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# Clinical development and evolution in plaque removal performance of a battery powered toothbrush

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#### Abstract

**Background and aim:** There is growing evidence that the new generation of electric toothbrushes are more effective than manual toothbrushes. The primary aim of these studies was to compare, as an indication of the stage of development, the plaque removal properties of a prototype battery powered toothbrush with an established product. A secondary aim was to utilise the data to appraise plaque accumulation together with the patterns of removal.

**Method:** The three studies presented used the same, single-examiner, randomised, single-blind cross-over design involving up to 24 healthy volunteers. The prototype brushes, E6500 versions s1, s2 and s3 and E8000 with head speeds of 6500 and 8000 oscillations/min were compared with a similar design marketed product (MP) with a head speed of 8800 oscillations/min. All brushes had circular brush heads with oscillating rotating actions. Subjects accumulated plaque over a 4-day period during which no oral hygiene measures were performed. On day 4, the plaque accumulation was scored by index. Subjects then used the allocated toothbrush for 2 min. This was followed by a re-scoring of the remaining plaque.

**Results:** Studies 1 and 2 showed significantly less plaque removed by prototype E6500 (s1) and prototype E6500 (s2), respectively, than by MP. In study 3, prototype E8000 removed similar quantities of plaque to MP (approximately 65%). In contrast prototype E6500 (s3) only removed 60% of accrued plaque. Differences, however, did not reach statistical significance.

**Conclusions:** The study methodology was appropriate to distinguish between the study toothbrushes and was furthermore able to establish a level of comparability for one of the prototype modifications with a similar MP.

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The plastic handle, nylon filament toothbrush introduced into the market place in the 1930s was arguably one of the greatest breakthroughs in the 6000 year history of oral hygiene products (Fischman 1997). Since this time the manual toothbrush has become the mainstay of oral hygiene practices in developed countries (Frandsen 1986). Despite numerous and continuing modifications to manual toothbrush design to improve efficacy the consensus is that there is no one superior design and the major variable is the dexterity of the user (for reviews see Frandsen 1986, Hancock 1996, Addy 1998, Jepsen 1998). Unfortunately, epidemiological data for gingivitis suggest that tooth cleaning by a significant proportion of individuals is inadequate, even from a young age (Addy et al. 1986, Hunter et al. 1994). This arises,

it would seem, from insufficiency of time spent on toothbrushing and disproportionate amounts of time being spent on relatively few tooth surfaces and little or no time on others (Rugg-Gunn & MacGregor 1978, De la Rosa et al. 1979, MacGregor & Rugg-Gunn 1979): the net outcome is that modest amounts of plaque are removed by many individuals (De la Rosa et al. 1979).

In recent years, there has been a reintroduction of electric powered toothbrushes for the most part replacement or rechargeable battery in type. By comparison with earlier models, which attempted to mimic reciprocal manual brushing style, design features appear of relevance to efficacy but, again, the user remains the major variable to outcome. Thus, conclusions of workshops have been that the reciprocating action electric toothbrush is of no benefit to plaque control over manual brushes except in less dextrous groups (Frandsen 1986). On the other hand, evidence for some of the more recently introduced designs of powered brushes supports a claim for greater efficacy compared with manual brushes (Hancock 1996, Warren & Chater 1996, Walmsley 1997, van der Weijden et al. 1998).

Although the time scale is shorter, just as the manual toothbrush has evolved, so too has the electric toothbrush. Different manufacturers have refined particular models particularly in respect of head movement and speed. Perhaps the most popular head movement has been the oscillating rotating action to which at least one manufacturer added a reciprocating action to one of their models to produce a threedimensional head movement. Robot laboratory studies (Ernst et al. 1997) on increasing head speed suggest that improved efficacy would be expected but studies have varied in the significance of differences (Grossman et al. 1996, van der Weijden et al. 1996, Renton-Harper et al. 2001). Optimum speeds for efficacy and safety for any particular head action have not been established. The studies presented here describe the development of a prototype electric powered toothbrush from conception to the marketplace. The aim of these studies was to compare the prototype brush at different stages of development with a similar marketed product (MP) for single use plaque removal. A secondary aim was to appraise the pattern of plaque accumulation and removal by the subjects.

