suggesting that the "mature" plaque was more tenacious than "new" plaque. The brush effect was such that the Sonicare Elite powered toothbrush proved to be better than the Sonicare Advance model at all sites.

CI, confidence interval.

p*<0.01, *p*<0.001.

The principal observation was that the Sonicare Elite powered toothbrush was more effective than the Sonicare Advance model in removing both mature (visits 3 and 5) and newly formed (visits 4 and 6) plaque (Fig. 2, Table 1). The overall magnitude of the differences between the toothbrush models for all posterior sites, interproximal and smooth surfaces, respectively, was 0.35 U (p < 0.001), 0.39 U (p < 0.001) and 0.32 U (p < 0.001) of the modified Quigley and Hein PI (Table 1).

There was no evidence of a significant period effect comparing data from visits 5 and 6 against those from visits 3 and 4 (Table 1). There was, however, a significant visit effect with all posterior sites (p < 0.01), interproximal (p < 0.001) and smooth surface (p < 0.01), post-brushing plaque scores being significantly lower at visits 4 and 6 than at visits 3 and 5 (Table 1).

In the entire study, 30 adverse events were recorded with 19 being minor abrasions, possibly or probably related to the brushes. The remaining 11 events included non-brush-related episodes of pericoronitis, dentine hypersensitivity, recurrent oral aphthae and debonding of an anterior orthodontic retainer.

Discussion

Our group has previously suggested models for testing the efficacy of powered toothbrushes in clinical trials (Heasman & McCracken 1999) and these models have been applied successfully to short-term studies of prototype toothbrushes for periods of up to 12 weeks (McCracken et al. 2000, 2002). Previously, the toothbrushes have been produced by the same manufacturer, principally with a view to eliminating or minimising reporting bias that might be associated with trials incorporating products from different manufacturers. The current study has continued to adopt this type of model, although this was the first occasion that we have adopted a cross-over as opposed to a parallel group design. The Sonicare Elite powered toothbrush was developed specifically with a view to improving cleaning of the less accessible tooth sites, notably the interproximal sites of premolars and molars. For this reason, the sites of interest in this study were limited to these teeth, but excluding the third molars because of their inconsistency in position and presence in the mouth.

The data confirm that both brushes are safe to use with only a minimal number of abrasion lesions being possibly attributed to the brushes. The plaque removal efficacy was significantly and consistently greater for the Sonicare Elite brush compared with the Sonicare Advance with differences correlating to 0.35, 0.39 and 0.32 U of the Quigley and Hein PI for all posterior sites, interproximal and smooth surface sites, respectively. The absence of a period effect indicated that there was no general change seen in plaque removal with time - an observation that would have been noted had there been a "learning effect" for the subjects throughout the study. The familiarisation period for the first 4 weeks after screening was introduced specifically to minimise any potential period effect later in the study. There was, however, a significant effect of visit on plaque removal with more plaque being removed by both brushes at visits 4 and 6 (new plaque) compared with visits 3 and 5 (mature plaque). At visits 3 and 5, plaque will have accumulated at the more inaccessible sites over a period of time with additional plaque growth over the 24 h period of abstinence from oral hygiene measures immediately prior to the visits. This was denoted "mature" plaque of which, at visit 5 for example, the Sonicare Elite removed 56% (SE 1%) (individual data not shown). At the conclusion of visit 5, all plaque was removed professionally to create clean tooth surfaces and the plaque that accumulated over the next 24 h leading up to visit 6 was denoted "new" plaque. The Sonicare Elite removed 60% (SE 2%) of the "new" plaque, an observation that might have been predicted as the more mature deposits would be thicker and perhaps, therefore, adhere more tenaciously to the tooth surfaces.

Although some subjects were lost to follow-up, the results of the study were not adversely affected. The power calculations and sample size had both been based on data from both our own, internal and other independent published studies. These calculations suggested that a sample size of 45 subjects would provide 75% power to detect a 5% difference in plaque removal between the groups. The highly significant difference that emerged between the toothbrushes with a sample size of 38-40 suggests that the power calculation will need to be revised on the basis of our current data for the cross-over trial.

Conclusion

The Sonicare Elite powered toothbrush was significantly more effective in removing dental plaque from all posterior tooth surfaces than the Sonicare Advance model. There was a period effect that suggested that the effectiveness of both brushes was greater for "new" plaque that had formed over approximately 24 h than for removing more "mature" plaque that will have accumulated at more inaccessible sites over longer periods of time.

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Address:

G. I. McCracken School of Dental Sciences University of Newcastle upon Tyne Framlington Place Newcastle upon Tyne NE2 4BW UK Fax: +44 191 232 5144 E-mail: g.i.mccracken@newcastle.ac.uk This document is a scanned copy of a printed document. No warranty is given about the accuracy of the copy. Users should refer to the original published version of the material.