# **Material and Methods**

Approval for each of the three studies was provided by the University of Bristol Healthcare Trust Ethics committee and all were conducted according to the guidelines for Good Clinical Practice.

The studies were of a multiple period single-blind cross-over design depending on the number of brushes under investigation. The studies involved up to 24 healthy dentate subjects. Studies 1 and 2 involved two different groups of individuals whereas study 3 involved subjects derived from both studies 1 and 2. The primary aim was to compare the plaque removal efficacy of three similar battery powered toothbrushes by scoring plaque before and after a timed brushing. The volunteers were recruited according to strict inclusion/exclusion criteria, which were determined to allow for the correct conduct of the study protocol without compromising the outcome measures. Each subject was medically fit and well, did not have any removable dental prostheses or orthodontic appliances, and had at least 20 scorable teeth.

The toothbrushes used in this series of studies were:

- 1. Experimental prototypes (Glaxo-SmithKline, Weybridge, UK) E6500 (s1), E6500 (s2) and E6500 (s3) all with head speeds of 6500 oscillations/min.
- 2. Experimental prototype (Glaxo-SmithKline) E8000 with a head speed of 8000 oscillations/min.
- 3. MP (Colgate Palmolive, London, UK) with a head speed of 8800 oscillations/min.

All brushes had an oscillating rotating action of a similar sized circular arranged filament brush head.

Study 1 compared E6500 (s1) with MP, study 2 compared E6500 (s2) with MP and study 3 compared E6500 (s3) with E8000 and MP. Modifications to E6500 (s1) to produce E6500 (s2), together with further modifications to produce E6500 (s3), were related to handle design and vibration dampening and were incorporated into E8000. Each of the subjects attended a screening visit 7-12 days prior to the start of the study and received a professional scale and polish. At this point, subjects were allocated one of the test toothbrushes according to the randomisation schedule and provided with instructions regarding use. This ensured that a period of 1-week home use was available to allow subjects to acclimatise to brush use while unsupervised. On day 1 of each study period, subjects attended the clinic area to brush for 2 min under supervision after which they were

requested to refrain from all oral hygiene measures. On day 4, subjects returned to the clinic where the accumulated plaque was disclosed with 1.4% erythrosin solution. Plaque was then scored on the buccal and lingual surfaces according to the criteria of the Turesky et al. (1970) modification of the Quigley & Hein (1962) plaque index. Subjects were then removed from the clinic area where a 2 min supervised brushing utilising the toothbrush allocated for that particular period was performed. Following brushing, the subject returned to the study clinician where the remaining plaque was rescored according to the same criteria and the test toothbrush exchanged for the next test product. The protocol was repeated until all periods of the study had been completed. All batteries in the test brushes were fully charged for brushings.

# Data handling and statistical methods

For all three studies, the primary outcome variables were the pre- and postbrushing whole-mouth plaque scores derived from the Turesky et al. (1970) plaque index for each subject during each period. Previous similar studies (Claydon & Addy 1996) have shown that the percentage of plaque remaining or equivalent percentage of plaque removed is an appropriate way to combine pre- and post-brushing plaque scores to characterise the effectiveness. The secondary outcome variables followed a breakdown of the primary data into each scoring area i.e. buccal and lingual for each of the teeth. For studies 1 and 2 data sets were acceptably Gaussian in distribution. Studies 1 and 2 were analysed by the procedure described by Hills & Armitage (1979) for two period cross-over designs examining effects of period and treatment by constructing 95% confidence intervals and corresponding t-tests.

Study 3 was a three treatment crossover design balanced for residual effects. The primary outcome measure was mean percentage plaque remaining calculated from pre- and post-brushing plaque scores for all sites. The secondary outcome measure was mean percentage plaque remaining for buccal and lingual surfaces. Initial analysis used three-way analysis of variance modelled by subject, period and brush. Contrasts between pairs of brushes were determined by constructing 95% confidence intervals as well as *p*-values. The data approached a Gaussian distribution reasonably well, therefore confirmatory non-parametric tests were performed, namely Friedman two-way analysis of variance followed by Wilcoxon's matched pairs signed-rank tests.

## Results Study 1

A subject group of 24 subjects were recruited. Twenty-one subjects provided complete data for period 1 but only 19 provided data for period 2. The analyses were therefore based on the complete data set for the 19 subjects (13 females, average age 29.0 years and six males, average age 28.2 years) who completed the study as per protocol. The mean plaque scores before and after brushing for all sites and buccal and lingual surfaces are shown in Table 1 together with the percent plaque remaining after brushing. In mean terms there was an absolute difference of 8% in plaque removal from all sites between the brushes in favour of the MP brush (44% removed by E6500, 52% removed by MP). This difference as indicated by the Hills-Armitage analysis was statistically significant (Table 2) as were differences at buccal and lingual surfaces.

#### Study 2

The group comprised 24 subjects all of whom completed the study satisfactorily so that a complete orthogonal data set was available for analysis. The demographic analysis of the volunteers who participated showed that 15 were females with an average age of 24.7 years and nine were males with an average age of 22.4 years. The mean plaque scores for all sites and buccal and lingual surfaces are shown in Table 3 together with the percent plaque remaining. Overall, in mean terms similar amounts of plaque were removed by E6500 and MP as in study 1, in the order of 45% and 55%, respectively. Again differences in favour of MP were statistically significant for all sites and buccal and lingual surfaces (Table 4). There was no evidence of a significant period effect.

#### Study 3

The group comprised 24 subjects, 18 of whom were females (average age 36.7

ıdy 1

	Mean pre- brushing (SD)	Mean post- brushing (SD)	Mean % plaque remaining (SD)
E6500 (s1)			
buccal	3.19 (0.58)	1.43 (0.53)	44.77 (16.56)
lingual	2.15 (0.35)	1.56 (0.35)	72.21 (10.23)
all sites	2.67 (0.42)	1.49 (0.33)	55.97 (10.84)
MP			
buccal	3.04 (0.54)	1.10 (0.42)	36.74 (15.66)
lingual	2.12 (0.35)	1.37 (0.40)	63.83 (12.82)
all sites	2.58 (0.39)	1.23 (0.29)	47.97 (10.44)

Summary statistics for subject mean plaque scores pre- and post-brushing, and percentage of plaque remaining after brushing. All sites, buccal sites and lingual sites, by brush used, based on n = 19 subjects.

MP, marketed product.

E6500 (s1) versus MP	95% confidence interval	<i>p</i> -value
all	+3.43 to +12.62	0.002
buccal	+2.23 to +14.08	0.010
lingual	+1.93 to +14.47	0.014

Difference between two brushes in plaque remaining after brushing, expressed as percentage of corresponding pre-brushing value. Ninety-five per cent confidence interval and *p*-value from Hills–Armitage analysis. All sites, buccal sites and lingual sites.

MP, marketed product.

#### Table 3. Study 2

	Mean pre- brushing (SD)	Mean post- brushing (SD)	Mean % plaque remaining (SD)
E6500 (s2)			
buccal	3.25 (0.47)	1.48 (0.67)	45.45 (18.56)
lingual	2.30 (0.30)	1.54 (0.36)	67.04 (13.22)
all sites	2.77 (0.34)	1.51 (0.45)	54.47 (13.90)
MP			· · · ·
buccal	3.13 (0.48)	1.09 (0.58)	34.42 (16.90)
lingual	2.24 (0.29)	1.33 (0.40)	59.04 (15.02)
all sites	2.68 (0.34)	1.21 (0.40)	45.05 (13.37)

Summary statistics for subject mean plaque scores pre- and post-brushing, and percentage of plaque remaining after brushing. All sites, buccal sites and lingual sites, by brush used, based on n = 24 subjects.

MP, marketed product.

Table 4.	Study	2
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E6500 (s2) versus MP	95% confidence interval	<i>p</i> -value
all	+13.24 to +5.61	< 0.001
buccal	+16.17 to $+5.88$	< 0.001
Lingual	+12.15 to +3.86	< 0.001

Difference between two brushes in plaque remaining after brushing, expressed as percentage of corresponding pre-brushing value. Ninety-five per cent confidence interval and *p*-value from Hills–Armitage analysis. All sites, buccal sites and lingual sites.

MP, marketed product.

years) and six males (average age 32.2 years). The study was completed with only one datum point missing from the final data set. The mean plaque scores before and after brushing and the

percent plaque remaining after brushing for all sites and buccal and lingual surfaces are shown in Table 5. Overall, more plaque was removed by all three brushes than seen in studies 1 and 2.

#### Table 5. Study 3

	Mean pre- brushing (SD)	Mean post- brushing (SD)	Mean % plaque remaining (SD)
E6500 (s3)			
buccal	3.31 (0.59)	1.01 (0.51)	30.80 (13.53)
lingual	2.40 (0.54)	1.24 (0.47)	51.83 (15.25)
all sites	2.85 (0.45)	1.13 (0.40)	39.59 (12.00)
MP			
buccal	3.09 (0.59)	0.83 (0.53)	27.29 (17.16)
lingual	2.25 (0.42)	1.11 (0.53)	47.34 (16.24)
all sites	2.67 (0.37)	0.97 (0.45)	35.80 (15.18)
E8000			
buccal	3.23 (0.58)	0.88 (0.45)	27.35 (12.57)
lingual	2.37 (0.46)	1.10 (0.47)	46.18 (16.38)
all sites	2.80 (0.39)	0.99 (0.36)	35.50 (12.04)

Summary statistics for subject mean plaque scores pre- and post-brushing, and percentage of plaque remaining after brushing. All sites, buccal sites and lingual sites, by brush used, based on n = 24 subjects.

MP, marketed product.

#### Table 6. Study 3

	95% confidence interval	<i>p</i> -value
All sites		
E6500 (s3) versus E 8000	-1.64 to $+8.77$	0.17
E6500 (s3) versus MP	-1.94 to $+8.47$	0.21
E8000 (s3) versus MP	-5.42 to $+4.82$	0.91
Buccal		
E6500 (s3) versus E8000	-3.04 to $+8.73$	0.34
E6500 (s3) versu MP	-2.98 to $+8.78$	0.33
E8000 versus MP	-5.73 to $+5.84$	0.98
Lingual		
E6500 (s3) versus E8000	-1.49 to $+11.70$	0.13
E6500 (s3) versus MP	-2.65 to $+10.54$	0.23
E8000 versus MP	-7.65 to $+5.32$	0.72

Difference between pairs of brushes in plaque remaining after brushing, expressed as percentage of corresponding pre-brushing value. Ninety-five per cent confidence interval and *p*-value from analysis of variance model. All sites, buccal sites and lingual sites. MP, marketed product.

Thus plaque removal from all sites was approximately 60% for E6500, 64% for MP and 64% for E8000. Parametric and non-parametric analysis of variance showed no significant evidence of differences between the three brushes for plaque removal although subject and period differences were significant (p < 0.05) as were pre-brushing plaque levels in period 1 compared with those in periods 2 and 3. The superiority of E8000 compared with E6500 for all sites had p = 0.17 by parametric analysis, but p = 0.045 by non-parametric, but no other paired comparison reached significance either for all sites or for buccal and lingual surfaces (Table 6). There were significant subject differences for plaque accumulation and removal (p < 0.001). The pattern of plaque accumulation and removal can be appraised observationally without

recourse to formal statistical analysis. Thus buccal plaque accumulation was always considerably greater (approximately one scoring unit of the index) compared with lingual sites. Plaque removal on the other hand was considerably less from the lingual sites and a difference of around 20% in plaque removal was seen between buccal and lingual surfaces in all three studies.

# Discussion

The limitations of manual toothbrushing are well recognised (Jepsen 1998, Dörfer et al. 2001) and usually stem from overzealous or inefficient use (Frandsen 1986). These shortcomings can frequently be recognised within the same subject, leading to a combination of clinical problems, which are confusing and difficult to explain to the patient. The habitual nature of toothbrushing produces a pattern of toothbrush use which is consistent, ingrained and monumentally difficult to change. The average cleaning time of 60 s (De la Rosa et al. 1979) is clearly insufficient to clean the whole-mouth to zero plaque levels but can be simply extended by the use of time-keeping devices.

The more difficult aspects of toothbrush use relate to the over cleaning of some areas of the mouth (buccal surfaces) and poor cleaning of surfaces in other areas (palatal and lingual surfaces). This is borne out by studies that demonstrated that at least 90% of brushing time is spent on the buccal surfaces whereas a maximum of 10% of the brushing time was allocated to the lingual surfaces (Rugg-Gunn & Mac-Gregor 1978, MacGregor & Rugg-Gunn 1979). The net result of this imbalance is plaque removal overall of the order of 50% (De la Rosa et al. 1979), with plaque accumulation and its sequelae on the uncleaned surfaces, together with the potential for tooth wear and recession on the over-cleaned surfaces (for reviews see Smith 1997, Jepsen 1998, van der Weijden et al. 1998). Collectively, these limitations may be overcome in part by the recommendation of powered toothbrushes, which hold two advantages over the manual version. Firstly, there is demonstrable superiority in plaque removal, particularly at the interproximal sites (Jepsen 1998, van der Weijden et al. 1998). Secondly, adaptation to the use of powered toothbrushes may provide the opportunity to break the habitual element of toothbrushing and to engender new more effective techniques (Renton-Harper et al. 2001).

The studies presented demonstrate the progress that has been made in the development of an effective and convenient battery powered toothbrush using standardised study protocols. The initial brace of studies compared prototype power toothbrushes E6500 (s1) and E6500 (s2) generating engine speeds of 6500 oscillations/min, with an established commercially available version (MP). Reviews on the subject of toothbrushing have concluded that the individual using the brush is the dominant factor in plaque removal (Frandsen 1986, Hancock 1996, Jepsen 1998). Without prejudicing the outcome result therefore, and given the cross-over study design, it was anticipated that the plaque-removing properties of two essentially similar appliances would be comparable. In the event, the first study demonstrated a plaque removing potential of 44% for the E6500 (s1) compared with that of 52% for the MP. Subsequent repetition of the same study protocol, with a different subject panel, yielded comparable data (45.5% and 55%, respectively). From an academic viewpoint, this vindicates the design of the study protocol but also highlights some shortcomings in the design of the E6500 (s1) and E6500 (s2) toothbrushes. The latter detail was addressed by further modifications to E6500 (s1) to produce E6500 (s3) and production of another version of the latter, E8000, by upgrading the power source to yield 8000 oscillations/min. The protocol was repeated to compare E6500 (s3) and E8000, the MP as the marketed comparator.

The results of study 3 are of interest for several reasons. The numerical difference in plaque removal between E6500 (s3) and MP, noted in studies 1 and 2, remained smaller and not statistically significant. The increased speed of E8000 without any change in the overall design of the device E6500 (s3) resulted in an efficacy comparable to that of MP and also a significant increase in efficacy over E6500 (s3). Other studies have similarly shown patterns for improved efficacy with electric brushes where the main design change relates to head speed (Grossman et al. 1996, Renton-Harper et al. 2001) although mean differences did not reach significance in both studies. The overall improved performance of subjects in study 3 as compared with studies 1 and 2 suggest acclimatisation or experience with the devices. Studies 1 and 2 used different groups of individuals yet study 3 used volunteers derived from both groups in studies 1 and 2. Thus, all subjects entered the same type of study for the second time and used toothbrushes essentially the same as used in the first two studies.

In study 3, the significant subject differences were to be expected as these reflect individual toothbrushing efficacy, which is known to vary. However, the significant period effects and the difference in pre-brushing scores between period 1 and the other two periods are difficult to explain. Consequently, further interpretation of the data is precluded.

### Conclusion

In conclusion, the three studies represent a development phase of a new battery powered toothbrush in which modifications to the E6500 (s1) version did little to increase efficacy to the level of a similarly designed product (MP). The efficacy of E8000, which had a head speed of 8000 oscillations/min, is similar to that of MP with a head speed of 8800 oscillations/min, and this suggests speed, in the present study, was one factor relevant to plaque removal.

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